



The Vale of Leven Hospital Inquiry Report

The Rt Hon Lord MacLean
Chairman

The Vale of Leven Hospital Inquiry Report

The Rt Hon Lord MacLean
Chairman

Laid before the Scottish Parliament by the Scottish Ministers
under section 26 of the Inquiries Act 2005.

November 2014
SG/2014/211

© Crown copyright 2014

ISBN: 978-1-78412-843-2

Published on behalf of The Vale of Leven Hospital Inquiry by APS Group

An online version of the Report is available at www.valeoflevenhospitalinquiry.org

email: information@valeoflevenhospitalinquiry.org

Contents

	Page
Chairman's letter to the Cabinet Secretary	ix
Foreword	x
How to read the Report	xii
Chapter 1 Introduction	1
Chapter 2 How the Inquiry worked	17
2.1 Inquiry procedures	18
2.2 Inquiry organisation and administration	30
Chapter 3 Healthcare Associated Infection and <i>Clostridium difficile</i>	35
3.1 Healthcare Associated Infection	36
3.2 Antibiotics and the bowel flora	36
3.3 <i>C. difficile</i> - what is it?	37
3.4 How <i>C. difficile</i> is spread	38
3.5 Laboratory diagnosis of <i>C. difficile</i> infection	39
3.6 Precautions against occurrence and spread of <i>C. difficile</i> infection	43
3.7 Treatment of <i>C. difficile</i> infection	44
3.8 Conclusion	45
Chapter 4 The number of patients with CDI and those who died	47
4.1 Discovery of the problem	48
4.2 Number of CDI cases	49
4.3 Number of <i>C. difficile</i> deaths	51
4.4 Conclusion	53
Chapter 5 <i>C. difficile</i> infection rates and undeclared outbreaks	55
5.1 Definition of an outbreak	56
5.2 The number of CDI results	57
5.3 Wards with CDI patients - the early period	64
5.4 Wards with CDI patients - the focus period	71
5.5 Conclusion	77

Chapter 6	National structures and systems	79
	6.1 Relevant parties and agencies	80
	6.2 Systems	81
	6.3 Accountability and monitoring	83
	6.4 Health Improvement, Efficiency, Access and Treatment (HEAT) Targets and CDI guidance	85
	6.5 The review system	86
	6.6 Healthcare Environment Inspectorate	87
	6.7 Conclusion	91
	6.8 Recommendations	93
Chapter 7	National policies and guidance	95
	7.1 National guidance on the prevention and control of <i>C. difficile</i> before 2008	96
	7.2 The role of Health Protection Scotland in developing guidance on <i>C. difficile</i>	101
	7.3 Developments from June 2008 onwards	103
	7.4 Was the guidance on HAI adequate?	104
	7.5 The provision of <i>C. difficile</i> guidance	104
	7.6 The monitoring of the implementation of guidance	105
	7.7 Conclusion	106
	7.8 Recommendations	107
Chapter 8	Changes in services at the Vale of Leven Hospital from 2002	109
	8.1 Prolonged uncertainty	110
	8.2 Shaping the Future	111
	8.3 Lomond Integrated Care Model	111
	8.4 A new strategy	112
	8.5 The Vision for the Vale	114
	8.6 Conclusion	116
	8.7 Recommendations	116
Chapter 9	The creation, leadership and management of the Clyde Directorate	117
	9.1 The dissolution of NHS Argyll and Clyde	118
	9.2 Integration	118
	9.3 Impact of integration on the Vale of Leven Hospital (VOLH)	120
	9.4 Leadership of the Clyde Directorate	122
	9.5 The leadership of Mrs den Herder	122
	9.6 Other managers in the Clyde Directorate	126
	9.7 Conclusion	129
	9.8 Recommendations	130

Chapter 10 Clinical governance	131
10.1 National policy	132
10.2 Clinical governance in NHS Greater Glasgow and Clyde	133
10.3 Clinical governance structures at divisional level	135
10.4 Clinical governance in the Clyde Acute Directorate	140
10.5 Clinical governance in the Rehabilitation and Assessment Directorate	146
10.6 Reporting from the Clyde Sector	149
10.7 The Clinical Governance Committee and NHS Greater Glasgow and Clyde	150
10.8 Changes in clinical governance since 2008	151
10.9 No non-executive director for Clyde	152
10.10 Conclusion	152
10.11 Recommendations	152
Chapter 11 The experiences of patients and relatives	153
11.1 Sources of evidence	154
11.2 The patients' and relatives' expectations	155
11.3 Patient care	156
11.4 The patients' and relatives' view on staffing	158
11.5 Communication	159
11.6 Ward fabric and cleanliness	162
11.7 Infection prevention and control issues	164
11.8 Conclusion	168
11.9 Recommendations	168
Chapter 12 Nursing care	169
12.1 The Nursing and Midwifery Council Code of Conduct	171
12.2 Use of nursing experts	172
12.3 Overall view of nursing experts	175
12.4 Record keeping	176
12.5 Nursing aspects of infection prevention and control	180
12.6 Isolation issues specific to ward F	189
12.7 Nursing assessments and care planning in the focus period	191
12.8 Nursing notes and charts in the focus period	198
12.9 Pressure damage in the focus period	205
12.10 Nursing care in the early period	210
12.11 Staffing issues and care	210
12.12 Overall conclusions on nursing care	213
12.13 Recommendations	214

Chapter 13 Antibiotic prescribing	217
13.1 Antimicrobial policy and prudent prescribing	218
13.2 The 2008 Action Plan	221
13.3 Significant failures in implementation and monitoring	223
13.4 The Antimicrobial Management Team	224
13.5 Conclusion	226
13.6 Recommendations	227
Chapter 14 Medical care	229
14.1 Inquiry medical experts	230
14.2 Record keeping	231
14.3 Medical staffing	232
14.4 Medical management of CDI	240
14.5 Do Not Attempt Resuscitation orders	247
14.6 Antibiotic prescribing	248
14.7 The process for testing for <i>C. difficile</i> toxin	255
14.8 Overall conclusion	262
14.9 Recommendations	262
Chapter 15 Infection prevention and control	263
15.1 The constitution of an Infection Control Team	265
15.2 The Infection Control Team for the VOLH	266
15.3 The infection prevention and control management structure	270
15.4 Implementation of policies and training	272
15.5 The Infection Control Manager	280
15.6 The Nurse Consultant	284
15.7 The infection control committee structure	286
15.8 Reporting within the infection control committee structure	294
15.9 The failure of the committee structure	298
15.10 Surveillance systems	301
15.11 Failure to identify outbreaks	306
15.12 Role of the Microbiologists	320
15.13 The Infection Control Doctor	326
15.14 Knowledge of Dr Biggs' failure as Infection Control Doctor	331
15.15 The secondment issue	335
15.16 The reporting of <i>C. difficile</i> data to Health Protection Scotland and the Public Health Protection Unit	341
15.17 Statistical Process Control Charts	343

15.18 The VOLH Laboratory accreditation	345
15.19 Risk registers	346
15.20 Hygiene, environment and audits	349
15.21 Changes after June 2008	361
15.22 Conclusion	367
15.23 Recommendations	368
Chapter 16 Death certification	371
16.1 Form of death certificate	372
16.2 The 1999 guidance on death certification and VOLH practice	372
16.3 Accuracy in death certification in the VOLH	374
16.4 Updated guidance	375
16.5 Collation, analysis of data and future changes	376
16.6 Conclusion	378
16.7 Recommendations	379
Chapter 17 Investigations from May 2008	381
17.1 The Independent Review	382
17.2 Vale of Leven Internal Investigation Report	382
17.3 Outbreak Control Team Investigation	386
17.4 Conclusion	390
17.5 Recommendations	391
Chapter 18 Experiences of <i>C. difficile</i> infection within and beyond Scotland	393
18.1 The 027 strain	394
18.2 The Stoke Mandeville, and Maidstone and Tunbridge Wells reports	395
18.3 The NHS Greater Glasgow and Clyde response to Stoke Mandeville, and Maidstone and Tunbridge Wells	397
18.4 NHS Quality Improvement Scotland response	398
18.5 The response to the Stoke Mandeville, and Maidstone and Tunbridge Wells reports by Health Protection Scotland	399
18.6 The Scottish Government response	404
18.7 The Northern Health and Social Care Trust, Northern Ireland	404
18.8 Ninewells Hospital, Dundee	406
18.9 Comparison between the VOLH, Stoke Mandeville, and Maidstone and Tunbridge Wells	407
18.10 Conclusion	409
18.11 Recommendations	410
Chapter 19 Conclusion and Recommendations	411

Appendices

AP1 Patients for whom individual expert reports were commissioned	420
AP2 The Inquiry Team	421
AP3 Core Participants and their legal representation	423
AP4 Expert witnesses instructed by the Inquiry	424
AP5 Witnesses who gave oral or written evidence	431
AP6 Organisations which provided documentary evidence	433
AP7 Acronyms	434
AP8 List of figures and tables	436
AP9 Timeline of investigations prior to the Inquiry	439

Chairman's letter to the Cabinet Secretary

The Vale of Leven Hospital Inquiry

Third Floor, Lothian Chambers, George IV Bridge, Edinburgh, EH1 1RN

Website: valeoflevenhospitalinquiry.org

Email: information@valeoflevenhospitalinquiry.org

Phone: (0131) 240 6809 Fax: (0131) 225 6710

Cabinet Secretary for Health and Wellbeing
St Andrew's House
Regent Road
EDINBURGH
EH1 3DG

November 2014

Dear Cabinet Secretary

On 21 August 2009, I was appointed by the then Cabinet Secretary for Health and Wellbeing to hold a public inquiry into the occurrence of *Clostridium difficile* infection at the Vale of Leven Hospital from 1 January 2007 onwards, in particular between 1 December 2007 and 1 June 2008, and to investigate the deaths associated with that infection.

The Terms of Reference were very wide-ranging and I have addressed these, I hope, comprehensively, as can be seen from the Report which I now present to you.

Yours sincerely,

RNM MacLean

Rt Hon Lord MacLean
Chairman

Foreword

The evidence adduced by the Inquiry was concluded on 28 June 2012. In July 2012 I entered hospital for what was then regarded as a fairly routine operation. The operation itself was concluded successfully but shortly thereafter my condition began to deteriorate as a result of an infection of unknown aetiology which necessitated a prolonged period of intensive care and hospitalisation for a total of five months. I may say that the irony of this was not lost on me during the time I remained in hospital. The experience did, however, enable me better to understand the plight of those who suffered from *C. difficile* infection and in some cases died from it, in the Vale of Leven Hospital.

I narrate all this, not in anyway to evoke sympathy for myself but in order to pay tribute to the Inquiry team who responded so superbly to the crisis they then had to face, namely carrying on the work of the Inquiry effectively without its Chairman. A central core of the staff, made up of the Secretary, leading Counsel to the Inquiry, and its Principal Solicitor, visited me regularly in hospital, consulted me there, and received instructions from me. After my discharge from hospital the same work was carried on during my convalescence at home. In order to ensure that Mr Neil, the Cabinet Secretary who succeeded Ms Sturgeon, was aware of the predicament I was in, I wrote a personal letter to him on 17 January 2013. He replied to this letter on 21 March 2013 and from the terms of that letter I believe he ultimately came to understand the problems I had had.

On 29 July 2009 I met the then Cabinet Secretary for Health and Wellbeing, Ms Nicola Sturgeon, in Glasgow. She thanked me for taking over from Lord Coulsfield. We discussed the terms of the remit. She was very keen on a time limit because, as she said, she wanted a short and sharp inquiry. She expected a report and recommendations on her desk by October 2010. In light of my previous experience as Chairman of two other Inquiries and membership of another (none of which had any time restriction) I demurred to such a time limit and explained that I did not consider it possible to fulfil the terms of such a wide remit within that time scale. I preferred a time limit of “as soon as possible”. The Cabinet Secretary, however, insisted, with the qualification that the Inquiry could always apply for an extension. I am clear that this was a mistake, for the reasons that are given more fully in the Report itself and summarised in the Introduction.

The result was that, as each so-called deadline approached and was not fulfilled, there was a familiar chorus of criticism from certain quarters. Significantly, none of it came from any representatives of Core Participants. Nevertheless, the Inquiry team had to face this criticism and respond to it as best they could, when, in my opinion, they were absolutely blameless.

If anything, the whole experience shows the futility of imposing time constraints on an Inquiry like this, simply because one cannot at the outset know what lies ahead of an Inquiry's investigation. My illness was just one aspect of this. Indeed, I doubt whether, unless in wholly exceptional circumstances, an Inquiry set up under the Inquiries Act should be limited in point of time.

I should add that, in my not inconsiderable experience, it is very rare to have such a cohesive and united unit as the entire Inquiry team. That is probably due to the quite exceptional skills of leadership demonstrated by the Secretary, Julie-Anne Jamieson who kept the show on the road, as it were, and maintained in the face of considerable difficulties, the high level of morale which has persisted to the end. She was exceptional.

I take this opportunity to express my gratitude to my single-minded and devoted Inquiry team. I am grateful to all those in the team who so faithfully assisted me.

A handwritten signature in black ink that reads "RNM MacLean". The letters are written in a cursive, slightly slanted style. Below the signature, there are a few small, faint marks that appear to be the end of the signature or some light scribbles.

Lord MacLean
November 2014

How to read the Report

Availability of the Report

The Inquiry Report is published by the Inquiry in a printed version and on the Inquiry website <http://www.valeoflevenhospitalinquiry.org>

The printed version

The printed version of the Report consists of two parts; the Executive Summary and the main body of the Report. The Executive Summary includes the Inquiry's key findings and recommendations.

The website version

Both parts of the Report are available electronically, in pdf and html versions, on the Inquiry website.

Structure of the Report

The Report comprises 18 Chapters that deal with topics identified in the title to each individual Chapter and an additional Chapter, Chapter 19, containing a brief conclusion and the recommendations. Many of the topics are interrelated and have been discussed in separate chapters for ease of presentation. An attempt has been made to keep repetition to a minimum but inevitably some evidence is referred to in more than one Chapter.

The Report has been written with the intention that the Chapters be read sequentially. It has not been entirely practicable to narrate events in chronological order but to the extent possible the Report follows a natural sequence. Chapter 3, for example, provides information on *Clostridium difficile* required for a proper understanding of what follows, and subsequent chapters set out much of the historical background to events at the Vale of Leven Hospital.

The Inquiry is nevertheless conscious that some readers may wish to refer only to particular Chapters. Care has therefore been taken to make individual Chapters as accessible as possible, for example by explaining the role of each person mentioned in the Chapter, and by cross referring to matters covered in other Chapters.

Readers may also find it helpful to refer to the timeline in Appendix 9 as part of the background to the establishment of the Inquiry.

Chapters 3 to 18 contain the Inquiry's conclusions on the material considered in each Chapter. In shorter Chapters these conclusions are at the end, but in longer Chapters they are to be found at the end of each Section.

Recommendations by the Inquiry are found at the conclusion of the Chapter from which they are derived. A full list of recommendations is also to be found at Chapter 19.

References

Each document on the Inquiry database is identified by a three-letter prefix and an eight digit number. The prefix indicates the origin or the nature of the document, for example, GGC for items provided by Greater Glasgow Health Board, and WTS for witness statements. The first four digits form the document reference number, and the last four digits indicate the page number within the document.

Many footnotes in the pdf and html versions of the Report are hyperlinked to the document itself. In a number of instances there is no hyperlink. This is because the document is of a sensitive or confidential nature and has not been made publicly available. An example of this would be a patient's medical records.

Some documents have parts which have been redacted by the Inquiry. Again, this will be due to the sensitive or confidential nature that part of the document.

Use of Tables

Tables are used in some Chapters to present information. On occasion, information contained in a Table has been highlighted as being of particular importance to the issue being discussed.

“Focus period” and “early period”

The Inquiry’s remit extended from 1 January 2007, but with a particular emphasis on 1 December 2007 to 1st June 2008. This later period is referred to in the Report as the “focus period”. Because patient records for that period were available the Inquiry was able to carry out a more detailed examination of patient treatment during that period, instructing expert reports in respect of each patient. Many patient records for the “early period” were no longer available, so that only a more limited examination of patient treatment could be carried out.

A list of those patients for whom individual expert reports were commissioned is at Appendix 1.

Names and designations

Each person mentioned in the Report is identified by his or her full name and given a designation, which may be as a patient or relative, or by reference to job title or profession. Witnesses who gave oral or written evidence to the Inquiry are in addition listed in Appendix 5, while experts instructed by the Inquiry are listed in Appendix 4.

Patients who did not make contact with the Inquiry or who wished to remain anonymous have been allocated a number (patients in the early period) or a letter (patients in the focus period).

Reference to “the Board”

The term “Board” can have different meanings. Firstly, each of the corporate bodies charged with delivery of NHS care in Scotland is called a Board, or Health Board. Secondly, each of these corporate bodies is itself governed by a Board, consisting of senior members of staff and other non-executive Directors.

The Inquiry has sought throughout the Report to make clear in which sense the term is used in its particular context, but readers should be alert to the distinction. Ultimately, of course, the Board in the sense of the governing body is responsible for the actions of the corporate body as a whole.

Scottish Ministers

“Scottish Government” is the executive branch of government in Scotland, responsible for the central administration of devolved matters such as health. The term has been used since 2007, and was formally adopted in 2012. It replaces the term “Scottish Executive”, which was in use immediately following the establishment of the Scottish Parliament. Before devolution the executive branch of government was known as the “Scottish Office”. All three terms are used in the Report, according to the timing of events, but have essentially the same meaning.

The term “Scottish Ministers” refers collectively to those holding ministerial office in Scotland. Ministers are ultimately responsible for the actions of the administration. Use of this term in the Report is intended to reflect that responsibility.

Other investigations

Chapter 17 of the Report examines the investigations undertaken by NHS Greater Glasgow and Clyde after the Vale of Leven Hospital *C. difficile* infection problem became apparent in June 2008. These were the Independent Investigation and the Outbreak Control Team reports. In addition, an Independent Review of cases of *C. difficile* infection was carried out by Professor Cairns Smith following upon an announcement of an Independent Review by the Cabinet Secretary on 18 June 2008. The reports of these investigations are referred to in several chapters of the Report although the reports of the NHSGGC investigations are not examined until Chapter 17.

Chapter 1

Introduction

Summary

Serious failures

Between 1 January 2007 and 1 June 2008, 131 patients who were or had been patients in the Vale of Leven Hospital (VOLH) tested positive for *Clostridium difficile* Infection (CDI). Of that number, 63 patients tested positive in the period from 1 December 2007 to 1 June 2008. During that particular period 28 of those 63 patients died with CDI as a causal factor in their deaths, either as the underlying cause of death or as a contributory cause of death. Another three patients who died in the course of June 2008 also had CDI as a causal factor in their deaths. In the period 1 January 2007 to 31 December 2008 the total number of deaths identified by the Inquiry in which CDI was a causal factor was 34. These figures are particularly damning when considered in the context of the VOLH, a hospital with around 136 beds in 2008.

CDI can be a devastating illness, particularly in the frail and elderly. It can lead to malnutrition and dehydration unless carefully managed. The frequency of diarrhoea, the impact upon patient dignity, and the challenges presented to staff are some of the factors that highlight the absolute necessity of treating CDI as a serious illness. Sadly, for reasons I set out in detail in this Report, there were deficiencies in medical and nursing care at the VOLH that seriously compromised the care of this group of patients. Furthermore, the infection prevention and control practices and systems were seriously deficient.

Governance and management failures resulted in an environment where patient care was compromised and where infection prevention and control was inadequate. The important principle of Board to ward and ward to Board means that there must be an effective line of reporting, accountability, and assurance. This was lacking for the VOLH. There were failures by individuals but the overall responsibility has to rest ultimately with NHS Greater Glasgow and Clyde (NHSGGC).

It is highly likely that there were a number of undeclared outbreaks of CDI transmission in the VOLH between 1 January 2007 and

1 June 2008. Many patients were exposed unnecessarily to CDI and had to suffer the humiliation and distress often associated with the infection.

Scottish Ministers have a duty to promote the improvement of the physical and mental health of the people of Scotland. The Scottish Government is the executive branch of government in Scotland. The duty to promote the health of the people of Scotland is discharged through Health Boards, particularly within the context of healthcare acquired infections such as CDI. There was a failure to have in place an inspection regime that could provide the necessary assurance that infection prevention and control was being properly managed and important policies and guidance implemented.

Inadequate attention was given by the Scottish Government and NHSGGC to the reports about other outbreaks in the United Kingdom. These identified failures similar to many of the failures at the VOLH discovered in the course of the Inquiry. Repeated warnings over a number of years about the importance of prudent antibiotic prescribing had no apparent impact. The Scottish Government failed to monitor the implementation of the prudent prescribing message and to remedy the failure by NHSGGC to implement that message.

Prolonged uncertainty over the future of the VOLH had damaging effects on recruitment, staff morale, and the physical environment of the VOLH. The hospital environment was not conducive to good patient care. It is hardly credible that in 2007 and 2008 a care environment existed in which gaps in floor joints were covered in adhesive tape. There was a lack of wash-hand basins in wards and toilets, and commodes were not fit for purpose.

A lack of strong management as well as personal and system failures contributed to the development of a culture in the VOLH that had lost sight of what is of the very essence of a hospital – a caring and compassionate environment dedicated to the provision of the highest possible level of care.

Background to the Inquiry

Creation of the Inquiry

On 22 April 2009 the then Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon, announced to the Scottish Parliament that a Public Inquiry would be held into the “outbreak” of *Clostridium difficile* at the VOLH. She explained that this would commence at the conclusion of ongoing investigations by the police and the Health and Safety Executive, and of any prosecutions resulting from those investigations. At the same time the Cabinet Secretary announced that the Rt Hon Lord Coulsfield had agreed to chair the Inquiry.

The C.diff Justice Group, which represents a number of surviving and deceased patients, was influential in the establishment of the Inquiry. In January 2009 the Group lodged a petition with the Scottish Parliament Public Petitions Committee calling for a public inquiry to ensure that lessons were learned across the NHS and that further deaths from *C. difficile* were minimised. The petition was considered by the Petitions Committee on 27 January 2009 and formally closed on 1 November 2011.

The Group’s determination to have a public inquiry has been fully vindicated by the Inquiry’s findings of significant failures from which important lessons must be learned.

In June 2009 the Lord Advocate intimated that there would be no criminal proceedings and steps were then taken to establish an Inquiry Team and define its Terms of Reference. The statements obtained by the police were passed on to the Inquiry Team.

Lord Coulsfield subsequently withdrew from the Inquiry for health reasons, and my appointment was announced in his place on 21 August 2009.

The Inquiry was formally set up on 1 October 2009. The procedure of the Inquiry was subject to the Inquiries Act 2005 (the 2005 Act) and the Inquiries (Scotland) Rules 2007 (the 2007 Rules).

No other person was appointed to sit with me. The important task of fulfilling the

Terms of Reference has therefore been my sole responsibility. In carrying out that responsibility I have been greatly assisted by my Assessors and the members of the Inquiry Team.

Appointment of Assessors

To assist me in my task I appointed two Assessors, under a power granted to me under section 11 of the 2005 Act. A summary of their qualifications and experience is set out in Appendix 2. The purpose behind their appointment was that of providing me with advice on matters within their own areas of professional expertise, which included nursing and medical expertise and also expertise in infection prevention and control.

The Assessors were appointed on 14 October 2009. They participated in the preparations for the oral hearings and attended the oral hearings, and I was able to rely on their advice in the course of the drafting of the Report. Their joint contribution to the Inquiry process proved invaluable, as nursing and medical matters and issues of infection prevention and control became central to the work of the Inquiry. I am extremely grateful to them for that contribution and for the commitment they continued to make to an Inquiry process that took longer than anticipated.

Meeting with NHS Greater Glasgow and Clyde Board members

Lord Coulsfield and the Secretary to the Inquiry met with NHSGGC Board members on 11 June 2009. That was an informal meeting and was not part of the evidence gathering process. It was agreed at that meeting that there could be a single point of contact within the Board for the Inquiry. I, however, did not consider it necessary to have a further meeting with Board members.

Meeting with patients/relatives

Lord Coulsfield met patients and relatives on 12 June 2009, and following my own appointment as Chairman I decided that it would also be appropriate for me to have a similar meeting. That meeting took place on 25 September 2009, and was attended by one former patient and 17 relatives of

patients. I found the meeting to be highly productive, and I gained the clear impression that the patient and relative group as a whole was anxious to be as helpful as possible to the Inquiry. Quite understandably they wanted to find out why CDI became such a problem in the VOLH.

The scope of the Inquiry

Terms of Reference

The Terms of Reference agreed with the Cabinet Secretary were in the following terms:

- a) To investigate the circumstances contributing to the occurrence and rates of *C. difficile* infection at the Vale of Leven Hospital from 1 January 2007 onwards, and any increases in such rates during that period and in particular between 1 December 2007 and 1 June 2008, with particular reference to the circumstances which gave rise to deaths associated with that infection.
- b) To investigate the management and clinical response at the Vale of Leven Hospital to the *C. difficile* infection rates during that period and to any such increases, and the steps taken to prevent or reduce the risk of spread or recurrence of the infection.
- c) To investigate the systems in place at the Vale of Leven Hospital to identify and notify cases, increased rates of infection outbreaks and deaths associated with *C. difficile* infection, including the action taken to inform patients, their relatives and the public and the steps taken at the Vale of Leven and in NHSScotland generally for recording such incidents including for the purposes of death certification.
- d) To investigate the actions of NHS Greater Glasgow and Clyde in response to the occurrence of *C. difficile* infection at the Vale of Leven Hospital, including informing patients and their relatives of the risks of such infection and the measures that should be taken to assist prevention and control.

- e) To investigate the governance arrangements of NHS Greater Glasgow and Clyde in relation to, and the priority given to, the prevention and control of the infection.
- f) With reference to experience within and beyond Scotland of *C. difficile*, to establish what lessons should be learnt and to make recommendations.
- g) To report by 30 September 2010 unless otherwise provided by the Cabinet Secretary for Health and Wellbeing.

The Cabinet Secretary granted several extensions to the reporting date in accordance with paragraph (g) of the remit.

The breadth of the Terms of Reference

What is significant about the Terms of Reference is their breadth. I have already made the point in the Foreword that I did not consider it possible to report by a specified date, initially 30 September 2010. The Cabinet Secretary's response was the addition of the provision in paragraph (g) for extending the time limit. That did not allay my concerns. While it is readily understandable that the responsible Minister should wish an inquiry to report at the earliest reasonable opportunity, until the work of an inquiry is well under way any prediction about a time limit cannot be accurate and may be totally unrealistic. The Inquiry Team must conduct an initial investigation. Only once that initial stage is substantially complete will it become apparent what further investigation is necessary. A further factor that could not have been foreseen at the outset was that of the problems encountered in the recovery of documents, discussed later in the Report. These problems became a running sore that bedevilled the work of the Inquiry even into 2012.

For reasons set out in this Report, including the nature and extent of the Terms of Reference and the size of the task that emerged, the successive deadlines were impossible to meet. When that was apparent to me, I notified the Cabinet Secretary at the

earliest opportunity. As it turned out, because of the amount of work involved in the initial investigation, the first phase of oral hearings did not take place until June 2010, just four months before the original latest reporting date of September 2010.

The first application for an extension of time was in fact made on 10 December 2009, and following that the reporting date was extended to 31 May 2011. Subsequent extensions were necessary to allow the Inquiry to carry out as thorough an investigation as possible into the terms of the remit. The final phase of oral hearings was not completed until June 2012.

The lesson to be learned from this experience is that, except in circumstances where the issue is clear and the remit is a relatively narrow one, specific deadlines should not be imposed on public inquiries of this kind. A formula “as soon as possible” or even “as soon as practicable” should be seen as a much better option. No inquiry Chairman would fail to respond to that form of remit in a timely manner. Unrealistic deadlines of the kind contained in the Terms of Reference create unrealistic expectations in the minds of those waiting for the Report to be published. They also create undue and unfair pressure on the Inquiry Team.

The broad nature of the remit as set out in paragraphs (a) to (g) of the Terms of Reference reflects the Cabinet Secretary’s intention, when the setting up of the Inquiry was announced in the Scottish Parliament on 22 April 2009, that relevant lessons “must be learned by everyone in the NHS”.

Interpretation of the Terms of Reference by NHS Greater Glasgow and Clyde

On 11 May 2011 the NHS Central Legal Office (CLO), acting on behalf of NHSGGC, delivered a Note to the Inquiry intimating an objection to evidence being led on aspects of the quality of nursing care provided to patients covered by the remit. That Note was revised on 12 May 2011. The principal thrust of the objection was in the following terms:

“On the ground of fairness specified in s.17 of the Inquiries Act 2005 (“the 2005 Act”), and also in reference to the need (s.17(3) of the 2005 Act) to avoid any unnecessary cost (whether to public funds or to witnesses or others), GGHB respectfully submits that no evidence should be allowed or taken into account concerning various aspects of the quality of nursing care (“the aspects objected to”) at the Vale of Leven Hospital in the period to date, namely hydration of patients; preparation of fluid balance charts and completion of these; nutrition of patients; completion of nutrition assessments and food charts, and the need to involve a dietician; weighing of patients; guarding against and dealing with skin and pressure damage, and taking tissue viability precautions; carrying out manual handling risk assessments; carrying out falls risk assessments; avoiding patients being injured through falling; providing proper pain relief; completion of care plans (except for care plans relevant to the contraction of *Clostridium difficile* illness or the mortality rate there from); assessing the mental state of patients and meeting their mental health needs; the quality of the personal care given to patients; Do Not Attempt Resuscitation (“DNAR”) decisions; and providing end of life care pathways”.¹

Ruling on NHS Greater Glasgow and Clyde’s objection

With little hesitation I repelled the objection taken on behalf of NHSGGC. The solicitor to NHSGGC was advised of my ruling and my reasons by letter dated 12 May 2011.² I concluded that the issues of concern raised in the nursing expert reports were in areas of nursing care which might be directly relevant to the circumstances contributing to the occurrence and rates of CDI at the VOLH. It has to be emphasised that good nursing care lies at the very heart of the appropriate management of patients who contract CDI. That care does not just begin when the diagnosis of CDI has been confirmed. Patient care has to be seen as a dynamic

¹ [INQ05480002-03](#)

² [INQ05610001](#)

process that involves regular assessment and reassessment. A patient who develops CDI may require to be managed not just for the direct effects of the infection itself, for example by the administration of antibiotics, but also for other aspects of care on which CDI might have an impact, such as hydration, nutrition, pressure management, and the risk of falls and impaired mobility due to the debilitating nature of the condition. While Do Not Attempt Resuscitation (DNAR) decisions may be only indirectly linked, these decisions can be relevant to the care of patients suffering from CDI.

Renewal of the objection

At the oral hearing on 23 August 2011 Counsel for NHSGGC renewed the objection to the leading of evidence on certain aspects of care.³ By this time almost all the evidence of the nursing experts had been led. At this point the challenge was more restricted in nature, with the focus now only on some aspects of care. For example, it was not now being suggested that the nursing management of hydration and nutrition was not relevant to the issues that I required to examine.⁴

Having heard the argument on this renewed objection I again refused to sustain it. It was in principle the objection that had been taken earlier and repelled, and no good reason was advanced for its renewal after almost all the nursing evidence had been led. It had been clear in advance from the nursing expert reports what evidence was going to be led. As I have already explained, there are aspects of nursing care that cannot be divorced from consideration of how a patient suffering from CDI is being managed. Hydration and nutrition are clear examples, and no doubt that is why NHSGGC did not renew its objection to those aspects of care at the oral hearing. Counsel for NHSGGC argued that the Inquiry should focus only on the care planning relevant to the contraction or persistence of CDI,⁵ but the fallacy underlying that argument is the assumption that the care planning for a patient who is suffering from CDI can be properly managed without regard to all that patient's problems.

Furthermore, I was satisfied that the issue of whether any aspects of patient management were outwith the Terms of Reference was a matter that could be determined at the end of the evidence without causing any material delay to the progress of the Inquiry. In addition, most of the nursing expert evidence having been led, I was of the view that, in fairness to nurses whose standard of care had been criticised, they should be given the opportunity to respond to that criticism.

The focus and early period division

The Terms of Reference stipulate in paragraph (a) that the starting date for my investigation of the circumstances contributing to the occurrence and rates of CDI is 1 January 2007. There is no specified end date, but that same paragraph does provide that particular attention is to be directed to the period from 1 December 2007 to 1 June 2008. This period had been looked at by other Inquiries. In this Report I have labelled the period from 1 January 2007 to 30 November 2007 the "early period", and the period from 1 December 2007 to 1 June 2008 the "focus period".

Clostridium difficile infection

Clostridium difficile

Clostridium difficile (*C. difficile*) is a bacterium that can cause infection in the colon. Up to 4% of healthy adults carry *C. difficile* in the colon.⁶ That percentage may increase to 50% in hospital, particularly in the elderly and newborn infants. These patients may not have the infection, but clearly the risk of the infection developing increases significantly in a hospital environment. There are numerous different strains of *C. difficile*, and some strains are said to be more virulent than others. These strains are normally referred to as "hypervirulent" strains because they produce high levels of toxins. It has to be stressed, however, that any strain of *C. difficile* has the potential to cause severe infection.

To acquire the organism, spores must enter the mouth and be swallowed. Many people are exposed to spores, but *C. difficile* generally does not colonise in healthy people and

³ [TRA00290073-109](#)

⁴ [TRA00290100](#)

⁵ [TRA00290081](#)

⁶ [TRA00090019](#)

cause infection. This is because the normal healthy bacteria in the colon protect against the development of the infection. It is when these protective mechanisms are disrupted that *C. difficile* can colonise in the colon and result in infection. This disruption is usually caused by the administration of antibiotics in the treatment of another infection, for example, a urinary tract infection. This is particularly so when patients are treated with broad spectrum antibiotics, because these antibiotics eradicate many normal bacteria in the colon, making the colon more susceptible to the development of CDI. This is why prudent antibiotic prescribing is so important in patient management. An infected patient will normally develop diarrhoea, and in a hospital there is the risk of the environment being contaminated, with other patients being put at risk. Good hand hygiene is important as a preventative measure.

From an infection prevention and control perspective, the isolation of a symptomatic patient from other patients is important. Unfortunately, as set out in the Report, the general practice in the VOLH was not to isolate patients until the infection was actually diagnosed by means of a positive laboratory result. This practice meant that other patients continued to be placed at risk of cross infection.

CDI symptoms

There are a variety of symptoms associated with CDI. I have already mentioned diarrhoea, which when caused by CDI is often described as “explosive”. Symptoms can also include abdominal pain, fever and nausea. In some cases the colon can become severely inflamed, a condition known as pseudomembranous colitis. This can become acute, resulting in toxic megacolon - acute distension of the colon. CDI must therefore be regarded as a serious illness that can be life-threatening, and I have already set out the number of patients covered by my remit who died with CDI involved in the death. The elderly are particularly vulnerable. Professor George Griffin, Professor of Infectious Diseases Medicine at St George’s University, London, whose evidence is considered later, provided the following graphic description of the impact of CDI:

“*C. difficile* is very unpleasant for patients. It is exceedingly unpleasant and distressing for relatives to see an old, loved patient in a bed in a pool of faeces. It is very difficult for nursing staff to have to clean a patient nine, ten times a day who is demented, immobile, (and) can’t help the nurse with moving”.⁷

For a patient to contract CDI in a hospital setting, a setting where the patient expects to be protected and safe, is especially tragic. CDI can deny an elderly patient a peaceful and uncomplicated death, and that is one particular reason, among others, why what was allowed to happen in the VOLH should never be allowed to happen again.

The Vale of Leven Hospital

Changes in hospital management

The Vale of Leven District General Hospital (this is its full title) is one of the smaller hospitals in the National Health Service in Scotland. It is located in the town of Alexandria, West Dunbartonshire. In 2002 the VOLH delivered a broad range of acute hospital services, and the bed complement was in the region of 234, but by 2008 this had been reduced to around 136.

Prior to 1 April 2006 the VOLH was managed by NHS Argyll and Clyde. By 2005 NHS Argyll and Clyde had incurred a cumulative budget deficit of £82 million, and on 19 May 2005 the then Minister for Health and Community Care announced in a statement to the Scottish Parliament that NHS Argyll and Clyde was to be dissolved. The administrative boundaries of Greater Glasgow Health Board (GGHB), also then known as NHS Greater Glasgow, and of NHS Highland were to be changed to allow them to take over responsibility for managing the delivery of the health services in Argyll and Clyde.

Following upon an integration process NHS Argyll and Clyde was dissolved on 1 April 2006. From that date a number of hospitals, including the VOLH, became the full responsibility of GGHB, which became known as NHS Greater Glasgow and Clyde (NHSGGC).

7 [TRA00730030-31](#)

Full integration of services did not, however, take place immediately, and a Clyde Acute Directorate was created to manage services in the former Argyll and Clyde hospitals now managed by NHSGGC, including the VOLH. Mrs Deborah den Herder was appointed as the Director of the Clyde Acute Directorate, although she did not take up her post formally until 1 October 2006.

Reduction in services

In the years up to 2007 and 2008 a significant reduction in the services provided at the VOLH had taken place. These are set out in Chapter 8. By then the future of the hospital had been uncertain over a prolonged period of time. This uncertainty had a damaging impact on recruitment and morale as well as on the hospital's physical environment. It also compromised patient care.

CDI at the VOLH

Discovery and extent of the problem

The problem with CDI in the VOLH was not apparent until May 2008. Those who worked in the VOLH did not appear to identify CDI as a particular problem over the period from 1 January 2007 to May 2008, even although a significant number of patients suffered from the illness during that period. As set out in the Report, the discovery of the extent of the problem was partly due to a press enquiry by a local newspaper requesting information on the number of cases of CDI at the VOLH in the six months prior to June 2008. Dr Brian Cowan, Medical Director and Acute Services Division Medical Director of Greater Glasgow and Clyde described his understanding of the position in the following way:

“Here was an outbreak which raged, or a series of outbreaks that raged, for a long period of time with a significant, highly significant, number of deaths”.⁸

In the period from 1 January 2007 to June 2008 there were 199 positive test results for *C. difficile* toxin from 131 patients in the VOLH, and in different wards at different times throughout that period there were patients suffering from CDI who were linked in time and place. Outbreak Policies in force

during that period⁹ made it clear that an outbreak consisted of two or more linked cases of the same illness, yet no outbreak was declared. The reasons for the failure to identify a problem include the dysfunctional nature of the Infection Control Team, the inadequacy of reporting systems and the failure of committee structures. Nevertheless, it is surprising that such a problem could effectively remain undiscovered for so long even in the face of such failures.

Levels of infection and fatality rates

As I set out at the beginning of this summary, in the period from 1 January 2007 to 1 June 2008 131 patients who were or had been in the VOLH tested positive for CDI. Although the focus of the Inquiry has been on the period up to 1 June 2008, patients continued to suffer from CDI until the end of 2008, but the rate was lower. The total number of patients covered by the Inquiry's remit who contracted CDI between 1 January 2007 and 31 December 2008 was 143.

I did not engage in a comparative exercise of CDI rates in Scottish hospitals, for such an exercise was outwith my remit. It is perfectly clear, however, that for a hospital the size of the VOLH the number of patients infected reveals that CDI had become a serious problem in the VOLH, even although that problem was not identified. The problem was compounded by the number of patients who died with CDI as the underlying cause or a contributory factor. In the six-month period from 1 December 2007 to 1 June 2008, CDI played a role in the deaths of 28 patients.

Death certification

Accuracy

Accuracy in death certification is important because it provides an understanding of the health needs of the population. There is also a personal need for family members to know why a relative has died. Of the 28 patients who died between 1 December 2007 and 1 June 2008 with CDI as the underlying cause or contributory factor, CDI was not mentioned in the death certificates of seven of these patients.

8 [TRA01230015](#)

9 [GGC00780145](#); [GGC27390001](#)

Death certification involves the exercise of professional judgement. Yet although in 2007 and 2008 the available guidance provided that it was “best if a consultant, general practitioner or other experienced clinician certifies the death”,¹⁰ it seems that in practice in Scotland consultants were rarely involved in death certification at that time.¹¹ Certainly in the cases examined from the VOLH the majority of the death certificates were signed by junior doctors without any recorded consultation with more senior medical staff.

New guidance

New guidance was issued on death certification after the emergence of the CDI problem at the VOLH. The most up-to-date guidance provides that death certificates for patients who have died in hospital should only be completed after discussion with a consultant. Ideally this should be the patient’s named consultant.¹² Boards also have to ensure that there are systems in place to identify *C. difficile* associated deaths.¹³

Scotland should not have developed the practice of consultants generally not being involved in the death certification of their patients. Consultants are best placed to accurately assess why a patient has died. I certainly endorse the mandatory duty now imposed to involve consultants. Furthermore, if a patient dies with CDI either as a cause of death or as a contributing condition, relatives should be provided with a clear explanation about the role played by CDI in the patient’s death.

Patient records

Examination of patient records by experts

In the interpretation of my remit I took the decision that the patient records of the patients who suffered CDI in the focus period should be subjected to careful scrutiny. This scrutiny had not been carried out during other investigations into the VOLH CDI problem. From that exercise it became apparent to me, with the assistance

of members of the Inquiry Team and my Assessors, that certain recurrent themes emerged. In order to explore those issues more fully, experts were commissioned in a number of disciplines so that the Terms of Reference could be properly complied with. The timescales involved in that process are set out in Chapter 2. I have already set out my reasoning for the division of cases into the early period and the focus period. Accordingly, expert reports were instructed on 1. medical care; 2. nursing care; 3. the prescription of antibiotics; 4. infection prevention and control; and 5. death certification for all patients who fell within the focus period. Patients for whom expert reports were obtained are listed in Appendix 1. Those patients and relatives who were core participants had an opportunity through their legal representatives to see these detailed reports.

A more restricted approach was taken in the early cases, but I still considered it necessary that, insofar as patient records were available, a nursing expert should examine these records to see whether trends apparent in the course of the focus period also existed in that early period.

Detailed examination of patient records, expert reports and all other evidence relevant to each patient’s care was undertaken during the Inquiry’s work in preparation of this Report. This approach reflected the approach taken during the oral hearings which involved detailed examination of patient care.

The results of that whole exercise are discussed in the Report. Suffice to say at this point that the unacceptable levels of care discovered were not the levels of care which I would have expected to find in any hospital in Scotland. That is why I have made firm recommendations in the Report which should be seen as fundamental to patient care. Ultimate responsibility for patient care in Scotland rests with the Scottish Ministers. To discharge that duty the necessary inspection and implementation systems must be capable of providing real assurance that patient care in Scotland is not at any risk of being compromised.

10 [INQ00790002](#)

11 [TRA01070009-10](#)

12 [INQ02980003](#)

13 [INQ02980005](#)

NHS Greater Glasgow and Clyde's position on the examination of patient records

In the course of submissions made on behalf of NHSGGC at the oral hearing on 13 June 2011 in connection with the legal representation of nurses, an issue addressed in Chapter 2, Counsel for NHSGGC made the following statement in connection with the reports of the nursing experts:

“The content of the reports came as somewhat of a surprise to Greater Glasgow Health Board”.¹⁴

As discussed in Chapter 17, the remit of the Internal Investigation set up by NHSGGC in June 2008 did not cover an examination of patient care with particular reference to the medical records. Nor did the Independent Review chaired by Professor Cairns Smith, Professor of Public Health at the University of Aberdeen. That was not part of the remit of either investigation.

Limited reviews of patient records were undertaken during the Internal Investigation. A case note review of 45 patient records was also carried out by senior nurses as part of the Outbreak Control Team's investigations that commenced in June 2008 to obtain certain data in relation to matters such as age, date of admission and to which wards patients were admitted.¹⁵ So far as the Outbreak Control Team report discloses, the purpose of that review was to make a comparison between the status of the patients who died and the status of patients who survived. The report's conclusion was that patients who died were, on average, older than those who survived.¹⁶ In addition, on 16 June 2008¹⁷ two senior Consultant Physicians from outwith the Clyde division undertook a case review of 15 patient records where *C. difficile* had appeared on the death certificates to consider whether the death certification was appropriate.¹⁸ The Outbreak Control report describes this as a “brief review”.¹⁹

I was surprised that NHSGGC had not taken steps to examine the patient records to evaluate the nature of care afforded to CDI patients, particularly the records of patients who died with CDI as a cause, or contributory cause, of death, in order to satisfy itself that there were no apparent deficiencies in care. I would regard such an examination as one that should be at the forefront of the thinking of any Health Board in the circumstances that had emerged in the VOLH by June 2008. Mr Robert Calderwood, Chief Executive of NHSGGC, did explain in his evidence that once the Independent Review was set up on 18 June 2008 NHSGGC was invited to assist with that Review and discontinue its own investigation,²⁰ but as already mentioned the Independent Review did not examine patient care in any detail.

Management

The importance of questioning

It was surprising how managers at different levels within an organisation like NHSGGC failed in one of the most fundamental aspects of management, namely to ask questions.

The culture

Quite apart from a number of individual failures to investigate and be aware of what was actually happening in the VOLH, it became apparent that there was a systemic failure. Ultimately this can only be described as a management culture that relied upon being told of problems rather than actively seeking assurance about what was in fact happening. To take an example from the evidence, a manager who has a responsibility to ensure the delivery of high quality care cannot fulfil that duty simply by relying on being told when a specific problem emerges and then reacting to the problem. Some managers with responsibilities for the VOLH also had responsibilities for other hospitals operated by NHSGGC, but the Inquiry's focus, of course, was only on the VOLH, and in consequence I cannot comment on their broader performance. Nor do I know how prevalent this style of management would be generally within NHSScotland. Nevertheless, the clear lesson to be learned is that an

14 [TRA00180010](#)

15 [TRA01140044-46](#); [GGC01480004](#)

16 [GGC00600047](#)

17 [GGC07260001](#)

18 [GGC07280001](#); [GGC0060058-59](#)

19 [GGC00600059](#)

20 [TRA01240116](#)

important aspect of management is to be proactive and obtain assurance that systems and personnel are functioning effectively.

Patients and families

Full co-operation

A Chapter in the Report has been devoted to the views of patients and families and their experiences at the VOLH. The oral evidence at the hearings from this group of witnesses was given in a measured and unexaggerated way. Those who provided written statements but were not called to give oral evidence co-operated fully with the Inquiry. These witnesses recognised the importance of having a local hospital and as a group wanted to support its continued existence.

The Inquiry's oral hearings began with the evidence of this group of witnesses. I was anxious that they should have an opportunity as early as possible to have their views expressed publicly. Much of the Inquiry's work was still to be done at that time, and that meant that when they gave their evidence they were not aware of the extent and range of criticisms that were to be made subsequently by the experts.

A common theme

A common theme from this group's evidence was the desire to have answers to what went wrong at the VOLH. A significant number of this group of witnesses had been actively engaged in a campaign for a public inquiry, and it became clear during the evidence that fundamental to their thinking was the desire that others should not be made to suffer in the same way that patients suffered in the VOLH as a result of contracting CDI. Although this group of witnesses was reluctant to be critical of the care provided to patients, many of the descriptions provided did show that there were failures in basic nursing care. Some witnesses attributed poor care to the nursing staff being too busy to render the necessary quality of care. Being busy is not an excuse. If the right kind of care requires more staff, then arrangements should be in place to have an adequate number of staff available.

Poor communication

Relatives were critical of poor levels of communication. This was particularly the case in relation to the presence and nature of CDI. One witness only became aware that his mother had been diagnosed with CDI when he saw *C. difficile* mentioned on her death certificate. Some relatives were told that it was a "wee bug". That is not an apt description of what can be a life-threatening infection. Mixed messages were provided to relatives who took patients' soiled laundry home to wash. Good communication and candour are important aspects of care.

Nursing and medical care

Nursing failures

In the Report it has been necessary to mention nursing failures. There were individual failures caused by a number of factors, including pressures of work, lack of training, and inadequate support. Poor leadership also contributed to an inadequate standard of nursing care. The individual nurses concerned may have been doing their best. What I have sought to identify is how, in a care environment that does not promote good quality care, nursing standards can deteriorate and become unacceptable. The message to be conveyed on this issue is one of the absolute importance of good quality nursing care.

There were a significant number of cases in which there were delays of over 24 hours between the taking of a specimen for laboratory analysis and the commencement of treatment. What was totally unacceptable were the delays in the commencement of treatment **after** the ward was aware of the positive result. Delay in the commencement of treatment in such circumstances represents an inexcusable level of patient care. Such failures would inevitably compromise patient care.

Medical care

The deficiencies that existed in relation to medical staffing are set out in Chapter 14. In effect, there was a layer of middle grade medical staffing missing, with the result that the brunt of the day to day care had to be borne by inexperienced junior doctors and that consultants were overstretched. The

medical review of patients suffering from CDI was inadequate, and for many patients there was no evidence that a proper clinical assessment of the patient's condition had been made. Scrutiny of antibiotic prescribing disclosed that many aspects of practice were poor. There were instances of antibiotics being prescribed when no antibiotic was necessary, and of the continued prescribing of antibiotics in cases where a laboratory test demonstrated that the organism was resistant to that choice of antibiotic.

Overall it is likely that patient care was compromised by the inadequate standard of medical care.

Infection prevention and control

Significant failures

Clearly infection prevention and control practices and systems had to be fully investigated by the Inquiry. Again experts were commissioned to assist the Inquiry in this task. The Chapter in the Report on infection prevention and control is one of the major Chapters, and there can be little doubt that the significant deficiencies in infection prevention and control practices and systems discovered by the Inquiry had a profound impact on the care provided to patients in the VOLH.

Local failures

There were personal failures by the senior nurse responsible for infection prevention and control in the VOLH. The failure not to consider as a real possibility that the number of cases with CDI was a result of cross infection was inexplicable. Over the period from 1 January 2007 to 1 June 2008 there were a number of opportunities presented when cross infection should have been actively considered.

The Infection Control Doctor

Dr Elizabeth Biggs was the Infection Control Doctor for the VOLH at least from 1 January 2007 up to early February 2008. Dr Biggs was based at the Inverclyde Royal Hospital (IRH) but was responsible as Infection Control Doctor for that hospital, the Royal Alexandra Hospital (RAH) and the VOLH. The main thrust of the evidence was that she did not attend the VOLH during that period.

Dr Biggs was under a duty to take a lead role in the effective functioning of the Infection Control Team. It is clear that Dr Biggs was unhappy with her general position and lacked professional line management support, but that does not excuse her attitude. Dr Biggs' attitude to her role as Infection Control Doctor for the VOLH was wholly inappropriate and professionally unacceptable.

Failure to address Dr Biggs' behaviour

Dr Biggs had raised issues in a number of emails and failure to address these, and to ensure an effective leader of the Infection Control Team was in place, was a serious management failure. One witness described Dr Biggs' behaviour as "accepted behaviour".²¹ Such an attitude is to be deplored. Accepted behaviour that puts patients at risk has no place in any Health Board's philosophy.

System failures

The failure to meet of committees within the infection control structure meant that the structure became unfit for purpose. This was compounded by the fact that the reporting systems within the infection control system itself and under the clinical governance arrangements in place at the time were inadequate. Adequate reporting systems must ensure that there is ward to Board and Board to ward accountability. Appropriate systems would have identified the local failures at the VOLH and the failure of Dr Biggs to carry out her duties. That in turn would have identified the problem with CDI in the VOLH much sooner and saved many patients from suffering from the infection and its consequences.

National structures and systems

Structures

In order to orientate the reader of the Report, some information is provided in Chapter 6 on how the National Health Service in Scotland has been structured. In summary, ultimate responsibility for the promotion and improvement of the physical and mental

21 [TRA01260022](#)

health of the people of Scotland rests with the Scottish Ministers. The Scottish Ministers discharge that duty through Health Boards. The Scottish Government is the executive branch of government in Scotland. There are a number of organisations that provide support including NHS National Services Scotland (NSS) of which Health Protection Scotland (HPS) forms part. The Scottish Government Health Directorate (SGHD) provides the central management of the NHS in Scotland. The Cabinet Secretary for Health and Wellbeing is the Minister responsible for the SGHD.

Systems

The impact of healthcare acquired infections (HAIs) on patients has been well recognised since at least the 1990s. The HAI Task Force was created in January 2003 in recognition of the ongoing challenges presented by HAI. Its primary responsibility is to advise on the development and delivery of Scottish Government policy in order to minimise HAIs. There is no doubt that the HAI Task Force has carried out some excellent work, including the implementation of the system of mandatory reporting of all positive tests for *C. difficile* toxins to HPS on a weekly basis since September 2006. This is in effect a national surveillance system in Scotland that provides information on the extent of CDI at a national level and allows a comparison to be made of trends and data over time and between Health Boards. It is to be emphasised that the system is not designed to identify the prevalence of CDI in a particular hospital.

The Scottish Government also set performance targets that Health Boards are expected to meet. These are known as Health Improvement, Efficiency, Access and Treatment (HEAT) Targets. In November 2006 the Scottish Government announced a HEAT Target for *Staphylococcus aureus* bacteraemia (including MRSA and MSSA). The target was an overall reduction of 30% in such cases by 2010, and that target was achieved by September 2009.

The importance of the HEAT Target system lies in the fact that it places an onus on Health Boards to meet the targets by having,

for example, effective infection prevention and control methods in place. CDI was only made a HEAT Target in 2009 in response to the discovery of the CDI problem at the VOLH. Had CDI been a HEAT Target earlier, that might have raised awareness of the infection, but it is to be stressed that the HEAT Target system was not designed to be a surveillance system of the kind that Boards had to have in place. Although there was no evidence that in the period prior to 1 June 2008 any consideration was being given to making CDI a HEAT Target, that is not a criticism because it was necessary to have adequate data available for comparative purposes, and as I have already indicated the system for mandatory surveillance did not come into operation until September 2006. The introduction of CDI as a HEAT Target in 2009 was an appropriate response by the Scottish Government to the emergence of the CDI problem at the VOLH.

Healthcare Environment Inspectorate

Prior to June 2008 there was no system of independent inspection dedicated to the infection prevention and control of HAI. Following upon the discovery of the CDI problem in VOLH the Cabinet Secretary had a number of meetings with family members of patients who had contracted CDI who made clear to her the view that there should be an independent inspectorate in place to review the actions taken in hospitals in relation to HAIs. This led to the establishment of the Healthcare Environment Inspectorate (HEI) in April 2009. The HEI carries out announced and unannounced inspections and publishes inspection results on its website. The inspection team measures hospitals against standards that are designed to minimise the risk of infection to patients, visitors and staff, based on evidence, best practice and expert opinion. The Health Board concerned must respond to any issues raised by the inspection process.

Inspections of the VOLH in 2011 and 2012

It is worthy of note that an announced inspection of the VOLH took place on 10 and 11 August 2011, and that an unannounced inspection took place there on 7 June 2012. The unannounced inspection in June 2012 concluded that the hospital was clean and

well maintained and that education in infection prevention and control was being well promoted. There is no doubt that had there been an inspection regime of that kind in 2007 and 2008, and had an inspection of the VOLH been carried out over that period, the conclusions would have been very different to the conclusions arrived at in 2012.

The absence of an inspection system – a failure

Since devolution the SGHD and other agencies have produced a significant amount of material for Health Boards on HAIs. For example, the Scottish Infection Manual published in July 1998 sent out a clear message on the importance of good infection prevention and control. Furthermore, the importance of prudent antibiotic prescribing had been well known at least since the 1990s. There was no doubt that the message on the importance of having sound systems in place to combat HAIs was a message that had been repeated many times over the years because of the importance attached to it. In such circumstances it is surprising and indeed regrettable that an effective inspectorate system had not been put in place prior to 1 June 2008. This is dealt with in detail in the Report, and represents a failure on the part of the Scottish Government.

Antibiotic prescribing

Prudent prescribing

The importance of prudent antibiotic prescribing had been recognised in Scotland for many years prior to 2007 to 2008. In a letter dated 21 May 1999²² addressed to a number of people, including Health Board General Managers and Chief Executives, the Scottish Office Department of Health included prudent antibiotic prescribing as an important goal in the reduction of ill health from hospital acquired infection. That message was subsequently repeated over a number of years. An Action Plan²³ published in 2002 by the then Scottish Executive again emphasised the importance of prudent antimicrobial use. A guide on the prudent use

of antibiotics published in 2005²⁴ highlighted as a challenge the inadequate supervision of prescribing and the inappropriate choice of antibiotics by junior doctors. Even as late as March 2008, shortly prior to the emergence of the problem with CDI at the VOLH, another Action Plan was launched by the then Cabinet Secretary for Health and Wellbeing.²⁵ This echoed the theme that had emerged in Scotland at least by 1999, and had been repeated over the years, that antibiotic prescribing was not being carried out in a prudent way.

Inadequate response to the prudent prescribing message

Reference has already been made to the failures in the prescribing of antibiotics in the VOLH, failures that persisted until the emergence of the CDI problem in May 2008. The repeated messages on prudent prescribing had not had an effective impact in the VOLH by June 2008. Dr Andrew Seaton, a Consultant Physician in Infectious Diseases and General Medicine in NHSGCC, said in evidence that what was happening in the VOLH in relation to antibiotic prescribing “was applicable to all our hospitals in Greater Glasgow and Clyde and, indeed, almost certainly all our hospitals in Scotland”.²⁶ It is not within my remit to consider the position of other hospitals in Scotland, but what was perfectly apparent to me was that there had been what I describe in the Report as a mismatch between expectation and implementation. There are two targets for criticism here – NHSGCC for failing to respond to the messages being sent on the importance of prudent prescribing, and the Scottish Government for failing to identify and remedy the failure to comply with the prudent prescribing messages.

Outbreaks elsewhere

Paragraph (f) of the Terms of Reference did permit the Inquiry to see what lessons could be learned from experience of CDI in and beyond Scotland. I was, however, of the view that that paragraph did not provide

22 [INQ04540001](#)

23 [GOV00360072](#)

24 [GOV00360003](#)

25 [GOV00360040](#)

26 [TRA01150114](#)

an open ended platform from which to look at the detail of how outbreaks of CDI were handled in other hospitals. That would have been an enormous task. In light of the Terms of Reference as a whole I was of the clear view that it would be outwith their scope to embark upon a critical analysis of the infection control policies of other organisations, the governance arrangements of such organisations and the handling of any outbreaks. What I did find useful was to have regard in particular to the available reports on CDI outbreaks in England, and compare the conclusions arrived at with the conclusions I have arrived at in connection with the VOLH. What was striking was the similarity of the problems identified in these reports and the problems identified by this Inquiry. Lessons had not been learned from these reports. This is considered in Chapter 18.

Scrutiny of other hospitals

There was regular traffic of patients to the VOLH from other hospitals. In particular, patients covered by the remit were transferred from the RAH, or transferred from the VOLH to the RAH. For that reason it became necessary for the Inquiry to examine some aspects of the treatment of those patients at the RAH. As discussed later in the Report, I concluded that the prescription and administration of antibiotics to patients prior to admission to the VOLH were relevant to my remit whether that occurred at another hospital or in the community under the authorisation of general practitioners. That did not mean, however, that I considered it to be within my remit to conduct an examination of practices, policies and patient care at any other hospital, or in the community.

The proceedings

Inquisitorial proceedings

In Scotland, legal proceedings are generally conducted by way of adversarial process. For example, in a civil litigation the parties to the litigation identify the issues that are of concern to them and decide what evidence to lead in support of their respective positions. Generally a witness led by one party can then be cross-examined by the other party and, if

necessary, re-examined. The judge presiding over the case has no direct part to play in that process. The judge's role is to ensure that parties conduct the case in accordance with the rules and the judge only intervenes in the evidence to seek clarification or further explanation. At the end of a case parties make submissions on the facts and the law to advance their respective positions and, ultimately, the judge decides the case by making findings in fact and law.

The purpose of an inquiry of this kind is quite different. The process is an inquisitorial one. Section 17 of the 2005 Act provides as follows:

“(1) Subject to any provision of this Act or rules under Section 41, the procedure and conduct of an inquiry are to be such as the Chairman of the inquiry may direct.

“(3) In making any decision as to the procedure or conduct of an inquiry the Chairman must act with fairness and with regard also to the need to avoid any unnecessary cost (whether to public funds or to witnesses or to others)”.

In an inquiry of the kind that I have conducted it was for me to decide who would give evidence to the Inquiry and what areas should be subject to investigation, all within the parameters of the Terms of Reference. It was not in any way part of my function to resolve issues as a judge might resolve issues between parties in a litigation. The role of Core Participants is quite different to the role played by parties to litigation. Indeed their role should be seen as being one where they are under a duty to assist the Inquiry in responding to its Terms of Reference. As I said at the preliminary hearing on 1 February 2010, the focus of the Inquiry was on investigating, and the Inquiry's questions were to be about finding out what happened, why it happened and, importantly, how to make a difference for the future.

Furthermore, the extent to which Core Participants may question witnesses is significantly constrained by the 2007 Rules. Rule 9 provides:

“(1) Subject to paragraphs (2) to (5), where a witness is giving oral evidence at an inquiry hearing, only –

- (a) the inquiry panel;
- (b) counsel to the inquiry;
- (c) if counsel has not been appointed, the solicitor to the inquiry; or
- (d) persons entitled to do so under paragraphs (2) to (4), may examine that witness.

(2) Where a witness, including a Core Participant, is being examined at an inquiry hearing, the Chairman may direct that the recognised legal representative of that witness may examine the witness”.

There are other provisions in the 2007 Rules regulating the examination of witnesses, but the clear message is that it is for the Chairman to decide whether a witness should be examined by a Core Participant or any other party representing a person.

Standard of proof

The 2005 Act and the 2007 Rules are silent on the standard of proof an inquiry under the 2005 Act should apply when making its findings. I have already mentioned Section 17, which provides that the procedures and conduct of the Inquiry are to be such as I may direct. Furthermore, as I have explained, I must act with fairness. It is worth pointing out that Section 2 of the 2005 Act provides that “an inquiry panel is not to rule on and has no power to determine, any person’s civil or criminal liability”. It is not the function of an inquiry under the 2005 Act to determine the rights and obligations of any parties. In the light of these provisions I considered it to be appropriate to apply the civil standard of proof, a standard of proof on the balance of probabilities.

Expert assistance

The contribution made by all the experts commissioned by the Inquiry cannot be overstated. An inquiry of this kind, with Terms of Reference that required investigation of a range of different factors leading to the development of the problem with CDI, could not perform its function without expert input from a number of different disciplines. I am extremely grateful to all the experts who assisted the Inquiry. Details of the experts are provided in Appendix 4.

Chapter 2

How the Inquiry worked

Introduction

The intention of this Chapter is to set out some aspects of the work undertaken by the Inquiry in preparation for the oral hearings, during the oral hearings and subsequently when the Report was being prepared.

2.1 Inquiry procedures

The Inquiries Act 2005 and the Inquiries (Scotland) Rules 2007

Section 17 of the Inquiries Act 2005¹ (the Act) provides that, subject to the Act itself and to the Inquiries (Scotland) Rules 2007² (the Rules), “the procedure and conduct of an inquiry are to be such as the chairman of the inquiry may direct”.

Guidance on procedures was published on the Inquiry website. As the Chairman explained there, in order to operate most efficiently and effectively an Inquiry needs to operate flexibly. Procedures need to be adopted or adapted to enable this. The Chairman also set out a number of broad principles for the conduct of the Inquiry:

“The Vale of Leven Hospital Inquiry is a public inquiry. It aims to be as open, accessible and transparent as possible.”³

The hearings of the Inquiry (at which witnesses give oral evidence) are designed to:

- deal with the issues in the most effective and efficient way, ensuring that all relevant issues are publicly explored,
- ensure that the material on the Inquiry website allows the public to be kept as fully informed as possible as the Inquiry proceeds,
- ensure that those who are witnesses are afforded a fair opportunity to give their evidence,
- ensure that Core Participants are given a fair opportunity, commensurate with the need for hearings to progress efficiently and with all reasonable speed, to participate in the process”.⁴

Core Participants

The Rules permit the Chairman to designate a person as a Core Participant in the Inquiry, but only with that person’s consent. The Rules also provide that:

“In deciding whether to designate a person as a core participant the chairman must have particular regard for the desirability of including as core participants persons who-

- (a) played, or may have played, a direct and significant role in relation to the matters to which the inquiry relates;
- (b) have a significant interest in an important aspect of the matters to which the inquiry relates; or
- (c) may be subject to significant or explicit criticism-
 - (i) during the proceedings at the inquiry, or
 - (ii) in the report (or any interim report) to be delivered under section 24 of the Act (submission of reports)”.⁵

The bodies and persons granted designation as Core Participants in the Inquiry by the Chairman are listed in Appendix 3.

A number of the individuals designated as Core Participants were former patients. Some were members of the families of patients who had died or were unable themselves to participate due to age or infirmity.

In a number of instances the Inquiry initially received applications from several individuals in respect of the same patient. The Chairman took the decision as a matter of fairness and practicality that only one person would be granted Core Participant status in respect of any individual patient. In the event families were able to reach agreement among themselves as to who should be the Core Participant, and it was not necessary for the Chairman to select any person in preference to another.

Applications were received from a small number of witnesses or potential witnesses

1 Inquiries Act 2005 (c. 12)

2 The Inquiries (Scotland) Rules 2007 (S.S.I. 2007/560)

3 [INQ05650001](#)

4 [INQ05650001](#)

5 Rule 4(2)

who were or had been employees of NHSGGC, but the Chairman took the decision that the role of these individuals was not such as to justify the granting of Core Participant status.

An application from one further individual was declined on the grounds that he had failed to satisfy any of the particular criteria specified in the Rules.

Having been granted Core Participant status, Tayside Health Board elected not to be represented at the first stage of the Inquiry hearings. They later intimated that they considered it unnecessary to remain a Core Participant, and the Chairman decided that Tayside Health Board should cease to be a Core Participant with effect from 10 December 2010.

Document recovery

Around 10,000 documents were recovered by the Inquiry in the course of its investigation. Of these, 5,000 documents were considered to be relevant to the Inquiry's Terms of Reference and were included in the Inquiry document management system. The documents on the document management system comprised 100,000 pages. Most of the documents recovered came from public bodies, and of these the majority came from NHSGGC.

The Inquiry began the document recovery process by sending informal requests to a number of public bodies in October 2009, inviting them to provide relevant documents. As part of that exercise the Solicitor to the Inquiry wrote to NHSGGC on 16 October 2009 and invited them to produce all documents in the custody or control of NHSGGC which fell within the Terms of Reference. The Solicitor to the Inquiry set out in that letter that the documents should be the originals or best available copies of those documents, accompanied by an inventory listing them. NHSGGC was asked to deliver all the relevant documents within four weeks of the receipt of the letter or, if this was not possible in view of the volume of material, to advise the Solicitor to the Inquiry of what additional time would be required.

Difficulties over production of documentation

Thereafter difficulties were encountered over the supply of documentation by NHSGGC. The inventory requested in the Solicitor to the Inquiry's letter of 16 October 2009 was not produced. The Inquiry instead prepared its own inventory of material produced, and provided that to NHSGGC on 20 November 2009. NHSGGC were asked to confirm that it was accurate and to add to it any documentation provided after that date. NHSGGC did not respond to this request, although further emails containing further documents continued to be received by the Inquiry.

On 11 December 2009 the Chairman wrote to the Solicitor for NHSGGC expressing his disappointment over the manner in which the production of documents was being managed. He set out a number of the difficulties in his letter, including discrepancies between the names of documents and their content, lack of confirmation of the number and name of documents, and the apparent lack of relevance to the Terms of Reference of some of the documents supplied. Another of the difficulties concerned an encrypted hard-drive that had been provided by NHSGGC without any instructions as to its encryption or format or as to what it contained.

In the same letter, the Chairman added that he was reluctant to issue a formal Notice to NHSGGC under Section 21 of the Act compelling it to produce documents, and sought an assurance that all documents requested together with a full inventory of all documents supplied would be delivered by 18 December 2009. No reply was received to the Chairman's letter of 11 December 2009. Accordingly on 7 January 2010 a Notice in terms of Section 21 of the 2005 Act was served on NHSGGC.⁶ That Notice set a deadline of 18 January 2010 for the production of documents. Subsequently, a further extension was given to 1 February 2010.

6 [INQ05510001](#)

Continuing difficulties with the production of documents

The difficulties over the recovery of documents from NHSGGC did not abate. As the Inquiry's work continued it was apparent that there was relevant documentation that should have been available but had not been produced. For example, in the period 1 April 2010 to 4 August 2010 some 60 or so requests were made by email by the Inquiry to NHSGGC to provide additional information or documentation. These included requests for documentation relating to the Infection Control Manual, Risk Registers, patient records, job descriptions, and clinical governance papers and minutes. This pattern continued.

In mid February 2011 it was apparent to the Inquiry that a significant number of laboratory reports detailing the results of tests for *C. difficile* toxin were missing from the patient records. It was only then that, at the request of the Inquiry, NHSGGC made available computer records in the form of spreadsheets providing highly significant information on the results of tests. There were other items missing from the patient records that were only supplied when specifically requested. Even through 2011 and 2012 requests for documents were being made by the Inquiry. A significant number of documents relevant to the work of the Inquiry were provided by NHSGGC over that period.

Problems with document content

The quality of the photocopying of patient records supplied by NHSGGC was extremely poor. Many dates were obscured in the copying process and items omitted. This, together with records out of chronological order and instances of poor record keeping, frequently made it difficult to ascertain what was missing, and entailed detailed enquiry to obtain fully legible copies and discuss whether:

- pages had not been copied;
- pages had existed but could not be traced; or
- patient records had ever existed.

The Inquiry readily acknowledges that NHSGGC devoted considerable time and effort to rectifying problems as they arose, but it is regrettable that no quality assurance process appears to have been carried out by NHSGGC at the original copying stage. Nor did it seem that lessons were being learned, as copies of patient records received in 2012 still had dates and notes which were obscured.

Failures by NHSGGC

The work of the Inquiry would have been greatly assisted, and its duration reduced, had NHSGGC:

- recognised at the outset the size of the task it faced;
- taken adequate steps to review what range of material was relevant to the Inquiry's Terms of Reference;
- established adequate management systems for the transfer of material; and
- put in place quality assurance measures for copying of documents.

The lesson to be learned from this experience is that, in an inquiry of this kind, a holder of documents should put in place a system dedicated to identifying relevant documents and a system of quality assurance designed to ensure that when documents are produced they are in a complete form and legible.

The Inquiry does, however, appreciate the work and the unfailing courtesy and helpfulness of those employees of NHSGGC who were responsible for handling the hundreds of different requests for documents that ultimately had to be made as the Inquiry progressed.

Witness statements and the statement taking process

The Inquiry engaged a number of statement takers, including lawyers and former police officers, to take statements from witnesses whose evidence appeared relevant to the Inquiry. The statement takers worked under the general supervision of the Solicitor and Deputy Solicitor to the Inquiry, and were given training and guidance to ensure that relevant issues were addressed and that each statement was comprehensive. In many

instances Counsel to the Inquiry provided details of issues to be addressed in taking the statements. Some statements were also taken by Junior Counsel and by the Solicitor and Deputy Solicitor, particularly in the later stages of the Inquiry.

The Inquiry sent letters to all those from whom they wished to take statements. The Inquiry had no power to compel a witness to meet with a statement taker, and engagement in this statement taking process was therefore voluntary. That was made clear to all potential witnesses, and almost all those asked to meet with statement takers were fully co-operative.

It was of course necessary for the Inquiry to seek the assistance of NHSGGC managers to arrange to take statements from those witnesses still in the employment of NHSGGC. For many the process had to be scheduled around or during working time. The Inquiry acknowledges the commitment of Ms Anne Harkness, Director of the Rehabilitation and Assessment Directorate, in putting arrangements into place to allow this to happen.

In a few cases where witnesses delayed in providing statements the Chairman made further use of his powers under Section 21 of the Act to require the witness to supply his or her own statement. A statement provided directly by a witness was of course less valuable to the Inquiry in that it did not necessarily address the issues of interest to the Inquiry in a satisfactory manner.

Each witness was offered the opportunity to have his or her own legal adviser, a colleague, or a union representative present when a statement was being given. In the case of nursing staff employed by NHSGGC, however, the Chairman refused to sanction attendance at interview of a solicitor acting on behalf of NHSGGC. The position adopted by a NHSGGC legal representative at that time was that no conflict of interest existed between NHSGGC and its employees, and that it would be appropriate for the Solicitor for NHSGGC to be present. The Chairman decided that witnesses should provide their statements in as free an environment as possible, and considered that the presence of an employer's legal

representative, rather than the witness's own representative, might inhibit the statement taking process.

After interview, the statement taker produced a draft statement. This was supplied to the witness, who was invited to make any corrections. Once satisfied with the final version the witness was asked to sign a copy.

The Inquiry used statements as the evidence of witnesses whom it was not necessary to call to give oral evidence. Where a witness did give oral evidence, he or she was asked to expand upon aspects of the statement rather than to repeat its contents.

Some witnesses were asked to give supplementary statements providing further detail on aspects of their earlier statements.

Preliminary hearing

No provision is made in the Act or in the Rules for a preliminary hearing, but using the broad procedural powers available to him the Chairman instructed that a preliminary hearing should take place at Dumbarton Sheriff Court on 1 February 2010. The process of designating Core Participants had not begun, but representatives of interested parties were invited to attend. The preliminary hearing proved a useful tool in engaging those parties and in raising public awareness of the Inquiry both locally and nationally. It also provided a focus of attention for local people, since it had by then become apparent that the main hearings would have to take place outwith the Dumbarton area. The Inquiry is grateful to the Sheriff Clerk at Dumbarton and his staff for allowing the use of court facilities for this hearing.

Appointment of experts

The ingathering of documents has already been discussed. Patient records were not received by the Inquiry until after 18 January 2010.⁷ The Inquiry reviewed the patient records and identified the need for an in-depth analysis by experts. Areas identified that required to be investigated included medical and nursing care. On 21 April 2010

7 [GGC33110001](#)

Dr Sheldon Stone was invited to assist the Inquiry in its consideration of the medical care given to CDI patients. Professor Brian Duerden was invited at the same time to provide expert assistance in relation to infection prevention and control. Mrs Christine Perry was also invited to be an expert to the Inquiry. At that time it was thought that her focus would be on nursing care. Later, on 4 June 2010, Mr Alex Smith was invited to assist the Inquiry's consideration of management issues.

By 17 June 2010 these experts had agreed to assist the Inquiry, although from October 2010 Dr Stone was unable to continue because of the nature of the commitment necessary. The Inquiry acknowledges the contribution of Dr Stone in first identifying many of the issues surrounding patient care that feature in the Report.

It became apparent that examination of the patient records with the necessary scrutiny required the number of cases allocated to a particular expert to be limited. That meant that a number of experts had to be commissioned in the areas of nursing, microbiology and medicine. That commissioning process continued through 2010 and up to March 2011.

The instruction of a number of experts in each field enabled the Inquiry to allocate cases from different wards to different experts. This allowed the Inquiry to see if there were common trends identified by the experts, and provided the Inquiry with an important cross-check of an individual expert's conclusions. Trends did emerge, and these trends are discussed in other Chapters of the Report.

Oral hearings

Oral hearings took place over 126 days from 7 June 2010 to 28 June 2012.

The first phase of oral hearings began on 7 June 2010, and was devoted to the evidence of patients and family members. As a sign of respect, hearings opened with a minute's silence in memory of those patients who died. The decision was taken to commence hearing oral evidence even although much of the

Inquiry's investigative work remained outstanding, and in particular expert input into areas of interest to the Inquiry was far from complete. Nevertheless, the Inquiry considered it to be important to hear from this group of witnesses as soon as possible after their signed statements had been completed.

Preparation of witnesses

As explained previously, Core Participants had full access to all documents on the Inquiry document management system, and those witnesses called to give oral evidence were able to use these in preparation for giving evidence.

Where necessary, and where requested, the Inquiry provided witnesses with information on the scope of questions which might be put to them, as well as copies of any documents to which they might be referred in the course of their evidence.

In the case of nursing staff, assistance in preparation was provided by the Royal College of Nursing (RCN). Members of the medical staff sought assistance from their own professional bodies.

Representation of witnesses

A number of patients and their relatives who gave evidence were represented by Messrs Thompsons, Solicitors, and by Senior and Junior Counsel instructed by them.

Guidance protocol

A protocol providing guidance on witnesses and the taking of evidence was published on the Inquiry website in December 2009, well in advance of the commencement of the oral hearings on 7 June 2010.⁸ That guidance reflected the terms of the Rules in explaining how evidence at the oral hearings would be managed. It also gave notice that anyone having a sufficient interest in the evidence of a witness should submit any line of questioning they wished Counsel to the Inquiry to put to the witness one week in advance of the witness giving evidence. The principle behind that provision was to allow Counsel to the Inquiry sufficient time to consider the lines of questioning proposed.

8 [INQ05660001](#)

In practice, there had to be flexibility. Many of the written questions suggested were in any event pursued by Counsel to the Inquiry in his own examination of the witness. As the Inquiry progressed, however, written questions were submitted at an increasingly late stage, including on the eve of the witness giving evidence or indeed even during the witness's evidence. This became very difficult to manage, particularly as on occasions hundreds of written questions were submitted. Unless reasonable notice is given, an arrangement where Core Participants submit written questions of the kind and quantity received by the Inquiry is not particularly helpful, and can hinder the progress of the Inquiry.

The Chairman did allow parties to conduct some oral examination of witnesses when it was evident that there was a reasonable basis for that to be done. Although the Act⁹ provides that the procedure and conduct of the Inquiry shall be such as the Chairman directs, and the Chairman had directed that all questions should be submitted to Counsel to the Inquiry, the Act also provides that the Chairman must act with fairness.¹⁰ When the Chairman considered it fair to do so he did allow a certain amount of leeway to parties in the questioning of witnesses.

Written questions and answers

In the case of some witnesses, mainly experts instructed by the Inquiry, each witness was asked to provide written responses to questions from other parties after giving oral evidence. These written answers were then published on the Inquiry website along with transcripts of the oral evidence of the witness.

Publication of evidence

A full transcript of each day's evidence was published on the Inquiry website, usually by about 18:00 on the same day.

Access to hearings

All hearings were held in public, and no application was made to hold any part of the hearings in private.

Restriction on publication

The Act permits the Chairman in certain circumstances to make a Restriction Order restricting the disclosure or publication of any evidence or documents given, produced or provided to an Inquiry.¹¹ The Chairman made one such order in the course of the Inquiry. Where patients had died, no issue of disclosure of personal data or sensitive personal data under the Data Protection Act 1998¹² arose. In the case of living patients whose cases were examined by the Inquiry, most gave consent to the use of records and to their identification. In three instances, however, patients were unable to grant consent. The Chairman considered that in order to fulfil the remit of the Inquiry it was necessary for their records to be examined at the hearings, but made an order that these patients should be referred to in public documents as Patients A, B and C. A further patient was later designated as Patient D.

Nurses contacted to obtain statements

Between 27 April and 9 December 2010 the Inquiry contacted 45 potential nurse witnesses. This number does not include Infection Control Nurses or nursing staff above Senior Charge Nurse level. The Inquiry took statements from 26 nurses and supplementary statements from five of those nurses. Nineteen nurses did not provide statements. The Inquiry excused two of these nurses from participation on medical grounds and the remaining 17 nurses could not be traced or failed to respond to requests. Where witness statements were taken, nurses were permitted to read and correct them before signing. It was not considered necessary to obtain statements from domestic staff or nursing auxiliary staff.

The evidence of the nurses and their legal representation

The Inquiry's original plan was that the oral evidence of nurses would begin on 31 May 2011 in the course of the session that was to commence on 16 May 2011. The first two weeks of that session from 16 May 2011 were to be dominated by nursing expert evidence. Citations were sent out to nurses on

9 Section 17(1)

10 Section 17(3)

11 Section 19

12 Data Protection Act 1998 (c. 29)

22 April 2011, with one of the nurses due to start her oral evidence on 31 May 2011. As matters developed, and as recounted later in this Chapter, because of the nurses' lack of preparation their evidence eventually had to be postponed to 23 August 2011.

Royal College of Nursing: initial involvement

The Royal College of Nursing (RCN) is the largest union and professional body for nurses in the United Kingdom, and provides support to its members including legal advice and representation. Shortly before the Inquiry was officially set up on 1 October 2009, the RCN, through their solicitors, expressed interest in participating in the Inquiry, but early in 2010 a solicitor acting on behalf of the RCN indicated that the RCN did not intend to apply for Core Participant status.

Subsequent RCN involvement

No further contact was made by the RCN with the Inquiry until March 2011. As already explained, at that time the plan was that nurses would be giving evidence to the Inquiry from 31 May 2011. It is clear that some nurses, on being contacted to give evidence, had made contact with the RCN seeking support. In the meantime the RCN had been provided with a summary of nursing expert reports by the Solicitor for NHSGGC. The RCN on 10 May 2011 submitted an application for Core Participant status, the purpose in so doing being to gain access to expert reports and witness statements. That application was granted by the Chairman on 13 May 2011.

No representation by the RCN

At the Inquiry hearing on 16 May 2011, Mr Dickson, Solicitor appeared on behalf of the RCN. He intimated that the RCN did not intend to represent their members who were due to give evidence to the Inquiry.¹³ Rather, the intention was that nurses who were to give oral evidence would be supported by being fully prepared to give their evidence.¹⁴ Thereafter the RCN held group information sessions with nurses due to give oral evidence, providing information on such matters as the nature of the Inquiry, the main

criticisms in the nursing expert reports, and the procedure for giving evidence at the Inquiry.

The NHSGGC position on representation

The first indication that NHSGGC would not be representing the nurses employed at the VOLH was provided in a Note submitted on behalf of the NHSGGC Board on 2 June 2011. In May 2010 the solicitor for NHSGGC had intimated that he would be representing the interests of nurse witnesses unless a clear conflict of interest emerged. Prior to June 2011 there was no suggestion from him that the position had changed.

Shortly before the start of the oral hearing of 6 June 2011, a written submission was lodged with the Inquiry Counsel. Counsel for NHSGGC was invited to address the Inquiry on the NHSGGC Board's position. Counsel then submitted that in his opinion there was a potential conflict of interest between NHSGGC and its nursing staff, and indeed between the nurses themselves.¹⁵

At the start of the oral hearing on 9 June 2011 Counsel for NHSGGC intimated that, having taken the advice of the Dean of the Faculty of Advocates the previous evening, he had been advised that there was a potential conflict of interest between the NHSGGC Board and its nursing staff.¹⁶ The Solicitor for NHSGGC had sought and received similar advice from his professional body, the Law Society of Scotland, and also from the senior legal adviser to the NHS in Scotland.¹⁷ It followed that Counsel and the other members of the legal team for NHSGGC could not provide any advice or assistance to the nurses who were to be called to give oral evidence. In intimating this position Counsel for NHSGGC described it as "an unfortunate development".¹⁸

It was indeed highly unfortunate. By this time a significant amount of nursing expert evidence had been led. Nursing expert reports containing criticisms of nursing care had been available to NHSGGC from early April 2011

13 [TRA00090004](#)

14 [TRA00090003](#)

15 [TRA00140002](#)

16 [TRA00170001](#)

17 [TRA00170002](#)

18 [TRA00170001](#)

and, in any event, most of the proposed areas of criticism had been intimated to NHSGGC on 17 March 2011.¹⁹ It had been obvious for some time that nurses were to be criticised for the care of patients suffering from CDI. It was now obvious that no assistance had been provided by NHSGGC to its nursing staff to prepare them to give evidence and to respond to the criticisms being made of the quality of nursing care.

Had a full examination of the patient records been carried out when the CDI problem emerged, the kind of potential conflict intimated by Counsel for NHSGGC in June 2011 might have been recognised much sooner. Steps of the kind that were ultimately taken to protect the interests of nurses could then have been taken. The failure of NHSGGC to carefully examine the patient records in June 2008 left the nursing staff in an unfortunate position, but a position that was ultimately rectified.

Assistance to nurses by the Inquiry

When it became evident that the nurses were not to be provided with legal representation by their employer or by the RCN, the Inquiry's Witness Liaison Manager made visits to the VOLH on 16 and 21 June 2011 and to the Royal Alexandria Hospital (RAH) on 22 June 2011 to meet with nurses. Nurses were given the option of meeting at the hearing venue at Maryhill if they preferred.

The Witness Liaison Manager met with 18 nurses individually during that period. At those meetings the nurses were provided with a list of the patients with CDI in their ward. They were given copies of patient records of those patients and other documents that might be referred to in evidence. They were provided with copies of timeline charts which provided information on when patients were confirmed with CDI, and an explanation of how to interpret the charts. Each nurse received a copy of the Statement of Principal Issues for Nursing Staff²⁰ prepared by the Inquiry outlining issues that might be addressed in hearings. Nurses also had access to the transcripts of evidence led

to date. Most nurses made use of this facility and read the evidence of other nurses and the evidence of patients and relatives.

The Inquiry arranged three familiarisation visits for the nurses at the hearing venue in Maryhill on 20 April, 26 April and 3 June 2011. These visits were attended by 17 nurses. Some nurses who attended the venue in Maryhill prior to giving evidence were able to listen to evidence being given at that time by other nurses.

Further representations by the RCN

The RCN decision not to represent any nurses, communicated at the oral hearing of 16 May 2011, of course came at a time before Counsel for NHSGGC intimated the Board's position on 9 June 2011. Following this disclosure, Mr Dickson again attended the Inquiry's oral hearing on 14 June 2011 to provide further clarification of the role the RCN would play now, particularly since NHSGGC was not going to advise or represent nurses. Mr Dickson explained that the RCN were not representing any individual nurse or group of nurses because it was considered there could be conflicts between different nursing groups.²¹ Mr Dickson did outline the information sessions that had been held with nurses, but he made it clear that he himself would not be in attendance at the oral hearings when RCN members were giving their evidence. That meant that if a nurse had a problem in connection with giving evidence no advice would be available to that nurse.

Although it came rather late in the day, the input that was now being provided by the RCN was to be welcomed, since up until this time the nurses had not been provided with assistance in preparing to give evidence to the Inquiry. The evidence of nurses due to be led in May had been postponed to 13 June 2011 and then to 4 July 2011 for reasons unconnected with the issue of representation, but as already mentioned the nurses were unfortunately not then ready to give evidence to the Inquiry. That evidence was then further postponed to 23 August 2011. Time was lost, but an adjustment to the order of witnesses was possible and that did mitigate the position.

19 [INQ05490001](#)

20 [INQ05360001](#)

21 [TRA00190124-126](#)

Financial support for legal representation of nurses

The RCN decided not to provide financial assistance to nurses to enable them to obtain legal advice from a separate legal firm. The RCN is only obliged to provide financial assistance to nurses in the event of a clinical negligence claim, so the decision on whether to support members involved in a public inquiry financially was a matter entirely for the RCN's discretion. The Chairman considered that as a matter of fairness any nurse who might be subject to criticism should have legal advice and representation available. In due course, the Chairman granted a number of applications from nurses for funding for legal representation.

Delay and expense

The decision of NHSGGC not to advise or represent the nursing staff resulted in some delay in the proceedings of the Inquiry, but not a material delay that affected the Inquiry's timescale. As a matter of fairness to nurses who might be subject to criticism, appropriate arrangements had to be put in place to protect their interests. Additional public expense was incurred through the provision of independent legal advice to nurses and on legal representation at the oral hearings, but no doubt if NHSGGC had taken a different stance a year earlier additional expense would have been incurred in any event. The whole process, however, could have been managed differently by NHSGGC. As it was, because of the Chairman's desire to make progress as quickly as possible, a number of different solicitors became involved acting for different nurses.

The nurses' oral evidence

Ten nurses gave oral evidence. It was considered important, where possible, to obtain oral evidence from SCNs on wards where CDI had been identified as a problem. It was also considered to be beneficial to hear evidence from some Staff Nurses on those wards. From the evidence given by those nurses, it did not appear that any nurse's position had been unfairly compromised by a lack of advice.

Extended statement procedure

The Inquiry identified five nurses from whom it was necessary to take further evidence in the form of extended statements. These nurses were interviewed by Inquiry Counsel, and a written record was taken of each witness's evidence which the witness checked and signed. The legal representatives of Core Participants to the Inquiry were also permitted to provide lists of questions to be put to those witnesses. Funding was provided for these nurses who wished to have legal representation.

The doctors who gave evidence and legal representation

The Inquiry obtained statements from 14 doctors who worked at the VOLH during the focus period. Eight of those also gave oral evidence.

All of the doctors who gave oral evidence were members of a professional union which provided legal representation for them.

Assistance given to medical witnesses by the Inquiry

All doctors who gave evidence at the Inquiry's oral hearings had access through their legal representatives to the Inquiry's database of evidence, which included patient records and the statements of other witnesses.

In addition, the Inquiry provided doctors giving evidence with a list of the CDI patients about whom they might be asked. Prior to giving evidence they were provided with copies of timeline charts prepared by the Inquiry which detailed which patients were confirmed with CDI and when that confirmation was made. They were also given an explanation of those charts by the Witness Liaison Manager before they gave evidence. Some doctors attended the hearing venue in Maryhill prior to giving evidence and were able to listen to evidence being given by other medical witnesses.

List of witnesses

Details of all witnesses who provided statements and gave oral evidence are set out in Appendix 5.

Key witnesses who did not give evidence

Three key witnesses, Mrs Deborah den Herder, Dr Elizabeth Biggs and Dr Elizabeth Jordan were unable to give evidence and the reasons for this are discussed later in this Chapter.

Mrs Deborah den Herder

Chapter 9 explores the background leading to the dissolution of NHS Argyll and Clyde on 1 April 2006 and the creation of the Directorate of the Acute Division (the Clyde Acute Directorate). Mrs den Herder took up the post of Director on 1 October 2006, a post that carried with it significant responsibility for healthcare in the Clyde area including the VOLH. The Inquiry therefore took the view that it would be desirable for Mrs den Herder to give evidence to the Inquiry.

Requests for a statement

By letter dated 29 June 2010 Mrs den Herder was invited to provide a statement to the Inquiry. At that time Mrs den Herder was living in the Netherlands, having resigned from her post as Director of the Clyde Acute Directorate in July 2008. On 6 July 2010 Mrs den Herder made a telephone call to the Inquiry office and spoke to the Witness Liaison Manager. In the course of that conversation she confirmed that she was living in the Netherlands. Her position was that she was not able to give a statement to the Inquiry. She said that she had suffered serious illness and had little recollection of anything that would be of particular assistance to the Inquiry. She followed that telephone conversation with a letter dated 30 July 2010 confirming that she was unable to contribute usefully to the Inquiry.

The Inquiry wrote again to Mrs den Herder on 28 September 2010. In that letter she was invited to reconsider providing a statement to the Inquiry. It was suggested that this could be carried out in the Netherlands at her convenience. No response to that letter was received.

Request to give evidence

As the Inquiry progressed it became more and more evident that Mrs den Herder, as the Director of the Clyde Acute Directorate, could

be in a position to provide important assistance to the Inquiry. Another letter on the Chairman's behalf was sent to her on 17 November 2011, again to her address in the Netherlands. In that letter Mrs den Herder was asked to confirm whether she was prepared to give evidence to the Inquiry.

Mrs den Herder's response to the Inquiry

Mrs den Herder responded in an email dated 2 February 2012 to which a letter was attached. By this time she had moved to live in Beijing, China. In her letter she said that she had only just received the letter of 17 November 2011 and had not received the previous letter of 28 September 2010. She explained that she had not lived in the Netherlands since the summer of 2010. In her letter of 2 February 2012 Mrs den Herder provided some information about her health, which should remain confidential, and she repeated her position that she had no recollection of events at the VOLH. She apologised for not being more helpful.

Mrs den Herder did not accept the invitation made in the letter of 17 November 2011 to give evidence to the Inquiry. Another letter dated 26 March 2012 was emailed to her and a further letter was sent by email dated 8 June 2012, towards the end of the oral hearings. The intention at this time was to invite Mrs den Herder to elaborate upon what she had mentioned in previous correspondence about the stress and "burnout" she experienced during her time as Director of the Clyde Acute Directorate. Mrs den Herder responded to that letter by email and attached a letter dated 22 June 2012. In the email itself, Mrs den Herder said that she had taken time to try to recollect the events of 2008 and the circumstances of her appointment. It is certainly the case that in the six page letter attached to the email Mrs den Herder does provide some detailed information on these issues, and in particular discloses that the nature of her post was causing significant stress that ultimately resulted in what she referred to as "burnout". This is considered in more detail in Chapter 9. In that letter Mrs den Herder asked to put on record her sincere regret for the incidents which occurred at the Vale of Leven Hospital in 2008.

Final correspondence

Mrs den Herder was sent another letter by email dated 20 August 2012. In that letter she was invited to respond to evidence provided to the Inquiry by certain witnesses. She was provided with hyperlinks to the transcripts of these witnesses' evidence, and also reminded that all the oral evidence heard by the Inquiry was available on the Inquiry website as were the witness statements. Mrs den Herder responded to that request by letter dated 13 September 2012. Her letter is discussed in Chapters 9 and 15 of the Report.

It was evident from the contents of Mrs den Herder's last two letters of 22 June and 13 September 2012 that by that time she was able to recollect events and respond to issues raised in the evidence, no doubt with the assistance of the materials available to her on the Inquiry website. The Chairman, however, took the view that the detailed information provided by her in those two letters could only be relied upon if the information was already available to and accepted by the Inquiry.

It is unfortunate that Mrs den Herder was not able to provide a witness statement or oral evidence to the Inquiry, but it must be stressed that the Inquiry had no powers to compel her to do so as she resided outwith Scotland.

Dr Elizabeth Biggs

During the period 1 January 2007 to early February 2008 Dr Elizabeth Biggs was the Infection Control Doctor (ICD) for the VOLH. She was also the ICD for the RAH and the IRH where she was based. As set out in this Report Dr Biggs failed in a serious way to carry out her responsibilities as the ICD for the VOLH.

Initial contact with Dr Biggs

When Dr Biggs was first contacted it appeared that she would be able to give evidence to the Inquiry. By email dated 9 February 2010 the solicitor for NHSGGC indicated that Dr Biggs would be a witness at the Inquiry. A letter from the Inquiry dated 21 June 2010 to Dr Biggs requested that she provide a statement of her evidence to the Inquiry. Subsequently Dr

Biggs forwarded to the Inquiry a letter from a General Practitioner (GP) setting out medical reasons, which should remain confidential, for seeking to have Dr Biggs' participation in the Inquiry postponed. On 5 October 2010 the Deputy Solicitor to the Inquiry wrote to the GP asking for an update as to whether Dr Biggs was fit to give a statement or oral evidence to the Inquiry. A response dated 14 October 2010 was received from the GP to the effect that Dr Biggs remained unfit to give evidence of any kind at that point in time. The GP provided contact details of a colleague should the Inquiry require a specialist opinion, and the Deputy Solicitor wrote to the specialist medical practitioner on 20 October 2010. By letter dated 4 November 2011 the specialist medical practitioner confirmed that Dr Biggs was unable to give evidence and indicated that to do so would be detrimental to her health. The Chairman agreed that the situation should be reviewed once the Inquiry reached the relevant chapter of evidence.

Further contact with Dr Biggs

One year later, the Inquiry reviewed the situation prior to leading evidence on microbiology and infection control issues. The Deputy Solicitor wrote to the GP on 18 November 2011 requesting an update on whether Dr Biggs was fit to give a statement or evidence to the Inquiry. The GP responded on 7 December 2011 to say that Dr Biggs remained unfit to give evidence and questioned whether she would ever be fit to engage with the Inquiry.

In March 2012, evidence critical of Dr Biggs was emerging during oral hearings, and the Chairman was concerned that for reasons of fairness Dr Biggs should be legally represented. He was also of the view that, if Dr Biggs wished to be excused attendance from the Inquiry, it would be appropriate for her to be examined by a specialist medical practitioner instructed by the Inquiry. The Solicitor to the Inquiry wrote to the GP on 5 April 2012 explaining the workings of the Inquiry, including the warning letter process, and suggesting that the GP discuss with Dr Biggs her participation in the Inquiry. The Solicitor to the Inquiry also advised that Dr Biggs should consult with her professional association and perhaps obtain legal advice.

Finally, he conveyed the Chairman's view that Dr Biggs should be reviewed by a specialist medical practitioner instructed by the Inquiry.

The GP telephoned on 26 April 2012 to say that Dr Biggs had been advised to contact the Medical and Dental Defence Union of Scotland (MDDUS) of which she is a member. Since by 14 May 2012 the Inquiry still had not had contact from Dr Biggs or a representative, the Solicitor to the Inquiry wrote again to the GP asking if there had been any progress. The following day the Inquiry received a letter from Dr Biggs' solicitors confirming that they were acting for her on the instruction of the MDDUS and requesting that the Inquiry only contact Dr Biggs through them. Correspondence followed between the Solicitor to the Inquiry and Dr Biggs' legal representatives outlining arrangements for access to documents and the engagement of a specialist medical practitioner to review Dr Biggs' ability to give evidence.

Independent Medical Review

A specialist medical practitioner was approached, and with Dr Biggs' agreement an appointment was arranged. On 25 May 2012 the Solicitor to the Inquiry wrote a letter of instruction to the specialist medical practitioner outlining what was required, and requesting that if the doctor thought that Dr Biggs was unfit to give oral evidence to the Inquiry a "Soul and Conscience Certificate" should be submitted.

The independent medical review dated 4 June 2012 concluded that Dr Biggs was unfit to attend the Inquiry or to provide a statement, but that she was fit to instruct her solicitors. Core Participants' legal representatives were advised of this on 11 June 2012.

Dr Elizabeth Jordan

Dr Elizabeth Jordan was the Associate Medical Director for Clyde Directorate until 12 August 2007. She left for Australia soon afterwards. Because she was living in Australia, and because she had left some time before the CDI problem had emerged, she was not contacted by the Inquiry until a late stage in the proceedings. It was only once her name had been mentioned several times in oral evidence that the Inquiry took the decision to

make contact with her. On 7 June 2012 the Secretary to the Inquiry wrote to NHSGGC to obtain contact details. An email was then sent to Dr Jordan on 12 July 2012 outlining the reasons for contact and seeking the best contact address for future correspondence, to which she responded.

The Solicitor to the Inquiry emailed Dr Jordan on 4 October 2012 to request her assistance, and attached a number of documents for her to consider along with a list of questions. The questions covered Dr Jordan's remit including her responsibilities for the VOLH, her knowledge of the difficulties with Dr Biggs, the arrangements for the secondment of Ms Marie Martin, the medical staffing arrangements at the VOLH, and questions about the Clinical Governance Committee.

Dr Jordan replied on 7 November 2012 saying that she was unable to assist the Inquiry due to the time which had elapsed since she had left for Australia. Her memory of structures and processes was such that she did not believe that she could validly respond to questions relating to that time.

It is unfortunate that Dr Jordan was not able to provide a witness statement or oral evidence to the Inquiry but the Inquiry had no powers to compel her to do so as she resided outwith Scotland.

Closing submissions

The Rules²² permit Core Participants to make opening and closing statements to the inquiry.

At the close of hearings on 28 June 2012 the Chairman intimated that the Inquiry would circulate a draft list of topics to be addressed in closing submissions. A number of additions to this list were proposed by Core Participants and certain amendments were made in the light of these. The final list was published on the Inquiry website.

Core Participants were invited to make written closing submissions through their legal representatives, and all did so with the exception of the Royal College of Nursing and Health Facilities Scotland. Other parties

22 Rule 10

wishing to make written submissions were invited to apply to the Chairman for leave to do so, and applications were allowed, again through legal representatives, in respect of the following:

Dr Javed Akhter
Dr Elizabeth Biggs
Dr Afaq Khan
Mrs Jean Murray
Mr Thomas Walsh

Once all the submissions were received, the Inquiry circulated submissions to all the parties concerned and provided them with the opportunity to make written responses to other parties' submissions. Following completion of that exercise the decision was taken that no further oral hearing was necessary.

Counsel to the Inquiry did not consider it necessary to make a closing submission on behalf of the Inquiry.

Warning letters

The Rules²³ provide that "The inquiry panel must not include any significant or explicit criticism of a person in the report (and in any interim report) unless -

- (a) the chairman has sent that person a warning letter; and
- (b) the person has been given a reasonable opportunity to respond to the warning letter."

Issue of warning letters

In accordance with the Rules, warning letters were sent out to a number of individuals and organisations because the Inquiry was considering making significant or explicit criticism of them in the final Report. They were all offered the opportunity to respond to the warning letters within a specified time, and the Chairman granted extensions of the time limit where that was necessary. The warning letters included a schedule summarising the nature of the proposed criticism and providing references to evidence that supported the criticism being made.

Confidentiality of warning letters

The Rules provide that the recipient of a warning letter may disclose it to the recipient's recognised legal representative.²⁴ Otherwise the contents of a warning letter are subject to an obligation of confidence owed separately by the Inquiry to the recipient and by the recipient to the Chairman.²⁵ That obligation of confidence may, however, be waived,²⁶ and the Chairman granted a number of applications for waiver to assist recipients in preparation of responses to the warning letters.

Responses to warning letters

All but one of the recipients of warning letters responded to their letters. The Chairman was able to give careful consideration to all the responses made and was able to take them fully into account in the final Report.

It is to be noted that in a number of the responses recipients maintained that the specific criticism proposed had not been put to them in the course of the oral hearings. This reveals a misunderstanding of the nature of the inquisitorial process, and confuses it with the adversarial process that normally exists in a court setting. The whole purpose of the warning letter process is to give notice to individuals and organisations of potential criticism, so that they have the opportunity of making an appropriate response to that proposed criticism. The warning letter process itself ensures fairness for anyone who may be criticised.

2.2 Inquiry organisation and administration

The Inquiry Team

Details of the members of the Inquiry Team are outlined in Appendix 2.

Inquiry premises - Lothian Chambers

The Inquiry leased office premises from Edinburgh City Council at Lothian Chambers, George IV Bridge, Edinburgh. These had

23 Rule 12(7)

24 Rule 12(6)

25 Rule 13(1)

26 Rule 13(2)

previously been occupied by the ICL Public Inquiry. The Inquiry would like to thank Edinburgh City Council for this office accommodation and Scottish Courts Service for providing the Inquiry's IT support.

Accommodation for hearings

All oral hearings were held at Maryhill Central Community Halls, Maryhill Road, Glasgow.

Before selecting premises in Glasgow the Inquiry actively sought a suitable venue for hearings in the Dumbarton or Vale of Leven area. Two potential sites were visited by members of the Inquiry, but it quickly became apparent that neither of these could accommodate the number of Core Participants and members of the public who might attend. Furthermore, the Inquiry was acutely aware that adaptation of premises to form a suitable chamber for hearings as well as ancillary and office accommodation would cost a significant sum and would take a considerable time to complete.

The hall at Maryhill had previously been adapted for the ICL Inquiry, and immediately prior to use by this Inquiry was being used for hearings by the Fingerprint Inquiry. This meant that there were cost efficiencies, as the venue had already been refurbished and furniture and some other equipment could be re-used. The Inquiry appreciates the assistance provided by all the staff and management at Maryhill Central Community Halls. Although that venue involved additional travel for any patients and families living in the Vale of Leven area who wished to attend, it was readily accessible by public transport.

A venue in the west of Scotland did of course also mean daily travel for members of the Inquiry based in Edinburgh.

Document management system

In its early stage the Inquiry engaged a specialist consultant, Mike Taylor, of I-lit, to advise on the procurement of a document management system and court reporting system. Tenders were invited for supply of these services, and following this, a contract for the court reporting system was awarded to Merrill Corporation and a contract for the

document management system was awarded to Bramble, which sub-contracted the service to Merrill Corporation.

An electronic document management system was established, and those documents recovered which were considered relevant to the Inquiry, as well as documents created in the course of the Inquiry such as spreadsheets and timelines, were uploaded to this.

Access to documents

Access to the document management system was available to the Inquiry using secure connections over the internet, both in the Inquiry Office and at remote locations. Core Participants could also access the document management system over the internet.

Document display at hearings

During public hearings at Maryhill Community Central Halls the Inquiry was able to use the Merrill Corporation "Trial Director" system of document display. The hearing chamber was fully equipped with all the necessary cabling and hardware to display document images to the Chairman, Counsel, Core Participants' legal representatives and witnesses. The process allowed individual documents to be called up on screens positioned in front of users. In addition, a number of screens were positioned in the chamber that allowed the public to view the images.

Merrill Corporation provided software to enable the display of individual pages using the specific reference and pagination number for each document. Merrill Corporation also provided a trained operator who displayed the documents used in the oral hearings.

Registration with Information Commissioner's Office

The Inquiry registered as a data controller with the Information Commissioner's Office on 4 January 2010. A meeting was also held with the Information Commissioner's Office on 17 March 2010 to discuss how the Inquiry could ensure best practice with regard to handling data under the Data Protection Act 1998.²⁷ This was particularly important given

27 Data Protection Act 1998 (c. 29)

that the Inquiry held patient records. The Inquiry developed a security policy and regularly reviewed data protection issues at team meetings. A security log was maintained to ensure that any potential breaches of the policy were identified and promptly resolved.

Website

In October 2009, soon after it was established, the Inquiry set up a website, www.valeoflevenhospitalinquiry.org. This site was used extensively to provide information to potential Core Participants, witnesses and other interested parties, particularly in the initial stages of the Inquiry. Among the items posted on the website in the initial stages were:

- Background information on the Inquiry Team
- Core Participants
- A list of “Frequently Asked Questions”
- Guidance on witnesses, Core Participants, funding for legal representation, documents, procedures
- Application forms for Core Participant status, funding, travel and subsistence expenses, and compensation for loss of time
- Key documents, including the Inquiries Act 2005, the Inquiries (Scotland) Rules 2007, the Scottish Ministers’ Determination on Costs, and the Inquiry’s Terms of Reference
- Press releases

As mentioned earlier in this Chapter, as the Inquiry hearings progressed, transcripts of each day’s proceedings were published on the website, as were context setting documents and witness statements.

Public relations

Given the significant media interest in the work of the Inquiry, the BIG Partnership was appointed through a procurement process to deliver a media and public relations strategy for the duration of the Inquiry.

The BIG Partnership was commissioned to prepare press releases and to pro-actively engage the media at critical points in the Inquiry’s lifespan. These included the call for evidence, launch of the Inquiry’s website, the

start of public hearings, and subsequent extensions to hearings. In addition, the Big Partnership represented the Inquiry at the oral hearings and at other meetings, preparing and handling media briefings as required. They also provided a media monitoring service on press coverage for the Inquiry and on any related articles on *C. difficile* and infection control issues. The Inquiry found the engagement of an external agency valuable in ensuring that the media and the public in general were kept informed of the Inquiry’s progress, while at the same time allowing Inquiry Team members to concentrate their efforts on the work of the Inquiry.

Visits to the VOLH

The Chairman, Assessors and other members of the Inquiry Team, as well as a number of the expert witnesses, visited the Vale of Leven Hospital to familiarise themselves with the facilities with which the Inquiry is concerned. Due to the numbers involved, and to the availability of personnel, a number of visits had to take place. The Inquiry wishes to record its appreciation to NHSGGC for putting in place arrangements for these visits, as well as to staff on duty at the hospital itself for their unfailing courtesy and assistance.

Relationship with Scottish Government: the Sponsorship Team and the Core Participant Team

The Inquiry was established by Scottish Ministers. To facilitate the establishment of the Inquiry and to provide support for administrative matters relating to the Inquiry, including the selection of office premises, certain aspects of staffing and financial support, Scottish Government set up the Vale of Leven Hospital Sponsorship Team. The Inquiry wishes to express its thanks to the Sponsorship Team for their support and assistance throughout the period of the Inquiry.

A Management Agreement²⁸ was put in place between Scottish Government and the Inquiry which set out the division of roles and responsibilities where not already specified in the Act and Rules, and outlined the day to day liaison arrangements. The Agreement was

28 [INQ05670001](#)

published on the Inquiry website and was updated during the course of the Inquiry.

It must be stressed, however, that in its investigations and in compiling its report the Inquiry acts independently of government.

Scottish Ministers as Core Participants

Following the establishment of the Inquiry the Scottish Ministers applied on 22 December 2009 to be designated as a Core Participant. The Chairman decided that that application should be granted, and intimation of that decision was made on 7 January 2010. That meant that the Scottish Ministers had the same status as all other Core Participants to the Inquiry.

Soon afterwards, in the course of the Inquiry's initial investigations, it became apparent that this dual role of Scottish Ministers presented both the Inquiry and the Scottish Government with certain difficulties over communication and confidentiality. In particular, in the course of the Inquiry's work certain information would require to be shared with the Sponsorship Team which it would not be appropriate to divulge to Core Participants generally. At the same time, it would be inappropriate for one Core Participant to be privy to information concerning the Inquiry which was not shared with other Core Participants. A structure was therefore required that kept the two interests of Scottish Ministers separate.

The Solicitor to the Inquiry raised this issue with the Solicitor to the Scottish Government in a letter dated 9 April 2010. The Solicitor to the Scottish Government replied on 22 April 2010 advising that immediate steps were being taken to ensure that Sponsorship roles and Core Participant roles would rest with separate individuals within the Health Directorate, with separate reporting lines to senior management. A note was attached setting out details of the proposed structure. The Sponsorship Team would continue in the role of supporting the functioning of the Inquiry. The Core Participant Team was to be guided by the provisions in the Act and the Rules and by the Inquiry's protocols, all subject to an obligation of confidence owed to the Chairman.

The Chairman was satisfied that this arrangement would ensure that the position of the Scottish Ministers as Core Participants was the same as that of other Core Participants. The Management Agreement between Scottish Government and the Inquiry was updated to reflect the new arrangements. This kind of arrangement could provide an appropriate model for future inquiries in which the sponsoring body is also a Core Participant.

Cost of the Inquiry

Section 17(3) of the Act requires the Chairman to avoid unnecessary expense.

Sections 39 and 40 put an obligation on Ministers to meet certain expenses. The Minister set maximum hourly rates for legal teams in terms of Section 39 and the expenses of witnesses were covered in terms of Section 40. The document entitled *Scottish Ministers' Determination*,²⁹ which sets out the qualifications and conditions for legal representation, was published on the Inquiry website.

The Inquiry's final expenditure will be published on the Inquiry website on conclusion of the Inquiry.

Governance

Governance of the Inquiry budget involved:

1. Monthly meetings with the Sponsorship Team to discuss expenditure in the preceding month.
2. Discussion between members of the Inquiry Team and a report to the Secretary, before the monthly meeting with the Sponsorship Team.
3. Quarterly submissions by the Inquiry to the Sponsorship Team of both expenditure to date and a forecast of the Inquiry's estimated total expenditure.
4. Inclusion of Finance as a standing item on the agenda for the regular Monitoring Meetings between the Inquiry and Sponsorship Teams.

29 [INQ05680001](#)

5. Audits by the Inquiry Team of all expenditure, with a composite document of these audit reports to be passed to Scottish Government at the end of the Inquiry.

Work with the National Records of Scotland

The Rules³⁰ require the Chairman to consult the Keeper of the Records of Scotland on the manner and format of creating, maintaining and then transferring the record of the Inquiry on completion of the Inquiry. To comply with that requirement the Inquiry engaged in a series of meetings with National Records of Scotland (NRS, formerly known as NAS). The first meeting was held in October 2009, and discussions and negotiations throughout the course of the Inquiry to establish what will be handed over to NRS to constitute a formal record of the Inquiry for archiving purposes.

NRS made clear that they will require documentation which influenced the findings in the Inquiry Report and which informed the Inquiry in reaching the conclusions arrived at. Any documents supplied to NRS will become part of their Digital Data Archive.

To identify the material required, the Inquiry conducted audits of all documents that it held, broadly covering electronic files, the document management system and hard copy documents. NRS staff also visited the Inquiry office to inspect the documentation and to discuss these in more detail. The Inquiry will in due course provide a Schedule of Documents to NRS, and a complete set of documents held on the document management system will also be supplied by Merrill Corporation to NRS at the end of the Inquiry.

At the end of the Inquiry, the Inquiry website will continue to be maintained by Scottish Courts Service, and ultimately will be incorporated into the NRS archives.

Chapter 3

Healthcare Associated Infection
and *Clostridium difficile*

Introduction

This Chapter sets the context by explaining Healthcare Associated Infection and the relationship between antibiotics and the bowel flora. The Chapter goes on to provide an explanation of *Clostridium difficile*: what it is, how it is spread, how *C. difficile* infection (CDI) is diagnosed and treated, and what precautions should be taken to prevent the occurrence and spread of CDI. Developments for future treatment of CDI are also considered.

3.1 Healthcare Associated Infection

Definition

Healthcare Associated Infection (HAI) is defined as infection acquired as a result of a healthcare intervention either in hospital or in a community setting. HAIs are recognised worldwide as a major public health problem affecting both morbidity and mortality. Increased risk of acquiring an HAI is associated with, for example, extremes of age, obesity, complexity of procedures, the underlying medical problem, and co-morbidities. HAIs can prolong inpatient stays in hospital or even result in death, and are a significant financial drain on the healthcare system.¹

The range of HAIs includes Urinary Tract Infection (UTI), Respiratory Infection (RI), Gastrointestinal Infection (GI, e.g. diarrhoea), Surgical Site Infection, and life-threatening Blood Stream Infection. The most common HAIs are UTI, RI and GI.

By no means are all HAIs preventable. But various sources indicate that a significant number of HAIs could be prevented by good infection prevention and control practice and good antibiotic stewardship.²

How common are Healthcare Associated Infections?

A survey of the prevalence of HAIs in acute hospitals in Scotland conducted between October 2005 and October 2006 found that 9.5% of inpatients were affected. A

similar but not entirely comparable survey conducted in Scottish acute hospitals in March 2011 yielded a prevalence of 4.9%. The improvement in prevalence is thought to reflect the implementation of the national programme of targeted HAI interventions in the intervening period.³

3.2 Antibiotics and the bowel flora

The development of antibiotics

Antibiotics are chemicals that show selective toxicity to bacteria. There is no doubt that their introduction over the past 60 years has been one of the major advances in medical science. Their use has opened up all forms of surgery, and the treatment of overt infections has allowed the advancement of cancer therapy without fear of excessive mortality from super-infection. But as with most medical treatments, the use of antibiotics is not without risks. These risks have to be balanced against the potential therapeutic advantages of antibiotic use in specific circumstances.

Resistance to antibiotics

Like all life forms, bacteria have a need to survive. They are particularly adept at becoming resistant to the use of antibiotics. Well known examples of acquired resistance that may adversely affect treatment include the meticillin resistant *Staphylococcus aureus* (MRSA) and multiple resistant Gram negative organisms.

Antibiotics also affect environmental bacteria including those that make up the normal bowel flora of animals and humans. It is unusual for a specific antibiotic to be only active against one particular bacterial species or group of species. Treatment of a specific infection with an antibiotic will therefore also be likely to have an effect on other bacteria that are normally present, for example in the respiratory tract or bowel.

The relationship between the body's bacterial flora and the individual patient is delicate, and the use of antibiotics is likely to upset this balance and allow more resistant

1 [GOV00460003-04](#)

2 [GOV00460003-04](#); [EXP02830012](#)

3 [GOV00460001](#); [GOV00460003](#); [GOV00510001](#); [INQ05220001](#)

organisms to grow in greater numbers. Alteration of the bowel flora with antibiotic use may result in self-limiting diarrhoea, which is the body's defence mechanism for upset of the normal balance. Sometimes the diarrhoea may be the result of a bacterial super infection caused by the overgrowth of a normally suppressed organism such as *C. difficile*.

The increasing bacterial resistance to antibiotics is a threat to the ability to treat infections.⁴ Whilst ongoing research continues to seek new antibiotics, it is important that the effectiveness of current drugs is not compromised by inappropriate and over-use of antibiotics. This has resulted in far-reaching guidelines for treatment of specific infective situations. Good antibiotic stewardship should have the dual effect of prolonging the usefulness of antibiotics and of reducing adverse side-effects such as *C. difficile* associated diarrhoea (CDAD).⁵

3.3 *C. difficile* – What is it?

The nature of the organism

The bacterial genus *Clostridium* is widely distributed in nature and includes a number of organisms that can cause disease in humans. These include *Clostridium perfringens* (*welchii*), *Clostridium tetani*, and *Clostridium botulinum*.

The clostridia are characterised as Gram-positive rod-shaped anaerobic spore-bearing organisms. That is, they stain darkly with Gram's stain. The descriptive "anaerobic" means that these organisms can only reproduce in the absence of oxygen. Such environmental conditions exist in deep necrotic wounds (for gas gangrene) or in the gut. The organisms survive the adverse conditions of oxygen absence by producing spores which are able to survive in air and in dry conditions for long periods. They are also resistant to certain antibiotics and many disinfectants.

Disease is usually a result of the organisms multiplying under ideal anaerobic conditions

such as poorly stored food, deep necrotic wounds, and the lower bowel. The organisms produce powerful exotoxins (toxins released by bacteria) that affect the body in ways characteristic of the particular species. Toxins produced by *C. perfringens* are responsible for food poisoning and gas gangrene, and the neurotoxins (toxins which attack the nervous system) of *C. tetani* and *C. botulinum* lead to tetanus and botulism respectively.

C. difficile is carried in the bowel of up to 4% of healthy adults, and under normal circumstances the organism does not cause symptoms in these people. The organism is in relatively small numbers and is held in check by the interaction of the other bacterial flora that make up the normal bowel flora of the healthy adult. If the organism becomes predominant, toxins may be produced that will lead initially to diarrhoea. If untreated the disease may lead to death of the bowel wall, septicaemia (blood poisoning), and death. Multiplication of the organism may be triggered by the use of broad spectrum antibiotics for suspected infection by other bacteria.

C. difficile, as spores, is also found widely in the environment, including soil and standing water, and in the vicinity of symptomatic patients. In hospital up to 50% of patients, particularly the elderly and newborn infants, may carry *C. difficile*, although in infants it is seldom responsible for symptoms. The carriage rate in care home residents will also be higher than the community background level of up to 4%.

C. difficile produces two major toxins known as A and B. These have a serious effect on the mucosal wall of the large bowel (which is exposed to the contents of the gut), leading to inflammation and tissue damage. The consequence of this damage is to allow leakage of fluid into the lumen of the bowel resulting in profuse CDAD. In severe cases the lining of the bowel may slough off and become detached, a condition known as pseudomembranous colitis. This condition is life threatening and requires urgent surgical intervention to remove the affected bowel.⁶

4 [EXP00690011](#); [EXP00600004-06](#)

5 [EXP00600005](#)

6 [EXP00600001](#)

Identification of ribotypes

There are numerous different strains of *C. difficile*, and it is important to identify which strains are prevalent in society, including the closed environment of a hospital or care home. This is significant for epidemiological purposes, both to identify probable incidents of cross infection and to identify hypervirulent strains that may incidentally be circulating. Ribotyping is the most common method used to identify specific strains of *C. difficile*, and routine typing of strains is carried out using the Polymerase Chain Reaction (PCR) technique to identify specific ribotypes.

In any given situation designated as an “Outbreak” it is likely that more than one ribotype will be circulating. Typing tests can demonstrate with certainty that two strains are different, but it is more difficult to state that two strains are the same. The term “indistinguishable” is used to reflect the fact that the strains examined cannot be separated on the basis of current specific testing protocols.

3.4 How *C. difficile* is spread

C. difficile is able to remain in the environment in the form of spores. Because these spores are resistant to drying, to many chemical disinfectants and to disinfection by boiling, they may persist in the environment and contaminate surfaces and other objects

such as clothing and door handles. A symptomatic patient may shed vast numbers of spores as a result of the diarrhoea. Hands of patients, staff and visitors who are in contact with these surfaces may transfer the spores to vulnerable individuals. Ingested spores may lead to symptomatic infection. The role of contamination of the ward air in the transmission of spores is much less certain, but this probably also occurs.⁷

For infection to result from ingestion of the spores of *C. difficile* certain risk factors are required, in particular increasing age, severe underlying disease, prolonged antibiotic therapy or specific antibiotics associated with CDI, and a weakened immune system. Drugs to reduce gastric acidity (proton pump inhibitors) may play a role, but this is not proven.

The incubation period for CDAD is imprecise. The onset of diarrhoea in susceptible patients is typically during, or shortly after, receipt of a course of antimicrobial treatment, but may occur from a few days to as long as 12 weeks after the termination of the therapy.

One problem important for epidemiological purposes is that of defining where acquisition of the organism occurred: in the community or in hospital. The “Guidance on Prevention and Control of *Clostridium difficile* Infection (CDI) in Care Settings in Scotland” (2014 edition)⁸ gives the following definitions:

“Definition of community associated CDI

This is a CDI patient with onset of symptoms while outside a hospital and without discharge from a hospital within the previous 12 weeks - or with onset of symptoms within 48 hours following admission to a hospital without stay in a hospital within the previous 12 weeks.

Definition of healthcare associated CDI

Healthcare associated CDI is defined as when a CDI patient has had onset of symptoms at least 48 hours following admission to a hospital or up to four weeks after discharge from a hospital.

Definition of unknown cases of CDI

This is a CDI patient who was discharged from a hospital 4 to 12 weeks before the onset of symptoms”.⁹

7 [EXP00600002](#)

8 [INQ05570001](#)

9 [INQ05570018](#)

Although the time interval used in some areas varies between 48 and 72 hours,¹⁰ it is noted that the definition of 48 hours was used in the VOLH at the time.¹¹

Antibiotics associated with CDAD

The particular antibiotics associated with CDAD are the cephalosporins, co-amoxiclav (and other broad spectrum penicillins), clindamycin, and ciprofloxacin (and other fluoroquinolone antibiotics). These are collectively referred to as the “four Cs”. It is worthy of note, however, that any antibiotic may result in CDAD, so the reasons for prescribing antibiotics need to be assessed against the risks of inappropriate prescription of these valuable and occasionally life-saving drugs. Antibiotic prescribing guidelines have been developed to assist appropriate prescribing and are commonplace in healthcare settings.

Broad spectrum antibiotic treatment is a major risk factor for *C. difficile* infection and the resulting CDAD. The elderly, incontinent patient with explosive diarrhoea from CDAD, disseminating spores into the environment, is a major risk factor in the spread of *C. difficile* and CDAD by cross infection.

Hypervirulent strains

These are strains of *C. difficile* that produce high levels of the toxins. The 027 (027/NAPI/BI) strain was associated originally with major outbreaks in North America and Western Europe, but 027 is now worldwide in distribution. Infection with the strain was also associated with increased severity of disease and higher mortality. Apart from the toxins A and B associated with CDAD, this strain also produces a binary toxin whose role in CDAD is uncertain. The 027 strain is also particularly associated with resistance to ciprofloxacin and other fluoroquinolone antibiotics. But it is important to be aware that, while 027 has often been described as a hypervirulent strain, **any** strain of *C. difficile* can produce severe CDAD.¹²

3.5 Laboratory diagnosis of *C. difficile* infection

No absolute test

There is no test that is both 100% sensitive and also 100% specific. This means that the laboratory must be aware of the reliability of any test and ensure that the likely prevalence of both false positive and false negative tests is appreciated. This is particularly important with regard to the diagnosis of CDAD in a patient with diarrhoea, where failure to repeat a negative result in the presence of persisting symptoms may lead to failure to initiate specific therapy.

It is also important that the laboratory attempts, to the best of its ability, to confirm a positive result by other tests in order to ensure that a patient is not given unnecessary and potentially harmful antibiotics. False negative results may also lead to the failure of infection control precautions. Symptomatic patients with diarrhoea should be adequately isolated until an infectious cause is firmly excluded, and if necessary there should be repeat testing of samples if a cause is not identified or excluded.

Types of tests

At present there are four groups of tests available for the diagnosis of CDAD.

1. Glutamate Dehydrogenase (GDH) Detection Tests: GDH is a surface expressed enzyme common to both *C. difficile* strains that produce toxins and those strains that do not produce toxins. They are useful screening tests, but because they detect the presence of the organism it is necessary to perform a toxin test on positive specimens. The presence of CDAD is associated with toxin production, not merely the actual presence of the organism. There are two types of tests for GDH: test well based and membrane based. In general, test well based tests are more sensitive but less specific than membrane tests, and membrane tests are more specific but less sensitive than test well based tests.

10 [TRA01060082-85](#)

11 [TRA01000088](#)

12 [INQ03140001](#); [INQ03150001](#); [INQ05290001](#); [INQ02890014](#)

2. Toxin A and B Detection Tests (CDT): these tests detect production of both Toxin A and Toxin B. They fall into two types: Enzyme Immuno-Assay (EIA) based tests, or cytotoxin-based assays. The latter are deemed the current “Gold Standard”, but are time consuming and expensive. They are also not perfect. EIA based tests are generally thought to have a sensitivity of some 60%.
3. Polymerase Chain Reaction (PCR) tests: these techniques are used to detect the conserved genes for toxin production. They are very sensitive, but identification of the relevant gene does not necessarily indicate that the gene is being expressed and therefore that toxin is being produced. The clinical relevance of PCR positive toxin negative strains is the subject of much discussion. The facilities to carry out molecular tests such as PCR are not widely available outside major hospitals and reference laboratories.
4. Culture for the organism: the growth and isolation of the organism using agar culture takes several days. Isolation of the organism is necessary to allow typing of the isolated strain by ribotyping or other molecular techniques. The simple isolation of the organism gives no information on whether it was producing toxin and therefore causing symptoms in the patient. To further complicate matters, more than one ribotype may be present in an individual, or reinfection may be with an identical or different strain.

The following recommendations are contained in the consensus guidance produced by representatives of the Scottish Microbiology and Virology Network (SMVN), the Scottish Salmonella, Shigella and Clostridium difficile Reference Laboratory (SSSCDRL) and Health Protection Scotland (HPS), published by HPS in December 2012 as the “Recommended protocol for testing for *Clostridium difficile* and subsequent culture”:

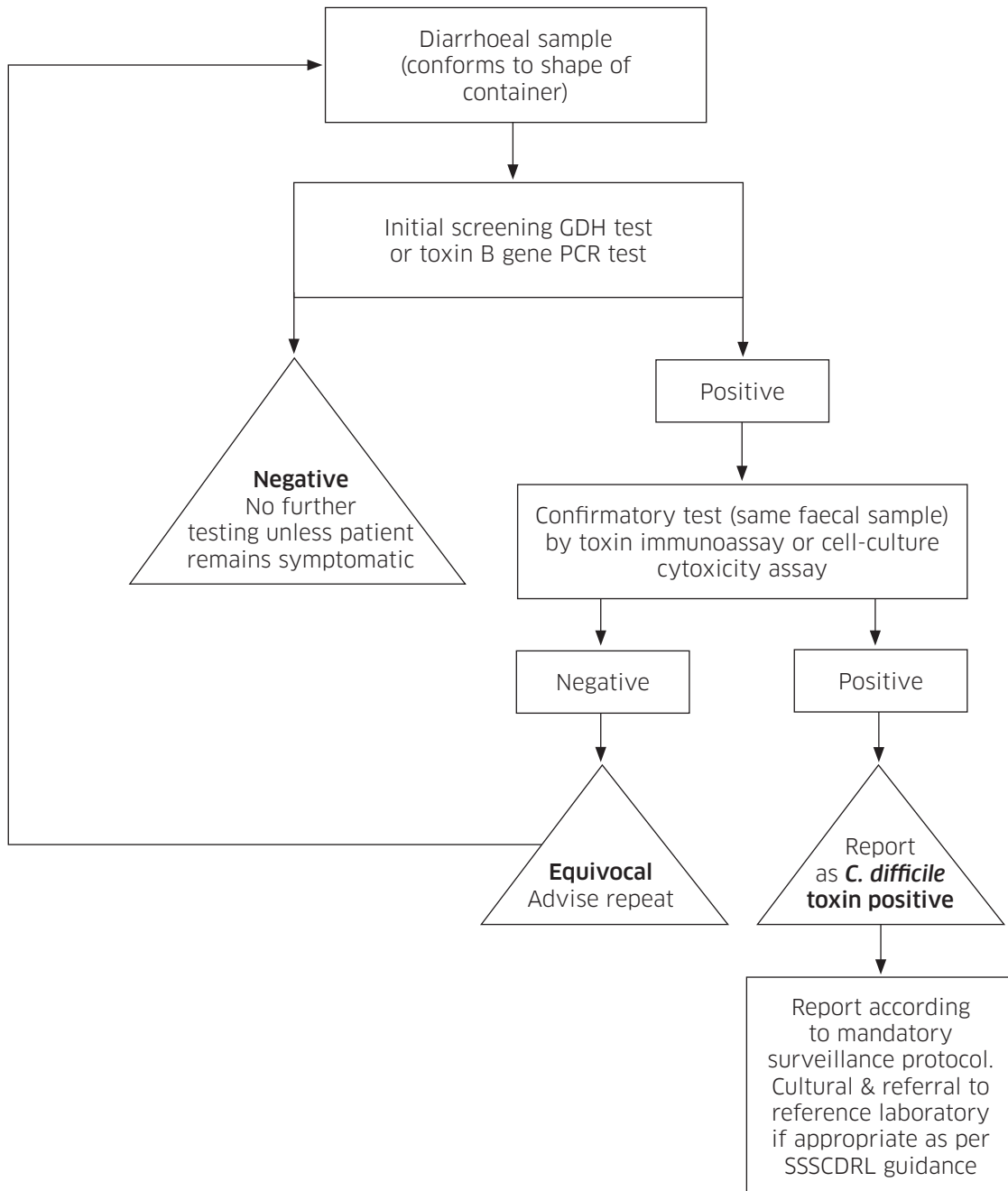
1. Any *C. difficile* toxin immunoassay (i.e. EIA or membrane assay) being used should be one of the better performing assays.
2. Diarrhoeal stool samples should be tested by an initial sensitive screening test (GDH test or toxin B gene PCR test). As with any other test, laboratories will have to satisfy themselves that any specific assay chosen as part of the algorithm is of an acceptable quality and performance standard.
3. Those samples which are screen-negative do not require further testing, and can be reported at this point e.g. "*C. difficile* screening test negative".
4. Initial screen-positive faecal samples should be tested for the presence of *C. difficile* toxin on the same sample. Samples which are also positive in this toxin assay can then be reported accordingly e.g. "*C. difficile* toxin positive". Only those stool samples which are positive in **both** the initial screening test **and** the subsequent toxin test are eligible for reporting under mandatory surveillance of CDI.
5. Some samples which are positive in the initial screening test will fail to confirm in the subsequent toxin assay. This may be due to the following:
 - Toxin concentration is below limit of detection (false-negative toxin test)
 - Toxin concentration yields a result within manufacturers indeterminate range (indeterminate toxin test)
 - Toxin is absent (true-negative toxin test). This may be due to the presence of *C. difficile* which are non-toxicogenic or not expressing the toxin gene

Occasionally the screening test may be positive in the absence of viable *C. difficile* organisms (false positive screening test)
6. These discrepant results should then be reported as equivocal e.g. "Equivocal result: *C. difficile* screening test positive but *C. difficile* toxin could not be detected in this sample. Advise repeat sample if patient remains symptomatic".
6. The use of an initial sensitive screening test will increase the Negative Predictive Value of the algorithm. The use of a confirmatory test (on the same faecal sample), as part of the diagnostic algorithm, will increase the accuracy of toxin-positive results. This algorithm was found to have the best clinical utility in the largest diagnostic algorithm study that has been performed to date. In this study, only algorithms that included a toxin test provided an acceptably high specificity in comparison with the gold standard of a well-performed cell-culture cytotoxicity test. This guidance is compatible with current ESCMID (European Society for Clinical Microbiology and Infectious Diseases) guidance. The guidance will be revised on an ongoing basis to take account of further diagnostic developments.
7. All of these assays will fail to detect some true toxin positive samples. If there remains a strong clinical suspicion of CDI then a repeat faecal sample should be sent and tested, and the need for empirical treatment considered.
8. Diagnosis of CDI is based on both the clinical presentation and the results of any laboratory tests; i.e. laboratory test results should not be interpreted without reference to clinical features. Issuing interpretative comments with reports may aid clinicians in understanding the significance of results.¹³

The protocol also provides an algorithm for testing faecal specimens, although only intended as a guide to be adapted to local

circumstances. This is reproduced in Figure 3.1.

Figure 3.1 Current recommendations for testing faecal specimens¹⁴



As indicated previously, PCR detects the presence of the genes coding for the toxin. It does not indicate that the organism is producing toxin. Thus, the test may over diagnose the presence of CDAD.

Clearance testing

Individuals can remain toxin positive for some weeks following the resolution of symptoms. Repeat testing of toxin positive samples is therefore **not** recommended.

3.6 Precautions against occurrence and spread of *C. difficile* infection

Transmission

C. difficile can be transmitted to individuals by a number of routes including direct hand to mouth spread, contamination of hands from surfaces contaminated with spores, and ingestion of airborne spores.

Good and appropriate hand hygiene is essential to prevent or reduce contamination. So too is good maintenance of the healthcare environment. The thorough cleaning of all areas is necessary to prevent contamination of surfaces.

As explained in paragraph 3.4, CDAD will only occur in individuals who are receptive to infection with the spores. This will include the elderly, the severely ill, and those patients receiving broad spectrum antibiotics. Good antibiotic stewardship with the reduced deployment of broad spectrum antibiotics will reduce the selection pressure on the bowel flora and the risk of overgrowth with toxin producing *C. difficile*.

How to prevent cross infection

The main way to prevent cross infection is to isolate the patient in a single room. In a proven outbreak situation it may be necessary to cohort patients because of a lack of single rooms, but this should always be a last resort, and under no circumstances should asymptomatic patients be in the same area as symptomatic patients.

Good hand hygiene practice is essential, using soap and water. Alcohol gels are not effective against *C. difficile* spores.

Appropriate personal protective equipment must be used by all persons entering the room. This will include gloves, aprons and gowns.

There should be regular cleaning of the patient environment with chlorine-based disinfectants. Once CDI patients have been discharged or transferred, the area should be cleaned. The use of controlled hydrogen peroxide vapour should be considered.

Dedicated equipment should be used with the infected patient. This would include blood pressure cuffs, stethoscopes, thermometers and commodes. Once the patient has been discharged, equipment should be decontaminated before return to use.

Definition of an outbreak

Any unexplained incident of loose stools (that is, where the specimen takes up the shape of the container; Bristol Stool Classification types 6 or 7) should be assumed to be infective until an alternative cause is confirmed. Two or more episodes of loose stools within 24 hours are classified as diarrhoea.

In the VOLH the definition of a potential outbreak of CDI included “two or more linked cases of unexplained illness (or isolates), which indicates the possibility that they may be due to a known or unknown infectious agent”.¹⁵

The presence of an outbreak can be confirmed once linked cases of infection with indistinguishable organisms are demonstrated. But the problem of defining an outbreak lies with the definition of “indistinguishable organisms”. As discussed previously, there are a number of different strains of *C. difficile*. These can be differentiated by several techniques, of which ribotyping is the most widely used for epidemiological purposes. And sporadic cases of CDAD will occur from time to time in the healthcare setting against the background of known carriage of the organism in various populations. So while on occasion two or more cases may occur concurrently, this does

15 [GGC27390003](#)

not necessarily mean that cross infection has occurred. The increased incidence may reflect a background of increasingly susceptible patients with other risk factors such as excessive use of broad spectrum antibiotics.

For a formal outbreak to be declared, epidemiological evidence is necessary to demonstrate that a single ribotype is being transmitted between patients as a result of failure of general infection control measures against a background of susceptible patients. An observed increase in CDAD may be due to an increase in background level of CDAD, or a result of cross infection. In many circumstances both situations will be identified at the same time.

A Health Board Outbreak Policy should be available to guide staff. Frequent support from the Infection Control Team will be required by both the Infection Control Doctor and the Infection Control Nurses. An Outbreak Control Committee should be convened to supervise control of the outbreak, to handle media and public relation concerns, and to review events once the outbreak is controlled and stopped.

3.7 Treatment of *C. difficile* infection

Existing good practice

National and local guidelines should be followed. The following is a broad outline of approaches to therapy:¹⁶

- Urgently review antibiotic chemotherapy and stop any non-clostridial antibiotics as soon as possible unless this would further endanger the patient's wellbeing
- Stop the use of anti-peristaltic agents, opiates and proton pump inhibitors
- Assess the severity of infection
- Primary or first recurrence
 - In cases of mild to moderate infection, commence treatment with oral or (exceptionally) intravenous metronidazole
 - In cases of severe infection, commence oral vancomycin (intravenous vancomycin does not reach the intestinal lumen and is not effective)
- Second or subsequent relapse
 - Prolonged use (for more than ten days) of vancomycin
 - Consider tapering (decreasing) doses of vancomycin
- Ensure that patient is hydrated and accurately monitor fluid input and output
- Ensure that the patient's comfort and dignity are preserved at all times
- Monitor progress of the patient. A surgical opinion should be sought if the patient's condition deteriorates and the development of pseudomembranous colitis is suspected.

Options for future treatment

Future treatment options include new specific antibiotics for CDAD treatment, super-colonisation with non-toxigenic strains of *C. difficile* for prevention of CDAD in susceptible patients, faecal transplants for recurrent infection, and immunotherapy.¹⁷

Of particular interest is the macrocyclic antibiotic fidaxomicin. This compound has a very narrow spectrum of activity which includes *C. difficile*, but it does not disturb the normal bowel flora. This may serve both to treat CDAD and to reduce the likelihood of recurrence. Studies are in hand to evaluate the place of this drug in the management of complicated CDAD.¹⁸

The use of vaccines in the prevention of CDAD is attractive, but to date no vaccine has proved to be of significant benefit. A number of clinical trials are in progress.

16 [EXP00600006](#)

17 [EXP00600007](#)

18 [EXP00600007](#)

3.8 Conclusion

There is no doubt that CDAD is a significant cause of morbidity and mortality in the elderly, the immunosuppressed, and severely ill patients on broad spectrum antibiotic chemotherapy. Diarrhoea in these groups of patients must be taken seriously, and attempts made urgently to establish firstly whether or not infection is involved, and secondly, if infectious, the specific cause. It is essential that *C. difficile* infection is confirmed or ruled out at the earliest possible moment.

Patients with diarrhoea must be isolated as soon as possible until infectious diarrhoea has been excluded or treated and symptoms resolved. Antibiotics specifically for CDAD must be commenced as soon as diagnosis is confirmed by the laboratory. Treatment should be guided by a locally approved accepted algorithm to ensure efficient use of specific antibiotics. Other antibiotics should be reviewed and stopped unless there are overriding clinical reasons to continue. Anti-diarrhoeal medication and proton pump inhibitors should also be stopped.

Diagnostic testing should use recognised test platforms and the testing algorithm should conform to National Guidelines.

In the light of ongoing research into the future of specific antibiotic treatment, vaccine development and the use of faecal transplants, there should be a regular review of local protocols for the management of CDAD.

Chapter 4

The number of patients with
CDI and those who died

Introduction

The focus of this Chapter is on the patients who contracted *C. difficile* infection (CDI) during the relevant period and the number of patients who died with CDI as a causative factor in their deaths.

4.1 Discovery of the problem

The research project

In the week beginning 7 April 2008 a specialist biomedical scientist¹ at the Scottish Salmonella, Shigella and *C. difficile* Reference Laboratory, who was engaged in an academic research project, obtained two results for the type 027 strain of *C. difficile* toxin from stool specimens. These had been taken from two patients at the Royal Alexandria Hospital (RAH) in August and September 2007 and stored pending investigation as part of the research project.² A senior Infection Control Nurse at the RAH was informed of these results,³ on or about 28 April 2008,⁴ and Dr Linda Bagrade, then Consultant Microbiologist and Infection Control Doctor for the RAH and the Vale of Leven Hospital (VOLH), was aware of the results by late April 2008.⁵

Coincidentally, an isolate from a stool sample taken from a deceased patient during a post-mortem⁶ on 17 March 2008 was sent for ribotyping, and was also discovered to be the 027 strain.⁷ The patient had died in the VOLH on 9 March 2008, but as was then the usual practice the post-mortem was carried out at the Western Infirmary in Glasgow. In the post-mortem report⁸ the cause of death was as follows:

- 1a: Septicaemia due to
- 1b: Pseudomembranous colitis due to
- 1c: *Clostridium difficile* infection

The Western Infirmary presumably made the request for ribotyping because, as narrated in the post-mortem report, the deceased had

a history of CDI requiring hospital treatment for approximately five weeks.⁹ The formal report¹⁰ of the result from the Reference Laboratory dated 7 April 2008 was sent to the Western Infirmary, the hospital which had made the request, not to the VOLH.

Two further isolates from a patient at the RAH were tested at the Reference Laboratory in April and the 027 strain identified. The first was from a specimen taken from the patient during surgery on 9 April 2008,¹¹ and the second from a specimen provided by the same patient on 20 March 2008.¹² Formal reports of these results dated 30 April 2008¹³ were sent to the RAH, although it appears that the Infection Control Team (ICT) at the RAH were made aware of the results two days earlier on 28 April 2008.¹⁴

Initial response

Initially the focus was on the RAH, but by mid-May¹⁵ there was growing recognition that there was a problem with CDI at the VOLH. At a meeting of the Infection Control Working Group on 14 May 2008¹⁶ it was minuted that:

“there have been five cases (four patients and one member of staff) in the last nine months in the RAH and VOL”.¹⁷

That same day a special meeting chaired by Dr Bagrade was convened to consider the five cases.¹⁸ On 21 May 2008 a meeting chaired by Mr Thomas Walsh, NHSGGC Infection Control Manager, was held in the RAH regarding cases of *C. difficile* 027 in the RAH and the VOLH.¹⁹ By that time the number of cases identified with the 027 strain had risen to six (five patients and one member of staff)²⁰ and there was a possible link between two patients and the staff member.²¹ A further meeting took place on

1 [WTS02100003-04](#)
2 [GGC09020001](#)
3 [WTS02100004](#)
4 [GGC09020002](#)
5 [TRA01020102](#); [WTS01930009](#)
6 [GGC00300014](#)
7 [GGC23680002](#)
8 [GGC00300012](#)

9 [GGC00300012](#)
10 [GGC23680001-02](#)
11 [GGC23700001](#)
12 [GGC23690001](#)
13 [GGC23690002](#); [GGC23700002](#)
14 [GGC09040002](#)
15 [TRA01020103](#)
16 [GOV00650002](#)
17 [GOV00650004](#)
18 [GGC01310001](#)
19 [GOV00650009](#)
20 [GOV00650010](#)
21 [GOV00650004](#)

28 May 2008, again chaired by Mr Walsh,²² by which time the number of CDI cases identified in the RAH and the VOLH with the 027 strain had risen to seven (six patients and one member of staff).

The look back exercise

Following considerable media interest, on 5 June 2008 Ms Sandra McNamee, the NHSGGC Infection Control Nurse Consultant, passed on to the ICT a press enquiry from the Dumbarton and Vale of Leven Reporter²³ which requested information on the number of cases of all strains of CDI at the VOLH in the previous six months and the number of deaths resulting.²⁴ That request provoked a review of all cases of CDI at the VOLH with a focus on the period 1 December 2007 to 31 May 2008, and it only then became evident that there had been a persistent problem with CDI and associated deaths during that period. Once that became apparent, the decision was taken on 9 June 2008 to set up an Outbreak Control Team (OCT) to investigate the position at the VOLH.

On the same date Mr Robert Calderwood, then Chief Operating Officer, Acute Services, commissioned an internal investigation into certain aspects of the CDI problem as it was then perceived by NHSGGC.²⁵

First Outbreak Control Team meeting

At the first Outbreak Control Team (OCT) meeting on 10 June 2008²⁶ 54 patients were identified as testing positive for CDI in the previous six months at the VOLH.²⁷ Of those, 16 deceased patients had CDI referred to on their death certificates. By the date of the publication of the OCT Report²⁸ in October 2008 the number of identified CDI patients from 1 December 2007 to 31 May 2008 had risen to 55.²⁹ By then it was also thought that CDI had contributed to the deaths of 18 patients.³⁰

What the previous discussion highlights is that the CDI problem at the VOLH was not initially identified at the VOLH or even within the Clyde Area. It came to light as a result of a combination of external events including an incidental research project and a press enquiry by a local newspaper.

4.2 Number of CDI cases

Epidemiological difficulties

The science relating to CDI has already been discussed in Chapter 3, where the system of ribotyping is explained. Because the problem with CDI was not identified until May 2008, many stool samples from the early part of the Inquiry focus period had already been destroyed. Consequently no ribotyping could be carried out in those cases.

Identifying where patients acquired the infection also gives rise to difficulties. Although an examination of the prevalence of CDI in the RAH was not part of the Inquiry's remit, it is clear that there were patients at the RAH who suffered from CDI during the relevant period. In addition, some patients who were transferred from the RAH to the VOLH received antibiotics in the RAH which might have predisposed them to acquiring CDI. It was therefore not possible, with the information available to the Inquiry, to carry out a detailed epidemiological analysis to show (a) where patients acquired the infection, or (b) whether any predisposing antibiotics were given in each patient's case. Patients were regularly moved between wards within the VOLH and transferred between the RAH and the VOLH.

Nevertheless, it has been possible to arrive at a number of conclusions in relation to (a) the numbers of patients covered by the Inquiry remit and (b) where the CDI might have been acquired. It is to be noted that, as discussed elsewhere in the Report, the conditions in the VOLH in the period 1 January 2007 to 1 June 2008 were ripe for cross contamination. Patients were rarely isolated when they first displayed symptoms of infection. Instead, staff waited for a confirmed diagnosis of CDI.

22 [GOV00650012](#)

23 [GGC09040002](#)

24 [GGC05670002-03](#)

25 [GGC00610002](#)

26 [GOV00650016](#)

27 [GOV00650018](#)

28 [GGC00600001](#)

29 [GGC00600005](#)

30 [GGC00600005](#)

Included in the remit are patients who the Inquiry considers acquired the infection at the VOLH or who in any event were treated for the infection at the VOLH.

C. difficile “focus” patients – 1 December 2007 to 1 June 2008

In the focus period (1 December 2007 to 1 June 2008) 63 patients have been identified as falling within the Inquiry’s remit. Of that number, 55 patients have been identified as likely to have acquired the infection within the VOLH. Nine of those patients probably acquired the infection in the VOLH, but were diagnosed in the community. This was usually after being discharged from the VOLH, and usually involved a re-admission to the VOLH after the onset of the infection. There were also patients within this group of 55 who acquired the infection at the VOLH, but who were not diagnosed as positive until being transferred to the RAH. The remaining eight patients may have acquired the infection in the VOLH, the RAH or the community. But in each of these cases either the onset of the infection or the CDI diagnosis was at the VOLH.

The period 1 January 2007 to 30 November 2007

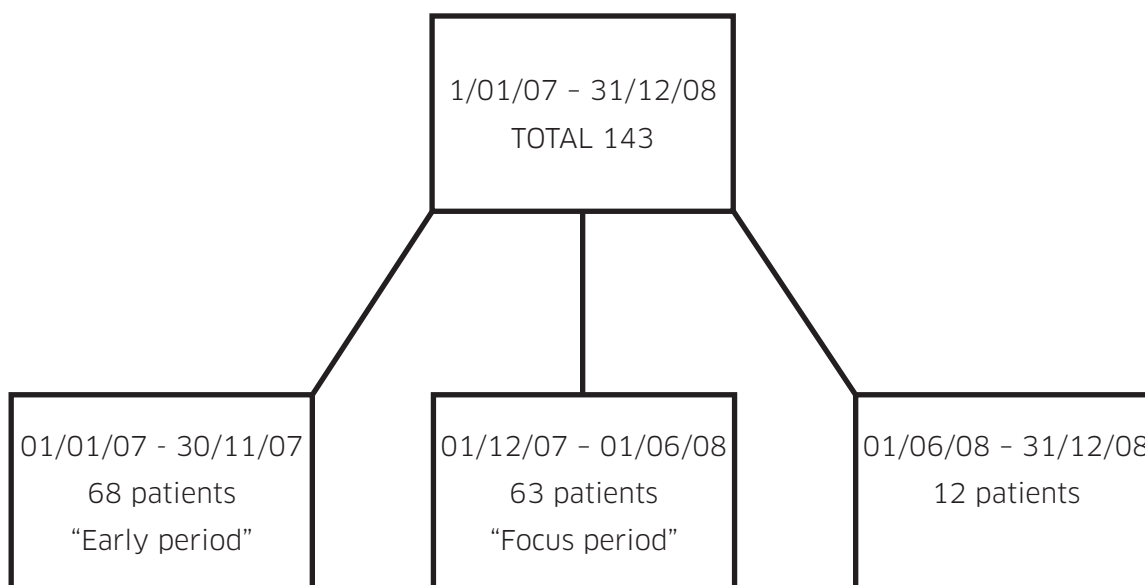
In the early period (1 January 2007 to 30 November 2007) 68 patients at the VOLH suffered from CDI. The family members of two of these 68 patients became Core Participants in the Inquiry and the medical records of these patients were subsequently examined by the experts commissioned by the Inquiry, who produced reports. Records were recovered for a further 37 of the 68 patients for that period, although nursing notes were missing from four sets of those records. No records for the remaining 29 of the 68 patients were available to the Inquiry.

The period 1 June 2008 to 31 December 2008

In the period 1 June 2008 to 31 December 2008 12 further patients at the VOLH tested positive for CDI. A number of patients who tested positive during the focus period tested positive again after 1 June 2008, but these patients are not included in this group of 12.

The figures for all three periods are set out in Figure 4.1.

Figure 4.1 Patients with CDI



4.3 Number of *C. difficile* deaths

Inquiry analysis

The Inquiry asked Professor George Griffin, Professor of Infectious Diseases Medicine at St George's Hospital, University of London, to carry out an analysis of patients covered by the Inquiry's remit who contracted CDI and subsequently died. He was asked to determine whether CDI was a causal factor in their deaths, either as the underlying cause of death or as a contributory cause of death. He examined the case records, prepared a report for each of the 43 patients who died, and also produced an overview report summarising his findings.³¹

Professor Griffin had carried out a similar exercise for an Inquiry into CDI in Northern Ireland in 2010.³²

When preparing reports for this Inquiry Professor Griffin did not see the reports produced by other experts commissioned by the Inquiry prior to the completion of his work. But after he had completed his work he did review such reports as a cross-check and in order to make a comparison. In 90% of the cases reviewed there was agreement on CDI as a cause of death.³³

In one of the cases where there was some disagreement, Professor Griffin had looked at records that had not been available to the other Inquiry medical expert.³⁴ In another case, where the Inquiry medical expert who had looked at the records could not express a view, Professor Griffin did consider that there was sufficient information available upon which to base an opinion.³⁵

The comparative exercise in such cases, where clinical judgement plays an important role, lends force to Professor Griffin's analysis.³⁶

Number of deaths between 1 December 2007 and 1 June 2008

There were 31 patients who died during the Inquiry focus period of 1 December 2007 and 1 June 2008. Of these, 28 patients had CDI as a causal factor in their deaths either

as the underlying cause of death or as a contributory cause of death.

Of these 28 patients, 26 acquired the infection at the VOLH and the remaining two acquired the infection either at a nursing home or the RAH. But both suffered the onset of the infection at the VOLH, where they eventually died.

Numbers of deaths before 1 December 2007

The patient records in the early period were not scrutinised by medical and nursing experts in the same fashion as the patient records in the focus period. As explained previously, many were unavailable, and Professor Griffin was therefore not in a position to carry out the same exercise for the early period as for the focus period. He did, however, consider the role CDI played in the deaths of the two patients in the early period whose family members were Core Participants. Professor Griffin concluded that CDI was a causal factor in the death of one of those patients, who had initially contracted CDI at the RAH. She remained infected and undiagnosed as a CDI patient in the VOLH despite suffering from loose stools, and died in the VOLH in October 2007. He did not find CDI a causal factor in the other patient's death.

Deaths after 1 June 2008

Professor Griffin examined records of ten further patients, who died after 1 June 2008. All these deaths occurred among patients from the focus period rather than among the 12 who first tested positive after 1 June.

Professor Griffin concluded that CDI was a causal factor in five of those ten deaths. Three of those five patients died during June 2008. He also concluded that CDI played a role in the deaths of two patients who died in the VOLH after June 2008, one in November 2008 and one in January 2009, but who had first contracted CDI prior to June 2008. The patient who died in January 2009 had *Clostridium difficile* enteritis entered on his death certificate as a contributory cause of death.

Professor Griffin concluded that CDI was not a causal factor in the five remaining deaths that occurred after 1 June 2008.

The figures for all three periods are set out in Figure 4.2.

31 [EXP02780001](#)

32 [TRA00730023](#)

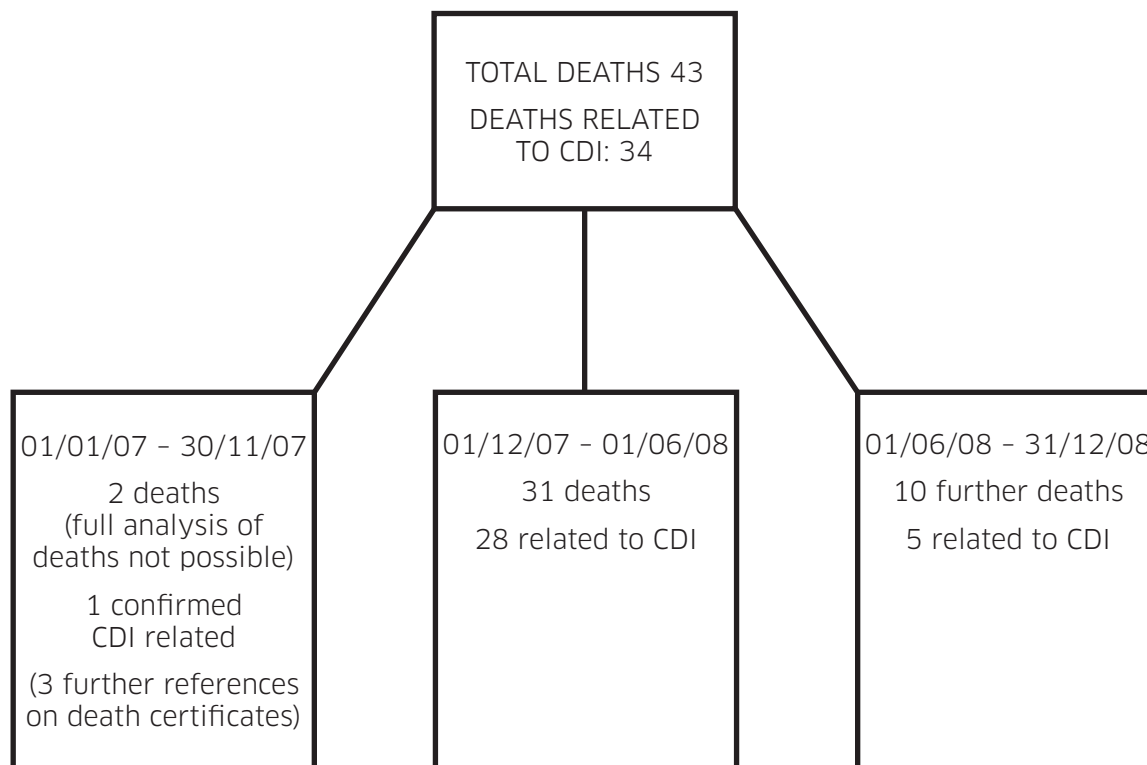
33 [TRA00730036](#)

34 [TRA00730036-37](#)

35 [TRA00730037](#)

36 [TRA00730036](#)

Figure 4.2 Deaths related to CDI



Total number of deaths

There is therefore a total of **34 patients** identified by the Inquiry in whose deaths CDI was a causal factor, either as a cause of death or as a contributory cause of death. Twenty-eight of these were in the focus period, providing a sharp contrast with the 18 identified during that period in the Outbreak Control Team Report.³⁷

In addition, while Professor Griffin could not carry out a full analysis of deaths during the early period, it is to be noted that, aside from the two cases he did examine, the death certificates of an additional three patients in the early period contained references to CDI as being involved in the patients' deaths.

Age range and health

The age range of those who died with CDI as a causal factor in their deaths was 56 to 94 years. Of these patients 60% were over

the age of 80. Many of them had chronic co-morbidities. This means that they had one or more diseases in addition to their primary disease or disorders. As Professor Griffin explained, such patients are clinically very vulnerable. Small fluctuations in their clinical state caused by an infection such as CDI can have profound effects.³⁸

Comparison with death certificates

Of the 28 patients who died during the focus period with CDI as a causal factor in their deaths, seven³⁹ patients did not have *C. difficile* enteritis entered on their death certificates.

Of the six patients who died outwith the focus period with CDI as a causal factor in their deaths, three patients did not have CDI entered on their death certificates.

This comparison is revisited in Chapter 16.

37 [GGC00600005](#)

38 [EXP02780003](#)

39 [EXP02780006](#)

4.4 Conclusion

The total number of patients covered by the Inquiry's remit who contracted CDI in the period 1 January 2007 to 31 December 2008 was 143.

There were 43 patients included in the Inquiry's remit who died having suffered from CDI. **CDI was a causal factor in the deaths of 34 of these patients**, either as a cause of death or as a contributory cause of death.

In relation to the early period, the figure is an underestimate since many records were unavailable. CDI was mentioned in the death certificates of three further patients who died in the early period.

As discussed in Chapter 5, what was significant about the CDI problem at the VOLH was that it persisted undetected for the whole of the period from 1 January 2007 to 1 June 2008, and this despite the fact that there were a significant number of deaths in which *C. difficile* was a causal factor. In the language of Dr Brian Cowan, Medical Director of the Acute Division:

“here was an outbreak which raged, or a series of outbreaks that raged, for a long period of time with a significant, highly significant, number of deaths”.⁴⁰

No doubt many of the patients had significant co-morbidities and shortened lifespans. But it was the fact that they were so vulnerable and frail that made the suffering inflicted by CDI so devastating. The evidence provided to the Inquiry by patients and relatives, discussed in Chapter 11, underlines the lack of dignity suffered by patients in their final period of life and the enormous distress caused to the relatives. The impact of *C. difficile* on patients was described by Professor Griffin in the following way:

“*C. difficile* is very unpleasant for patients. It is exceedingly unpleasant and distressing for relatives to see an old, loved patient in a bed in a pool of faeces. It is very difficult for nursing staff to have to clean a patient nine, ten times a day who is demented, immobile, can't help the nurse with moving”.⁴¹

CDI can deprive the elderly patient of a peaceful uncomplicated death. These are reasons why CDI must be regarded as a serious infection in its own right.

Recommendations which are relevant to this Chapter are set out in other Chapters of this Report.

Chapter 5

C. difficile infection rates
and undeclared outbreaks

Introduction

One of the striking aspects of the evidence available to the Inquiry was that no *C. difficile* infection (CDI) outbreaks were declared at the Vale of Leven Hospital (VOLH) prior to June 2008. This was despite the high number of CDI cases diagnosed and the number of known CDI patients present on the wards. There were a number of opportunities to identify a CDI problem in the period beginning 1 January 2007. This Chapter considers when potential outbreaks may have occurred and what information was available at that time.

5.1 Definition of an outbreak

Greater Glasgow Health Board Infection Control Committee produced an Outbreak Policy which was regularly updated. The Outbreak Policy¹ issued in July 2006, which remained in place until December 2007,² contained a definition of an outbreak as:

“two or more linked cases (or isolates) of unexplained illness, which indicates the possibility that they may be due to a known or unknown infectious agent identified in healthcare premises”.³

In the updated December 2007 Outbreak Policy⁴ an outbreak was defined to include:

“two or more linked cases of the same illness (i.e. associated in person, place or time)”.⁵

The Infection Control Guidelines⁶ produced in 2001 for use at the VOLH under Argyll and Clyde NHS Trust defined an outbreak as “two or more cases of infection caused by an identical organism in the same ward or unit.”⁷ This was prior to the dissolution of NHS Argyll and Clyde. There is uncertainty whether the Argyll and Clyde definition or the 2006 NHSGGC definition was applied at the VOLH prior to December 2007, but that is of little significance since the general

principle of all three definitions is that two linked cases of an infection such as *C. difficile* would represent a possible outbreak. An example of two linked cases would be two cases in the same ward at about the same time, and this was well understood by the Infection Control Nurses⁸ at the VOLH. It is of note, however, that although both the NHSGGC policies stipulated that “healthcare workers must follow this policy”,⁹ as discussed in Chapter 15, not all healthcare workers were in fact aware of the definition of an outbreak.

The outbreak procedure

The 2001 Infection Control Guidelines¹⁰ required that a number of people, including the Medical Director,¹¹ be notified if there was the suspicion of an outbreak of an infectious disease. The Medical Director had in turn to inform the Chief Executive and/or the Chairman.¹² These guidelines also envisaged that an Outbreak Control Team would be set up.¹³ Both the Greater Glasgow Health Board Outbreak Policy issued in June 2006 and the Outbreak Policy in place from December 2007 stipulated that all reports of possible outbreaks had to be investigated.¹⁴

Detailed guidance was provided in all these documents as to how such investigations should be conducted and what control measures should be put in place. This included, for example, the closure of wards, depending upon the scale of the problem.¹⁵ The Outbreak Policy in place from December 2007 also outlined a communication chain of those who were to be informed, including, “if appropriate, the Chief Officers of NHS Greater Glasgow and Clyde Board”.¹⁶

The philosophy contained in the guidance was repeated in the evidence of the Infection Control experts commissioned by the Inquiry, Professor Brian Duerden¹⁷ and Mrs Christine

1 [GGC27390001](#)
2 [TRA00320003](#)
3 [GGC27390003](#)
4 [GGC00780145](#)
5 [GGC00780148](#)
6 [INQ03960001](#)
7 [INQ03960107](#)

8 [TRA00950033](#); [TRA01010039-40](#)
9 [GGC27390002](#); [GGC00780147](#)
10 [INQ03960001](#)
11 [INQ03960107](#)
12 [INQ03960115](#)
13 [INQ03960107](#)
14 [GGC27390002](#); [GGC00780147](#)
15 [GGC27390007](#); [GGC00780149](#)
16 [GGC00780154](#)
17 [TRA01050058](#)

Perry.¹⁸ Once it is apparent that there **may** be an outbreak, it is necessary to presume that there **is** an outbreak and investigate, and if necessary close a ward to further admissions.¹⁹

The point is made in the introduction to this Chapter, and bears repetition, that despite all the guidance in place no CDI outbreaks were declared at the VOLH between 1 January 2007 and 1 June 2008. None of the investigations expected by the Outbreak Policy were undertaken and no ward was ever closed.

5.2 The number of CDI results

Testing

Between 1 January 2007 and 1 June 2008 there was a total of 929 reported *C. difficile* toxin test results for VOLH patients from the Laboratory there. Table 5.1 sets out this total number by positive and negative test results. It also divides these results between the early period (1 January 2007 to 30 November 2007) and the focus period (1 December 2007 to 1 June 2008).

Table 5.1 All positive and negative CDI test results

	Early period	Focus period	Total period 1 January 2007 to 1 June 2008
Positive results	109	90	199
Negative results	432	298	730
Total results	541	388	929

For a hospital the size of the VOLH this Table discloses a high level of activity in the testing for *C. difficile* toxin during these periods.

Between 1 January 2007 and 1 June 2008 there was a total of 199 *C. difficile* toxin positive results at the VOLH. Table 5.2 sets

out those positive testing results broken down by each ward. It is clear that CDI was present on the wards throughout the early and focus periods, particularly wards F, 3, 6, 14 and 15, which have been the primary focus of the Inquiry's investigations.

¹⁸ [TRA01050030](#)

¹⁹ [TRA01050030](#); [TRA01050022-23](#)

Table 5.2 Positive CDI results by ward

Ward	Early period	Focus period	Total period
F	12	16	28
3	16	11	27
5	11	2	13
6	22	25	47
14	24	17	41
15	11	11	22
4/CCU	5	2	7
HDU	3	1	4
MAU	0	2	2
Fruin	0	3	3
Outpatient	1	0	1
Unknown ward	4	0	4
TOTAL	109	90	199

Pattern of CDI in the VOLH

As described in his report²⁰ and evidence,²¹ Professor Christopher Robertson, a Statistician commissioned by the Inquiry, investigated the pattern of diagnoses of CDI in the VOLH in the period from 1 January 2007 to 1 June 2008. He looked at three periods of particular interest: January to June 2007, July to November 2007 and December 2007 to June 2008.

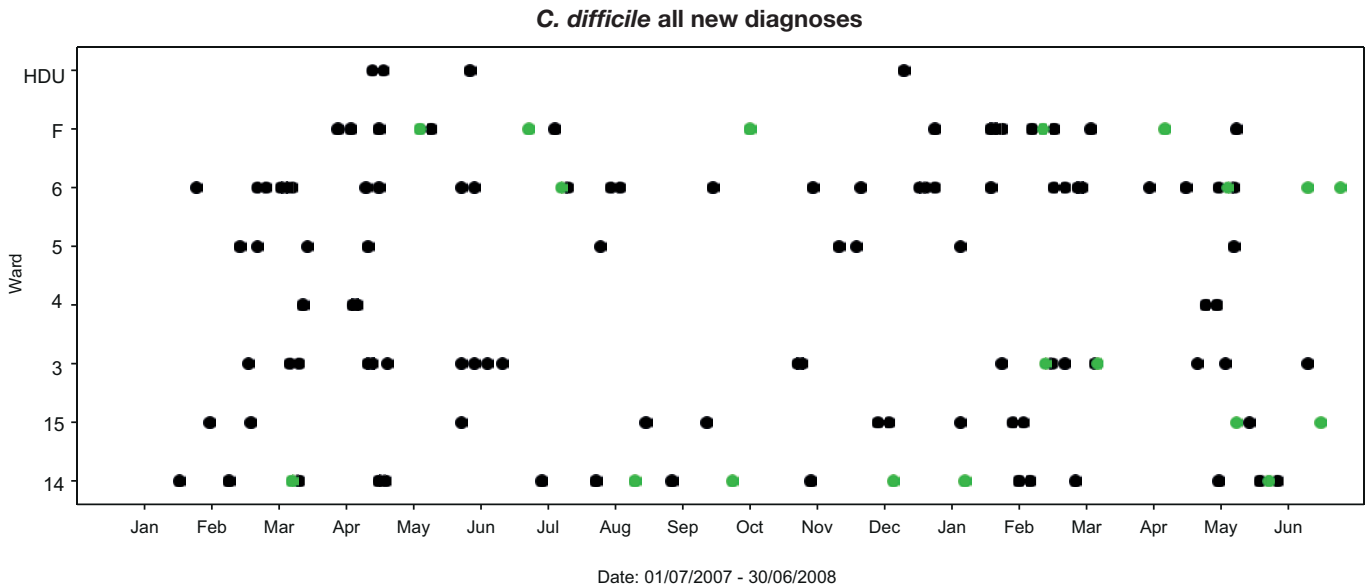
Some patients tested positive for *C. difficile* toxin more than once, so Professor Robertson had to attempt to distinguish between a positive CDI result that indicated a new infection of a patient and a result that indicated the ongoing infection of a patient who had tested positive for CDI previously. He adopted the approach that a new infection occurred when the positive result was more than 28 days after the previous positive result.²²

20 [EXP02840001](#)

21 [TRA01080001](#)

22 [EXP02840007](#)

Figure 5.1 New diagnoses of CDI by ward



Black spots show the first positive CDI result. Green dots show a presumed new infection in a previous CDI patient. Only results at the VOLH are shown.

Figure 5.1 sets out the pattern of all new diagnoses of CDI by the ward where the patient was diagnosed. It is evident from this statistical presentation that CDI was present throughout the whole period from January 2007 to June 2008.²³ Testing for *C. difficile* toxin occurred in virtually all wards in the hospital, especially wards 3, 5, 6, 14, F and HDU.²⁴ When two similar periods of time are compared: January to June 2007 and December 2007 to June 2008, no significant difference in the rates of CDI is found.

Potential outbreaks

The Inquiry can only identify where **potential** CDI outbreaks occurred. This is because, as explained in Chapter 3, there are a number of different strains of *C. difficile*. Two CDI patients may contract different strains of the infection, and in this scenario there would not in fact be an outbreak. As Mrs Perry explained:

“without further strain testing (ribotyping) of *C. difficile* samples, it is not possible to definitively state that an outbreak has occurred”.²⁵

No investigations were made at the time. It is therefore only possible to identify retrospectively where outbreaks **may** have occurred. Nevertheless, any such potential outbreak should have activated the VOLH’s outbreak procedures, and subsequent testing would have identified whether patients had contracted the same strain of *C. difficile*.

Instances of potential CDI outbreaks have now been identified using laboratory testing data, hospital admission spreadsheets and patients’ records available to the Inquiry. These data were collated and categorised by the Inquiry, and analysed by Professor Robertson to identify instances of two or more CDI patients associated in time or place, which would in turn identify any potential outbreak.

23 [TRA01080012](#)

24 [TRA01080016](#)

25 [INQ03970001](#)

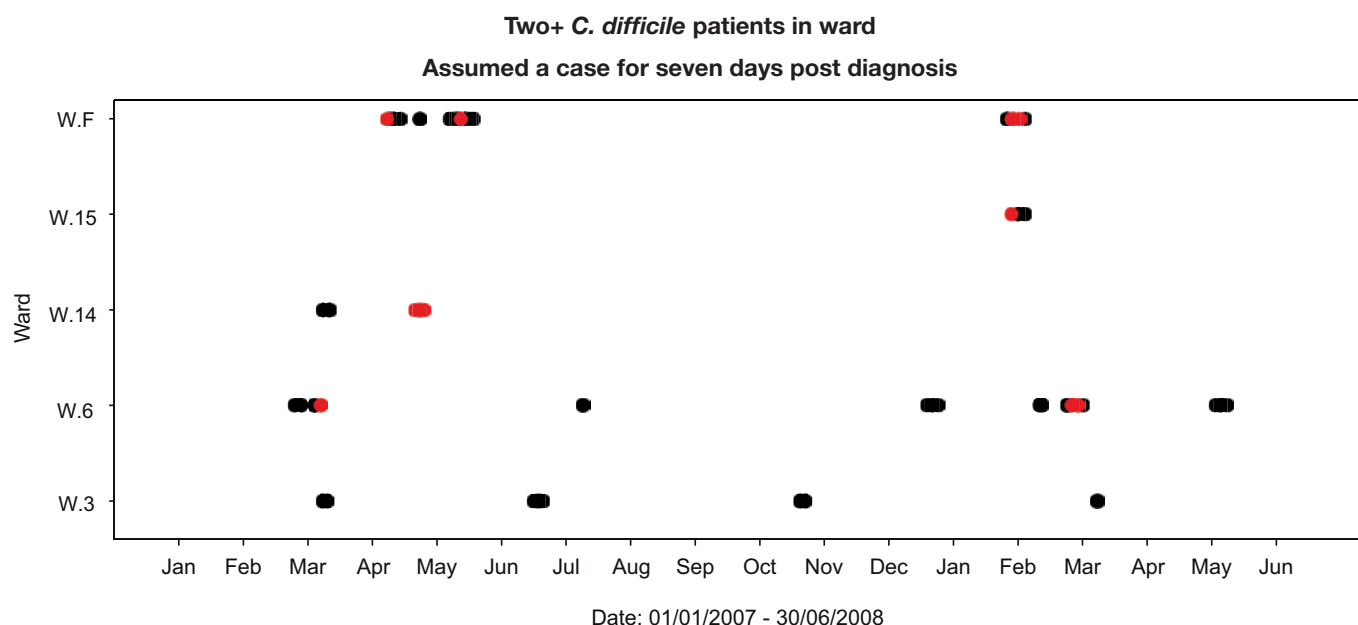
Professor Robertson emphasised that, due to limitations in the available data, a number of qualifications had to be borne in mind when investigating whether there were potential outbreaks in particular wards. There were some patients where it was difficult to identify from the medical records their precise date of admission to the VOLH. There were other patients who moved between wards and it was not clear when that occurred.²⁶ Professor Robertson also had to make a number of assumptions in his analysis about the length of time a patient remained symptomatic with CDI after any positive test. Without access to the individual patient records, his general assumption was that the symptomatic period was seven days.²⁷

Even with the assumption that the symptomatic period only lasted for seven days, Professor Robertson suggested that there were potential outbreaks in wards 3, 6, 14, 15 and F in the period January 2007 to June 2008.²⁸

Figure 5.2 sets out Professor Robertson’s statistical analysis of the times when the number of positive cases on a ward represented a potential outbreak. A black spot illustrates when two patients were positive on the same ward at the same time, and a red spot illustrates when there were three or more patients positive on the same ward at the same time.

Even allowing for the limitations in the data, Professor Robertson’s general conclusion was that it seemed likely that there had been a number of occasions when the numbers of CDI patients in a particular ward exceeded the number required to constitute an outbreak.²⁹ In particular, this occurred in wards F, 14, 6 and 3 during January to June 2007 and in wards F, 15, 6 and 3 during December 2007 to June 2008.

Figure 5.2 Potential outbreaks



A black spot shows when there are two CDI patients on the ward on the same date. A red spot indicates three or more CDI patients. No potential outbreaks were observed in any ward not listed.

26 [TRA01080042](#)

27 [TRA01080043](#); [EXP02850037](#)

28 [TRA01080046](#)

29 [EXP02850052](#)

Length of time patients were CDI symptomatic

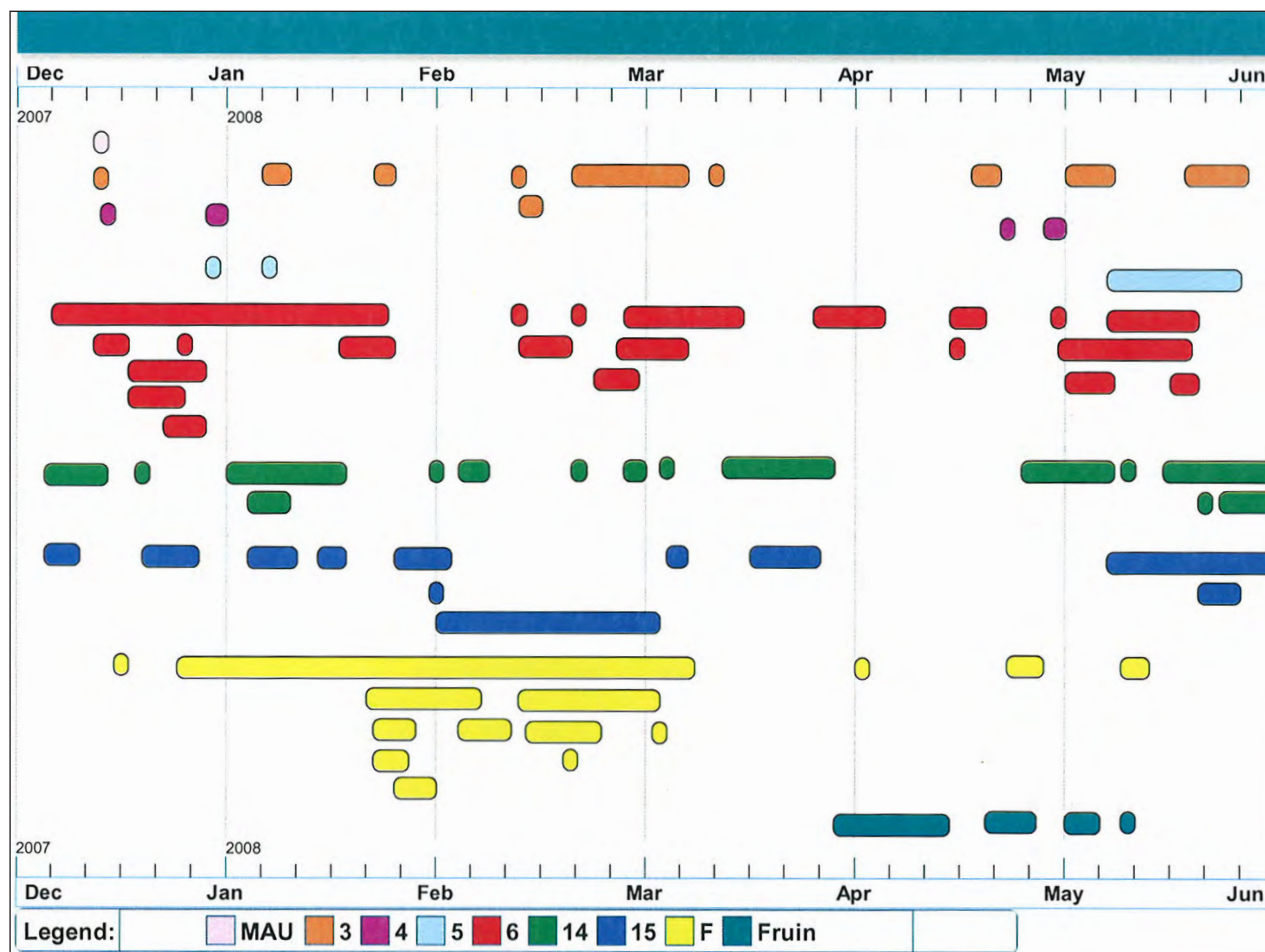
While Professor Robertson's analysis is based on estimates of the length of time patients were symptomatic, the Inquiry carried out a further analysis of patients from the focus period to see if any conclusions could be drawn from the **actual** length of time patients were confirmed as being symptomatic for CDI. This was done by examination of entries in the patient records, although that too introduces an important qualification, since it is clear that there were deficiencies in record keeping at the VOLH. This is discussed further in Chapters 12 and 14. It is also apparent that parts of the patient records supplied to the Inquiry by NHSGGC were missing.

The Inquiry found that in the focus period there were 90 instances when patients tested positive for *C. difficile* toxin. For the following analysis, 17 of those results have been discounted because they came from the subsequent re-testing of a patient already

confirmed as having contracted CDI. A further three results have been eliminated because it has not been possible to ascertain from the patient records when each patient stopped being symptomatic. That means that 70 *C. difficile* toxin positive results form the basis of the analysis.

Figure 5.3 contains a presentation of the Inquiry's analysis of the **actual** length of time each CDI patient remained symptomatic from the date his or her CDI result was known by ward staff. Each entry represents an individual patient and how long that patient was symptomatic on a particular ward. It is also clear how many patients were symptomatic on a ward on a particular date. The presence of two or more patients on the same ward on the same day signifies a potential outbreak on that ward. More than 70 results are recorded, because patients who moved ward may appear more than once.

Figure 5.3 The number of days patients were symptomatic



There is a timescale running along the top and bottom from 1 December 2007 to 1 June 2008. Each colour block shows a separate symptomatic CDI patient. The length of the block shows the number of days that patient was symptomatic. Each ward has a different colour shown on the legend above. From mid December 07 ward 4 also comprised CCU and HDU.

Professor Robertson carried out analyses using periods ranging from three to ten days,³⁰ with a particular focus on seven days. But of the 70 positive results included in the Inquiry’s analysis, there were only 38 CDI results (54%), representing 37 patients, where the patient was symptomatic for ten days or less. Ten days is the normal period for initial antibiotic treatment with metronidazole.

The Inquiry’s analysis revealed there were 32 results (46%) where patients were symptomatic for more than ten days. These 32 results accounted for 29 different patients, since three patients had two separate episodes of CDI with symptomatic periods of greater than ten days. A closer

analysis of cases where patients were symptomatic for longer than ten days revealed:

- Eighteen patients were symptomatic for between 11 to 19 days
- Eight patients were symptomatic for between 20 to 29 days
- Six patients were symptomatic for more than 30 days

A high number of patients therefore remained symptomatic and a risk to other patients for lengthy periods of time. Table 5.3 sets out the 32 results of patients who remained symptomatic for more than ten days and the wards in which they were diagnosed.

30 [TRA01080043](#)

Table 5.3 Patients symptomatic more than ten days

	Ward	First symptomatic	Last symptomatic	Total days symptomatic
Patient B	6	14/12/07	25/12/07	11
Isobel Cameron	14	03/12/07	14/12/07	11
Mary Broadley	15	16/12/07	27/12/07	11
Elizabeth Valentine	6	16/02/08	28/02/08	12
John Boyle	15	22/01/08	03/02/08	12
Mary Millen	F	30/01/08	11/02/08	12
Margaret Dalton	6	17/12/07	31/12/07	14
Patient A	6	06/05/08	20/05/08	14
David Somerville	15	07/02/08	21/02/08	14
Charles Cook	14	07/05/08	22/05/08	15
Christina Miller	6	20/03/08	05/04/08	16
Janet Fitzsimmons	14	22/04/08	08/05/08	16
Martha McGregor	6	19/02/08	07/03/08	17
Isabella Lettis	14	01/01/08	18/01/08	17
William Hunter	3	18/02/08	07/03/08	18
George Drummond	3	19/04/08	08/05/08	19
Moira McWilliams	6	25/02/08	15/03/08	19
Mary Burns	6	05/12/07	24/12/07	19
Jacqueline Patrick	5	06/05/08	26/05/08	20
Coleman Conroy	14	08/03/08	28/03/08	20
Ellen Gildea	F	11/02/08	04/03/08	22
Mary Hamilton	F	01/02/08	23/02/08	22
Rosa Rainey	F	16/01/08	07/02/08	22
Irene Harnett	Fruin	13/04/08	06/05/08	23
Moira McWilliams	6	24/04/08	19/05/08	25
Alister Brand	F	07/02/08	03/03/08	25
Margaret Kelly	Fruin	25/03/08	26/04/08	32
Margaret Gaughan	15	30/01/08	03/03/08	33
Margaret Stevenson	14	15/05/08	18/06/08	34
David Somerville	15	01/05/08	21/06/08	51
Anne Agnew	14	08/05/08	29/06/08	52
Patient C	F	24/12/07	08/03/08	75

Six patients were symptomatic for more than 30 days. Of those, three patients were symptomatic for three times the normal period of initial antibiotic treatment. Three patients were symptomatic for more than five times the period that would be expected.

The most extreme case was that of Patient C, who was symptomatic for some 75 days in the period 24 December 2007 to 8 March 2008. This was a patient who for a period of time only received a sub-therapeutic dose of vancomycin, and it was of no surprise to an Inquiry expert microbiologist that her CDI persisted.³¹ The patient was also prone to wander, and posed a serious cross infection risk to other patients.

Of the six patients symptomatic for more than 30 days, two were patients in ward 14, two were patients in ward 15, and Patient C was in ward F.

Given that 46% of the positive test results analysed disclosed that these CDI patients remained symptomatic for in excess of ten days, Professor Robertson's conclusions on analysis of the number of instances of potential CDI outbreaks in Figure 5.2, based on an estimate that patients were symptomatic for seven days, were indeed conservative. It is clear that there were in fact more occasions than those identified by him upon which two or more patients were symptomatic for CDI on the same ward at the same time. Each occasion should have identified a potential outbreak and triggered the outbreak procedure.

5.3 Wards with CDI patients - the early period

Position during the early period generally

As identified by Professor Robertson, there were a number of instances during the early period when at least two patients were suffering from CDI in the same ward at the same time in the VOLH. An impression of the problem overall can be gained from Figure 5.4, which sets out all *C. difficile* toxin positive results in the early period from 1 January to 30 November 2007. Each entry identifies the patient and the date the ward became aware of the positive CDI result, and the wards are colour coded to indicate the ward the patient was on at the time.

Figure 5.4 shows that the problem was not confined to one ward. Most of the wards were affected. It is very likely that the regular movement of patients between wards only served to exacerbate the risk of cross infection from ward to ward.³²

31 [TRA00600129](#)

32 [TRA01060044](#)

Missed opportunities to investigate in the early period

The Inquiry is able to conclude that in the period 1 January 2007 to 30 November 2007 there were several occasions when the number of patients suffering from CDI in different wards at the VOLH should have been fully investigated. The following analysis by ward is based on all the information available to the Inquiry, including medical records, where available, and on Infection Control Cards on which the Infection Control Nurses themselves recorded patient information.

Ward 14

According to what was recorded in the Infection Control Database held at the VOLH, three patients tested positive for *C. difficile* toxin in the period 11 to 19 April 2007. Another patient also tested positive during

that period whose name and details do not appear on the database material made available to the Inquiry. Table 5.4 sets out the information on these patients the Inquiry has extracted for ward 14 from a number of sources, and it can be seen from this presentation that in the period 13 to 17 April 2007 the ward was aware of four patients testing positive for *C. difficile* toxin. Patients from the early period are identified by a patient number rather than by name.

Patient 1 had been on the ward for about two weeks. Patient 2 had been on the ward for nearly three months. The Infection Control Card for Patient 1 recorded that the patient was in a four-bedded bay with other positive patients. The Infection Control Card for one of the other patients recorded that the patient was in a four-bedded bay because there was no side room available.

Table 5.4 CDI patients on ward 14 in April 2007

	Admission to VOLH	Admission to ward 14	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 1	19/03/07 to ward 3	28/03/07	unknown	13/04/07	13/04/07	17/04/07
Patient 2	12/01/07 from RAH to ward 5	15/01/07	unknown	13/04/07	13/04/07	17/04/07
Patient 3	10/04/07 from WIG* to ward 14	10/04/07	unknown	16/04/07	14/04/07	17/04/07
Patient 4	21/03/07 to ward 6	13/04/07	16/04/07	17/04/07	16/04/07	19/04/07

*Western Infirmary, Glasgow

Subsequently, in July 2007, two other patients in ward 14 tested positive for *C. difficile* toxin, one of whom tested positive twice in respect of specimens collected in a three-day period. Table 5.5 presents the details relating to those patients who tested positive in July 2007. Patient 5 had been

in ward 14 for about a month and Patient 6 for about six weeks. The Infection Control Card for Patient 5 indicates that this patient was being accommodated in a four-bedded bay with one other patient who had tested positive for *C. difficile* toxin.

Table 5.5 CDI patients on ward 14 in July 2007

	Admission to VOLH	Admission to ward 14	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 5	26/06/07 from RAH to ward 14	26/06/07	unknown	23/07/07	20/07/07	24/07/07
Patient 6	08/06/07 from RAH to ward 14	08/06/07	23/07/07	unknown	23/07/07	25/07/07
Patient 5	26/06/07 from RAH to ward 14	26/06/07	unknown	unknown	23/07/07	25/07/07

There were therefore two separate instances of two or more CDI patients on ward 14 at the same time, each of which should have alerted the ward to a potential outbreak and prompted investigation procedures.

Ward F

In ward F the ward was aware of three patients being positive for *C. difficile* toxin between 27 and 29 March 2007. Each of these patients had been in ward F for more than a month.

Subsequently, in May 2007, four patients tested positive for *C. difficile* toxin on dates closely associated in time. Patient 9 and Patient 11 had been in ward F for several months. Patient 12 and Patient 13 had been in the ward for about two weeks.

Table 5.6 sets out the position in ward F in March and May 2007. The Infection Control Cards of patients 12 and 13 recorded that these patients were being nursed in a room with other patients who had tested positive for *C. difficile* toxin.

Table 5.6 CDI patients on ward F in March and May 2007

	Admission to VOLH	Admission to ward F	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 8	09/02/07 to ward 6	20/02/07	26/03/07	27/03/07	26/03/07	28/03/07
Patient 9	19/01/07 from RAH to ward 6	26/01/07	29/03/07	29/03/07	29/03/07	02/04/07
Patient 10	unknown	21/02/07	29/03/07	29/03/07	29/03/07	02/04/07
Patient 11	09/02/07 from Beatson to ward 6	18/02/07	unknown	02/05/07	02/05/07	04/05/07
Patient 9	19/01/07 from RAH to ward 6	26/01/07	unknown	03/05/07	02/05/07	04/05/07
Patient 12	20/04/07 to ward 4	26/04/07	unknown	08/05/07	06/05/07	10/05/07
Patient 13	17/04/07 to ward 4	22/04/07	unknown	unknown	07/05/07	10/05/07

There were therefore two separate instances of two or more CDI patients on ward F at the same time, each of which should have alerted the ward to a potential outbreak and prompted investigation procedures.

Ward 3

Table 5.7 sets out the position in ward 3 in June 2007. Once again patients tested positive for *C. difficile* toxin on dates closely associated in time and place. Patient 15 and Patient 16 had been in the ward for several weeks. Patient 14 and Patient 17 had been discharged from the VOLH earlier, one of them from ward 3 just three days before re-admission to the same ward.

According to the Infection Control Database, Patient 16 and Patient 17, whose formal positive reports from the laboratory are

both dated 15 June 2007, were being accommodated in a multi-bed bay where all the patients were *C. difficile* toxin positive. Likewise the Infection Control Cards for Patient 16 and Patient 17 note they were being nursed in a four-bedded bay where all the patients were positive for *C. difficile* toxin. Similarly, the Infection Control Cards for Patient 14 and Patient 15, whose formal reports are dated 6 and 12 June respectively, indicate that they too were being nursed in a four-bedded bay and that all the patients in that bay were positive for *C. difficile* toxin.

There was therefore a clear instance of ward 3 being aware of two or more CDI patients on the ward at the same time. This should have alerted the ward to a potential outbreak and prompted investigation procedures.

Table 5.7 CDI patients on ward 3 in June 2007

	Admission to VOLH	Admission to ward 3	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 14	01/06/07 to ward 3 (previously discharged 15/05/07)	01/06/07	unknown	unknown	02/06/07	06/06/07
Patient 15	17/05/07 to ward 4	19/05/07	unknown	08/06/07	07/06/07	12/06/07
Patient 16	21/05/07 to ward 3	21/05/07	unknown	14/06/07	13/06/07	15/06/07
Patient 17	11/06/07 to ward 3 (previously discharged 08/06/07)	11/06/07	unknown	unknown	12/06/07	15/06/07

Ward 6

Table 5.8 sets out the position in ward 6 in February, March and April 2007. Again it can be seen that there were patients over that period whose positive results were closely associated in time. Patient 18 tested toxin positive on three separate occasions during that period. One patient had been transferred from the Royal Alexandra Hospital (RAH) the day before the positive sample was collected

on the ward. Patient 23 was transferred from the RAH two days before the sample was described in the report as “collected”.

During this period there are clear instances of two or more CDI patients on ward 6 at the same time. Despite this, no outbreaks were declared and no Outbreak Policy investigations were ever initiated.

Table 5.8 CDI patients on ward 6 from February to April 2007

	Admission to VOLH	Admission to ward 6	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 18	08/02/07 to ward 6 (Previous discharge 01/02/07)	08/02/07	unknown	15/02/07	14/02/07	17/02/07
Patient 19	05/02/07 from RAH to ward 6	05/02/07	unknown	16/02/07	15/02/07	19/02/07
Patient 20	07/02/07 from RAH to ward 6	07/02/07	unknown	unknown	21/02/07	27/02/07
Patient 21	26/02/07 from RAH to ward 6	26/02/07	unknown	01/03/07	28/02/07	05/03/07
Patient 22	17/02/07 to ward 4	21/02/07	unknown	unknown	28/02/07	02/03/07 (Transferred to RAH 01/03/07)
Patient 18	08/02/07 to ward 6 (Previous discharge 01/02/07)	08/02/07	12/03/07	13/03/07	12/03/07	16/03/07
Patient 18	08/02/07 to ward 6. (Moved to ward 15 13/03/07)	28/03/07	29/03/07	unknown	29/03/07	03/04/07
Patient 23	03/04/07 from RAH to ward 6	03/04/07	04/04/07	05/04/07	04/04/07	09/04/07
Patient 24	08/04/07 to ward 6	08/04/07	unknown	10/04/07	08/04/07	11/04/07
Patient 25	21/03/07 to HDU	24/03/07	13/04/07	13/04/07	13/04/07	17/04/07

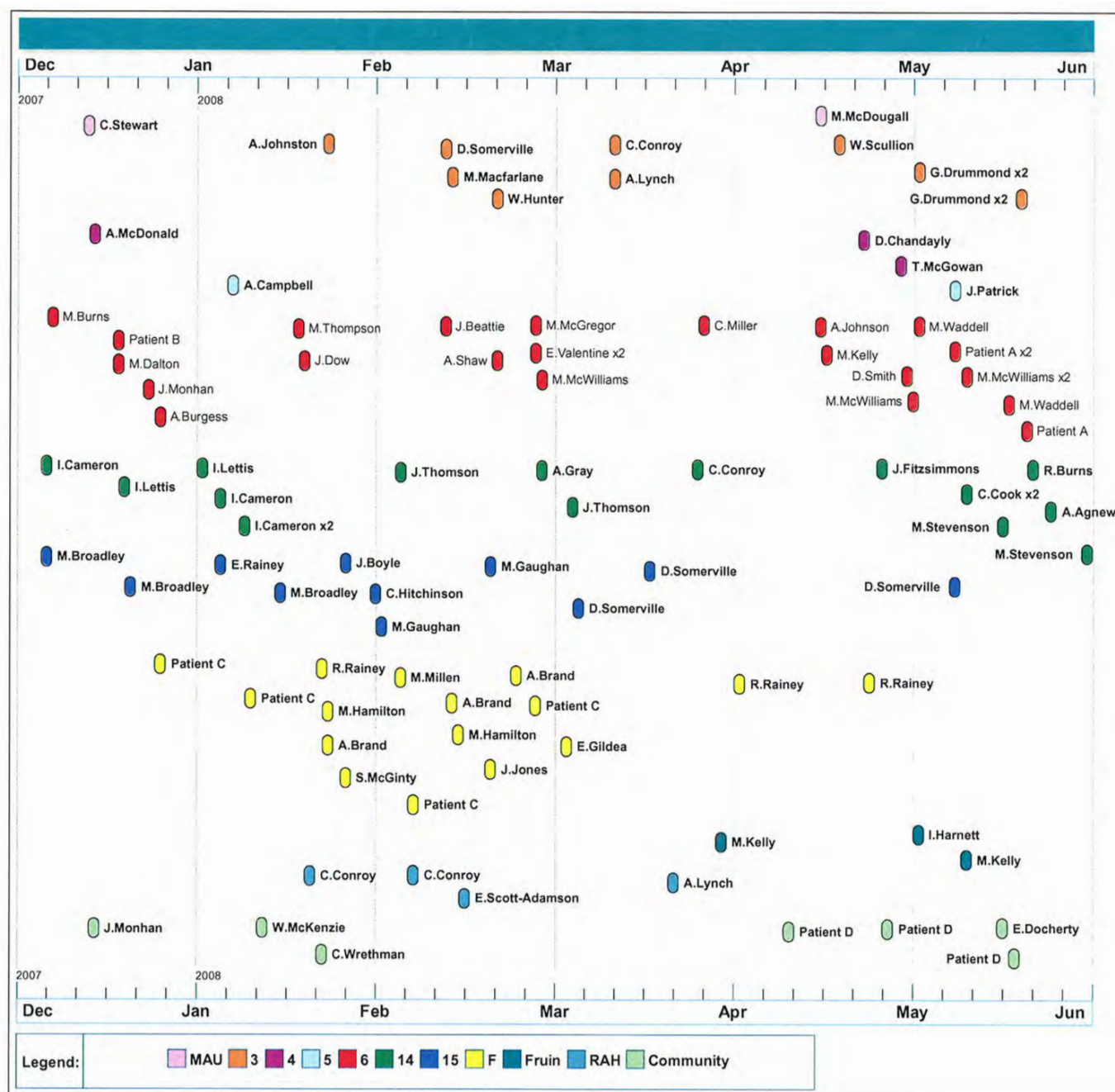
5.4 Wards with CDI patients - the focus period

Position during the focus period generally

There were several occasions during the Inquiry focus period when at least two patients were suffering from CDI in wards in the VOLH. An impression of the problem overall can be gained from Figure 5.5, which sets out all *C. difficile* toxin positive results

from 1 December 2007 to 1 June 2008. Each entry identifies the CDI patient and the date the ward became aware of the positive result, and the wards are colour coded to indicate the ward that the patient was on at the time. Most CDI patients in the focus period are identified by name, although four patients are simply referred to as Patients A, B, C and D to preserve their anonymity.

Figure 5.5 *C. difficile* toxin positive test results 1 December 2007 to 1 June 2008



There is a timescale running along the top and bottom from 1 December 2007 to 1 June 2008. Each colour bar shows the date the ward was aware of the CDI result for the named patient. Each ward has a different colour shown on the legend above. Results obtained in the RAH and the community are also identified.

Figure 5.5 shows that the CDI problem was not confined to one ward. Most of the wards were affected, ward 6 and ward F in particular. As with the early period, it is very likely that the regular movement of patients between wards only served to exacerbate the risk of cross infection from ward to ward. The Inquiry is able to conclude that in the focus period, just as in the early period, there were several occasions when the number of patients suffering from CDI in different wards at the VOLH should have been investigated in accordance with outbreak procedures. The following analysis by ward during the focus period is based on all the information available to the Inquiry including medical records where available and Infection Control Cards.

Ward 6

Table 5.9 sets out some details of patients who tested positive for *C. difficile* toxin on ward 6 in December 2007. For Catherine Stewart, Julia Monhan and Agnes Burgess the conclusion entered into the Infection Control Database was that the infection was community acquired. This is understandable when their admission dates are considered. Nevertheless, Julia Monhan and Agnes Burgess had been patients in ward 6 of the VOLH earlier in December 2007 and Catherine Stewart had been a patient in the RAH until 29 November 2007.³³ These circumstances should have prompted closer scrutiny.

Table 5.9 CDI patients on ward 6 in December 2007

	Admission to VOLH	Admission to ward 6	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Mary Burns	05/12/07 from RAH	05/12/07	05/12/07	06/12/07	05/12/07	07/12/07
Catherine Stewart	11/12/07 to MAU	12/12/07	12/12/07	12/12/07	11/12/07	14/12/07
Margaret Dalton	18/11/07 to ward 4 (Moved to HDU 19/11/07)	03/12/07	17/12/07	17/12/07	17/12/07	19/12/07
Patient B	07/12/07 to ward 6	07/12/07	15/12/07	17/12/07	15/12/07	17/12/07
Julia Monhan	Previously discharged 07/12/07. then <i>C. difficile</i> + in community	21/12/07	21/12/07	22/12/07	21/12/07	24/12/07
Agnes Burgess	20/12/07 to ward 3 (previously discharged 07/12/07)	21/12/07	22/12/07	24/12/07	22/12/07	24/12/07

33 GGC00530063; GGC00580193; GGC21640013

The other three patients were considered to have acquired the infection in hospital.³⁴ Mary Burns had been transferred from RAH to the VOLH on 5 December 2007, with diarrhoea. She had previously tested positive³⁵ for *C. difficile* toxin twice while in the RAH. Margaret Dalton and Patient B had been patients in ward 6 for a sufficiently long period of time for the infections to be considered hospital acquired infections. The

ward also became aware of their positive results on the same day (17 December 2007).

Table 5.10 sets out details of patients who tested positive for *C. difficile* toxin on ward 6 in February 2008. In that period there are CDI patients closely associated in time and place, which should have identified a potential outbreak.

Table 5.10 CDI patients on ward 6 in February 2008

	Admission to VOLH	Admission to ward 6	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Jean Beattie	09/02/08 to ward 6 (previously discharged 07/02/08)	09/02/08	09/02/08	11/02/08	09/02/08	13/02/08
Annie Shaw	19/01/08 to ward 6 (transferred to RAH 28/01/08)	08/02/08	18/02/08	19/02/08	18/02/08	20/02/08
Elizabeth Valentine	08/02/08 to ward 6	08/02/08	21/02/08 x2	22/02/08	21/02/08	25/02/08
Martha McGregor	20/01/08 to ward 6	20/01/08	25/02/08	25/02/08	25/02/08	27/02/08
Moira McWilliams	14/02/08 from RAH to ward 6	14/02/08	25/02/08	26/02/08	26/02/08	28/02/08

34 INQ02970001

35 GGC26320029; GGC26320063

Table 5.11 provides details of CDI patients on ward 6 in April and May 2008. Once again there are patients who are closely associated

in time and place. This should have identified potential outbreaks and activated Outbreak Policy investigations.

Table 5.11 CDI patients on ward 6 in April and May 2008

	Admission to VOLH	Admission to ward 6	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Mary McDougall	10/04/08 to MAU 11/04/08 to ward 4	12/04/08	unknown	14/04/08	10/04/08 (MAU)	14/04/08
Annie Johnson	11/03/08 to ward 6	11/03/08	10/04/08	unknown	10/04/08	14/04/08
Margaret Kelly	01/08/07 to ward 4 (various wards) (transferred to Fruin 19/03/08)	14/04/08	14/04/08	15/04/08	14/04/08	16/04/08
Doris Smith	28/04/08 to ward 6 (previously discharged 18/04/08)	28/04/08	28/04/08	28/04/08	28/04/08	30/04/08
Moira McWilliams	14/02/08 from RAH	14/02/08	29/04/08	29/04/08	29/04/08	01/05/08
Muriel Waddell	22/04/08 to ward 6	22/04/08	unknown	01/05/08	unknown	02/05/08
Patient A	06/05/08 to ward 6 (previously discharged 25/04/08)	06/05/08	06/05/08 x2	07/05/08	06/05/08	09/05/08
Moira McWilliams	14/02/08 from RAH to ward 6	14/02/08	unknown x2	09/05/08	06/05/08	09/05/08
Muriel Waddell	22/04/08 to ward 6	22/04/08	14/05/08	16/05/08	14/05/08	19/05/08
Patient A	06/05/08 to ward 6 (previously discharged 25/04/08)	06/05/08	19/05/08	19/05/08	19/05/08	22/05/08

Ward F

Table 5.12 sets out details of patients who tested positive for *C. difficile* toxin in ward F in January and February 2008. The ward was aware of five patients testing positive between 9 and 25 January 2008. Each of these patients had been admitted to the ward at least several weeks before the positive results were obtained. The ward was aware on 9 January 2008 that Patient C tested positive for *C. difficile* toxin. As described earlier in this Chapter this patient was prone to wandering, and remained symptomatic for a very long period of time. She tested positive again in early February.

These five patients were closely linked in time and place. This cluster of infection should have been identified as a potential outbreak and outbreak procedures activated.

The position became more acute in February when there were still a number of CDI patients in the ward. It was at this time that an asymptomatic patient was admitted to a bay in which there were at least two symptomatic CDI patients,³⁶ putting her at risk of cross infection. That patient did subsequently contract CDI, and tested positive for *C. difficile* toxin on 18 February 2008. This episode is discussed in Chapter 15.

Table 5.12 CDI patients on ward F in January and February 2008

	Admission to VOLH	Admission to Ward F	Medical records		Laboratory report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient C	09/12/07 to ward 6	14/12/07	unknown	09/01/08	09/01/08	11/01/08
Rosa Rainey	27/12/07 to ward 6	28/12/07	18/01/08	21/01/08	18/01/08	21/01/08
Mary Hamilton	27/12/07 to ward 6	28/12/07	21/01/08	22/01/08	21/01/08	24/01/08
Alister Brand	18/12/07 from RAH to ward 5	30/12/07	unknown	22/01/08	21/01/08	24/01/08
Sarah McGinty	03/12/07 to ward 6	04/12/07	25/01/08	25/01/08	25/01/08	28/01/08
Mary Millen	18/12/07 to ward 3	03/01/08	03/02/08	04/02/08	03/02/08	06/02/08
Patient C	09/12/07 to ward 6	14/12/07	05/02/08	06/02/08	05/02/08	11/02/08
Alister Brand	18/12/07 from RAH to ward 5	30/12/07	07/02/08	unknown	07/02/08	12/02/08
Mary Hamilton	27/12/07 to ward 6	28/12/07	11/02/08	13/02/08	10/02/08	13/02/08
Jessie Jones	02/02/08 from RAH to ward F	02/02/08	unknown	18/02/08	16/02/08	20/02/08
Alister Brand	18/12/07 from RAH to ward 5	30/12/07	22/02/08	22/02/08	22/02/08	25/02/08
Patient C	09/12/07 to ward 6	14/12/07	25/02/08	25/02/08	25/02/08	28/02/08

Lack of ribotyping

As mentioned previously, because no investigations were made at the time, only potential outbreaks can be identified by the Inquiry. Such investigations would have included ribotyping, which is the most widely used technique for identifying different strains of *C. difficile*.

As Professor Duerden explained,³⁷ it is only by ribotyping that scientific proof can be obtained that patients who are closely linked in time and place are infected with the same strain of CDI, since there are a number of different strains of *C. difficile*, and two or more patients who have CDI may not necessarily have the same strain. This is explained more fully in Chapter 3. No investigations were carried out at the time into the cases of CDI that existed in the VOLH in the period from 1 January 2007 to May 2008, so no ribotyping was carried out which would have confirmed or negated the existence of a specific ribotype outbreak.³⁸ The Inquiry is restricted, therefore, to identifying where potential outbreaks occurred. Any potential outbreak should have nonetheless activated outbreak procedures.

When investigation did take place in May 2008 there were only isolates from 16 patients available for ribotyping. Testing of those revealed that 14 patients had ribotype 027, one patient had ribotype 078 and one had ribotype 106.³⁹ Professor Duerden was of the opinion that, because 14 of the 16 isolates that were later ribotyped were of the 027 strain, it was likely that the majority of the cases in the VOLH had been caused by the same strain of *C. difficile*.⁴⁰

The lack of response to the persisting CDI problem is discussed in Chapter 15.

The analysis of the Infection Control Database

As well as the information available to nursing staff and the Infection Control Team on the wards, there was additional information available to the Infection Control Team in their Infection Control Database. The database is discussed further in Chapter 15. The information on that database had been entered by the Infection Control Nurses at the VOLH, and was therefore known to them at the time it was entered.⁴¹ Mrs Perry carried out an analysis on behalf of the Inquiry⁴² based on the data stored on the Infection Control Database, and as presented by Mrs Perry they show that in the period from 1 January 2007 to 30 April 2008 there were a number of potential outbreaks in different wards at the VOLH which should:

“have prompted the initiation of outbreak actions whilst investigating if the cases were the same strain”.⁴³

It is to be noted that Mrs Perry was relying solely on the information contained in the Infection Control Database for this analysis. In particular she was relying on the accuracy of the description that the CDI was hospital acquired. The conclusion as to whether or not the infection was hospital acquired was arrived at by the Infection Control Nurse when she put the information into the database.

37 [TRA01050058](#)

38 [TRA01050058](#)

39 [INQ01660001](#)

40 [TRA01050059](#)

41 [INQ02970001](#)

42 [INQ03970001](#)

43 [INQ03970002](#)

5.5 Conclusion

The Inquiry's analysis of the patient records, Mrs Perry's analysis of the Infection Control Database, and Professor Robertson's statistical interpretation all support the conclusion that there were a number of occasions between 1 January 2007 and 1 June 2008 when at least two patients linked in time and place were suffering from CDI. **It is inconceivable that there were no outbreaks of CDI in the VOLH during that time.** Because no appropriate investigations were carried out into cases of CDI, it is impossible to say exactly when the outbreaks actually occurred. But it can be said with confidence that outbreaks did occur in 2007 and 2008.

If the outbreaks which clearly did occur in 2007 had been identified at the time, this would have raised the profile of CDI. The investigations required under the Outbreak Policy would have been put in place. It is reasonable to assume that the impact of the continuing problem that persisted, certainly to June 2008, would have been significantly reduced. Patients would not have continued to suffer the distressing and unpleasant consequences of infection. CDI would not have been a causal factor in so many deaths. Even if the cases of CDI in early 2008 had been properly investigated, that the impact of the infection in the VOLH would have been reduced. These omissions were serious failures.

Chapter 6

National structures and systems

Introduction

This Chapter looks at the national structures in place that formed an integral part of the National Health Service in Scotland in the period 1 January 2007 to 1 June 2008, as well as the systems in place during that period and the relevant developments since June 2008. It considers the role played by Scottish Ministers and other agencies in relation to health and the monitoring of healthcare associated infections, but with a particular focus on *C. difficile*.

6.1 Relevant parties and agencies

Duties of Scottish Ministers

Scottish Ministers have a duty under legislation¹ to promote the improvement of the physical and mental health of the people of Scotland. Scottish Ministers have a wide remit and may do anything which they consider is likely to assist in discharging that duty.² The Scottish Government (formerly known as the Scottish Executive) is the executive branch of government in Scotland.

Health Boards

It is through Health Boards that Scottish Ministers discharge many of their statutory functions relating to health. As at January 2007 there were 14 territorial Health Boards and a number of Special Health Boards. These Health Boards were also under a general statutory duty to promote the improvement of the physical and mental health of the people of Scotland.³ That general duty is linked to a duty of quality under which each Board has an obligation to put and keep in place arrangements for the purpose of monitoring and improving the quality of the healthcare it provides to individuals.⁴

Healthcare Improvement Scotland

Between January 2007 and June 2008 NHS Quality Improvement Scotland (NHS QIS) was a Special Health Board for the whole of Scotland. Its remit was to ensure the quality of healthcare provided by NHSScotland. On 1 April 2011 Healthcare Improvement Scotland (HIS) was created, with the general duty of furthering improvement in the quality of healthcare in Scotland, and on that date NHS QIS was dissolved,⁵ with all property rights and liabilities of NHS QIS being transferred to HIS.

NHSScotland

The Regional and Special Health Boards and HIS make up what is generally known as NHSScotland.

Common Services Agency

The Common Services Agency (CSA) was originally created by the National Health Services (Scotland) Act 1972,⁶ and retained under the National Health Services (Scotland) Act 1978.⁷ The CSA is now known as NHS National Services Scotland (NSS), providing strategic support services and expert advice to NHSScotland and in particular to NHS Boards. NSS is under a similar duty of quality to that of Boards⁸ and is accountable to the Scottish Government.⁹

Health Protection Scotland

Health Protection Scotland (HPS) is a division of NSS and is therefore accountable to NSS.¹⁰ HPS was established on 1 April 2005 to strengthen and co-ordinate health protection in Scotland.¹¹ The HPS remit also includes the provision of expert advice on policy development¹² and specific duties

1 National Health Service (Scotland) Act 1978 (c. 29), s. 1A(1) as inserted by the National Health Service Reform (Scotland) Act 2004 (asp 7), s. 9(1); S.S.I 2004/361, art. 2(c)

2 National Health Service (Scotland) Act 1978 (c. 29), s. 1A(2) as inserted by the National Health Service Reform (Scotland) Act 2004 (asp 7), s. 9(1); S.S.I 2004/361, art. 2(c)

3 National Health Service (Scotland) Act 1978 (c. 29), s. 2A as inserted by the National Health Service Reform (Scotland) Act 2004 (asp 7), s. 9(2); S.S.I 2004/361, art. 2(c)

4 National Health Service (Scotland) Act 1978 (c. 29), s. 12H as inserted by the Health Act 1999 (c. 8) s. 51; S.S.I 1999/90, art. 2(a), Sch. 1

5 National Health Service (Scotland) Act 1978 (c. 29), s. 10A(1) as inserted by the Public Services Reform (Scotland) Act 2010 (asp 8), ss.108, 134(7); S.S.I 2011/122, art. 2, Sch.

6 National Health Service (Scotland) Act 1972 (c. 58), s. 19(1)

7 National Health Service (Scotland) Act 1978 (c. 29), s. 10(1)

8 National Health Service (Scotland) Act 1978 (c. 29), s. 12H as inserted by the Health Act 1999 (c. 8), s. 51; S.S.I 1999/90, art. 2(a), Sch. 1

9 [TRA01090116](#)

10 [TRA01090116](#)

11 [TRA01090115-116](#)

12 [HPS02910003](#)

in relation to outbreaks,¹³ all set out in a Memorandum of Understanding in March 2007¹⁴ between the then Scottish Executive Health Department and HPS. HPS has about 110 staff with different fields of expertise, including consultant medical staff, consultant nurses, scientific staff and statisticians.¹⁵

HPS is divided into three main clinical groups. One of these is the healthcare associated infection, antimicrobial resistance, infection control and decontamination group,¹⁶ which in 2007 to 2008 was led by Professor Jacqui Reilly.¹⁷

Scottish Government Health Directorate

The Scottish Government Health Directorate (SGHD) provides the central management of the NHS in Scotland by way of a Management Executive that oversees the work of the Health Boards. The SGHD is also responsible for the development and implementation of policy in health and community care. The Cabinet Secretary for Health and Wellbeing is the Minister responsible for the SGHD.

In 2007 to 2008 Dr Kevin Woods was the Director General of the Health and Social Care Directorate within the Scottish Executive, later the Scottish Government. His role involved supporting and advising the Cabinet Secretary on NHS policy and putting the policy into effect. He was also the Chief Executive for NHSScotland, and as such led the central management of NHSScotland and was accountable to the Scottish Government for the performance of the service. Paul Martin, later Professor Martin, was the Chief Nursing Officer and Interim Director for Health Workforce, with responsibilities that included providing advice to Ministers on all matters relating to nursing, midwifery and allied health professionals. Professor Martin was the lead in the development and implementation of the Scottish Government Healthcare Associated Infection Action Plan.¹⁸

NHS Education for Scotland

NHS Education for Scotland (NES) was established on 1 April 2002.¹⁹ Its aim is to provide better patient care by designing, commissioning, quality assuring and, where appropriate, providing education, training and life-long learning to the NHS workforce in Scotland.

An example of the work of NES is its significant involvement²⁰ in the Scottish Executive Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection²¹ which was issued in May 2004. Its involvement in the section dealing with staff education in particular is clear. The statement that “HAI is everybody’s business”²² appears in that section of the report, and is repeated in other policy documents.

One of the key educational resources produced by NES was the Cleanliness Champions Programme, first launched in September 2003.²³ This Programme, which is explained in more detail in Chapter 15, is designed to provide education in the basic principles of prevention and control of infection.

6.2 Systems

Healthcare Associated Infection Task Force

The background and key recommendations of “The Watt Group report”²⁴ (a review of the outbreak of salmonella at the Victoria Infirmary, Glasgow, between December 2001 and January 2002) are explored in Chapter 7. The Watt Group report led to the creation of the Healthcare Associated Infection (HAI) Task Force in January 2003, following an announcement made by the then Minister for Health and Community Care in November 2002.²⁵ Its creation was a reflection at a policy level of an understanding of the growing challenges around HAI.²⁶ The Task

13 [HPS02910006-08](#)

14 [HPS02910001](#)

15 [TRA01090114](#)

16 [TRA01090117](#)

17 [TRA01090117](#); [TRA01090113](#)

18 [TRA01080063-64](#)

19 [NES00240006](#)

20 [NES00240009](#)

21 [GOV00090001](#)

22 [GOV00090008](#)

23 [NES00240010](#)

24 [GOV00130001](#)

25 [TRA01080062](#)

26 [TRA01080063](#)

Force was initially chaired by the Chief Medical Officer, and has been chaired since April 2005 by the Chief Nursing Officer. It is a multi-agency advisory body,²⁷ and is responsible for advising on the development and delivery of Scottish Government policy to minimise healthcare associated infections.

The membership of the Task Force is drawn from a wide range of expertise including medical directors, nurse directors and consultant microbiologists.²⁸ The relationship of HPS with the Task Force was characterised by Professor Martin as one in which HPS provided the “science”²⁹ for the work of the Task Force. At the time of its creation the intention was that the Task Force would carry out a three-year programme up to November 2005,³⁰ but it became evident that its work in the area of HAI should continue, and the then Minister for Health and Community Care agreed to that. The remit of the Task Force was altered, and the first meeting of a modified HAI Task Force took place on 20 March 2006.³¹

A second delivery plan was drawn up for the period April 2006 to March 2008.³² *C. difficile* infection (CDI) was identified as a priority in that plan, and HPS was charged with developing programmes for its reduction.³³ Professor Martin, Chief Nursing Officer at the time, recalled that there were references “specifically and directly to the actions around *C. difficile*”³⁴ at most Task Force meetings after this date.

The HAI Task Force report on the Scottish Executive’s two HAI programmes (“Action Plans”) between January 2003 and March 2008 was published in June 2008.³⁵ This document collated the outcomes from the two Action Plans and highlighted progress against particular actions.³⁶

A new HAI delivery plan³⁷ was developed in April 2011 and builds on earlier programmes. The current plan includes non-NHS care settings such as care homes. The plan also supports the Quality Strategy³⁸ of patient-centred, safe and effective care.

The Task Force relationship with Health Protection Scotland

Much of the HAI work of HPS is carried out in conjunction with the HAI Task Force. HPS and other members of the HAI Task Force propose project work to the Task Force.³⁹ Proposals are considered by the Task Force, and then discussed with the HAI Policy Team at Scottish Government level. In her evidence Professor Reilly used the introduction of the mandatory surveillance system for CDI on 1 September 2006 to illustrate the practical operation of this system.

The background to mandatory reporting

In 2004 and 2005⁴⁰ the emerging literature in medical journals raised awareness of the concern with CDI in hospitals. At that time Health Boards reported cases of CDI on a voluntary basis. Around 2004 there appeared to be about 4,500 cases of CDI across Scotland per year,⁴¹ and there were five CDI outbreaks in that year, three hospital related and the other two in care homes.

In 2004 the scale of the CDI problem had been recognised in England and mandatory reporting had been introduced.⁴² A protocol for a surveillance system for Scotland was developed in late 2004 and early 2005 and was included in the HAI Task Force programme of work in 2005. The protocol represented the advice of HPS that mandatory reporting should be introduced in Scotland.⁴³

The Task Force gave approval in principle in September 2005,⁴⁴ and a business case for funding the project was then submitted

27 [WTS01670002](#)

28 [TRA01080064](#)

29 [TRA01080065](#)

30 [WTS01670003](#)

31 [GOV01310001](#)

32 [GOV00150001](#)

33 [GOV00150008](#)

34 [TRA01080136](#)

35 [GOV00710052](#)

36 [TRA01080066](#)

37 [GOV01460001](#)

38 [GOV01460001](#)

39 [TRA01100121](#)

40 [TRA01090119](#)

41 [TRA01090119](#)

42 [TRA01090121](#)

43 [TRA01100121](#)

44 [TRA01100121](#)

by HPS to the HAI Task Force. Funding was approved by the Scottish Government in May 2006,⁴⁵ which enabled HPS to develop the surveillance protocol in July 2006.⁴⁶ In a letter⁴⁷ dated 10 July 2006 the then Scottish Executive Health Department gave notice to all Health Board Chief Executives that Health Boards had to have systems in place from July 2006 for collecting the CDI data, and that surveillance of CDI was to be mandatory from 1 September 2006.

Reporting of positive specimens

Since 1 September 2006 specimens of diarrhoea from patients aged 65 years or over in healthcare settings have to be tested for *C. difficile* toxin.⁴⁸ The results of all positive tests for *C. difficile* toxins have to be sent to HPS on a weekly basis.⁴⁹ The intention behind this system is the national surveillance of CDI in Scotland. It is also to look at the burden of CDI at a national level and to compare trends in the data over time and between Health Boards.⁵⁰ The system is not designed to monitor the prevalence of CDI in a particular hospital.⁵¹

The data collected are reported by HPS in its quarterly and annual reports by reference to each NHS Board.⁵² The first quarter for which data were available was October to December 2006.⁵³ In the quarterly report for the period January 2007 to March 2007⁵⁴ HPS concluded in its summary of CDI rates in Scotland that there had been a 50% increase in cases for that quarter (from 1,204 to 1,775) compared to the previous quarter. When hospital activity in both acute and non-acute hospitals was taken into account, this translated into a 29% increase in prevalence of disease.

From 1 April 2009 surveillance for CDI has included the collection of data for those aged 15 and above, rather than those over 65.

45 [TRA01100121](#)
 46 [GGC15380001](#)
 47 [GOV00430001](#)
 48 [GGC15380009](#)
 49 [TRA01090124](#)
 50 [TRA01090132-133](#)
 51 [TRA01090128](#)
 52 [TRA01100104](#)
 53 [HPS03090002](#)
 54 [HPS03090001](#)

The Scottish Salmonella, Shigella and *C. difficile* Reference Laboratory

The Scottish Salmonella, Shigella and *C. difficile* Reference Laboratory (the Reference Laboratory) was originally known as the Scottish Salmonella Laboratory and was based at Stobhill Hospital in Glasgow. The part of the Reference Laboratory that focuses on CDI opened in November 2007.⁵⁵ Previously this service had been provided by the Cardiff Anaerobic Laboratory in Wales, but such a service was required in Scotland because of the introduction of mandatory surveillance of CDI in September 2006. It was important to have a clear picture of the epidemiology of CDI in Scotland,⁵⁶ so the ribotyping of isolates had to be available to enable outbreaks to be identified and to allow for the identification of emerging strains. The Cardiff Laboratory did not have the capacity to type all such requests from Scotland.⁵⁷

The establishment of the Reference Laboratory was part of the HAI Task Force's 2005 to 2008 Programme.⁵⁸ Certain referral criteria have been devised for submitting isolates, including the suspicion that an outbreak may have occurred or that the infection is the 027 strain.⁵⁹

6.3 Accountability and monitoring

Meetings with the Cabinet Secretary

The Cabinet Secretary, accompanied by Dr Woods and senior officials, met with Health Board Chairpersons on a two-monthly basis.⁶⁰ Dr Woods gave an example of one such meeting that took place on 26 November 2007. Prior to that meeting the Cabinet Secretary had addressed a conference of medical and nursing directors on the subject of patient safety and HAI, and at the meeting with the Health Board Chairpersons the Cabinet Secretary took the opportunity of conveying to them the importance she attached to the management of HAI.⁶¹

55 [TRA01220004-05](#)
 56 [INQ04170003](#)
 57 [TRA01100122](#)
 58 [TRA01080063-65](#); [TRA01100132](#)
 59 [INQ04170009-10](#)
 60 [TRA00970075-76](#)
 61 [TRA00970077](#)

Meetings with Chief Executives

Dr Woods and senior officials, including the Chief Nursing Officer, also met with Health Board Chief Executives. At these meetings issues of particular importance to the Scottish Government would be discussed, including HAI.⁶²

Annual review process

The other main aspect of accountability at a senior management and government level was the annual review and associated meetings that took place each autumn. That review involved the Cabinet Secretary, Dr Woods and senior officials. It included meetings with professional leaders, with trade unions and with patients chosen by an independent body,⁶³ designed to inform the Cabinet Secretary and government officials of how well the particular Board was doing from the perspective of these different groups. Part of the time was also spent in public, discussing an agenda that focussed on issues that Scottish Ministers considered of particular importance⁶⁴ and the process concluded with a question and answer session during which members of the public had the opportunity to submit questions to the Cabinet Secretary and to the Health Board Chairpersons. Following the annual review, the Cabinet Secretary wrote to the Chairpersons of the Health Boards summarising the main points discussed and actions agreed.

Annual review 2007

Following the annual review in October 2007, the Cabinet Secretary recorded in a letter to the Chairman of NHS Greater Glasgow and Clyde (NHSGGC)⁶⁵ dated 13 November 2007 that:

“over the last year you had also completed the development of single system working across the Glasgow and Clyde area. This would ensure consistent infection control practice and enable more effective monitoring of performance”.⁶⁶

In his evidence Mr Robert Calderwood, currently Chief Executive, NHSGGC but then Chief Operating Officer, Acute Services, explained that:

“in relation to this particular paragraph in that letter, the annual review, it is my understanding that this was related to healthcare acquired infection and the work that the Board had taken forward to move to single system working for policies and procedures in this area”.⁶⁷

He accepted that at that time there was not a single system in place. That system did not come into place until after June 2008, when the problem with CDI at the VOLH had been recognised. He offered the explanation that the context of the reference in the Cabinet Secretary’s letter was “the infection control manual and the successful rollout of the manual across Greater Glasgow and Clyde”,⁶⁸ but this does not fit with the terms of the Cabinet Secretary’s letter, which clearly records that NHSGGC had completed the development of single system working within the context of effective monitoring.

Statement of internal control

The role of the Clinical Standards Board for Scotland (CSBS) is set out in Section 6.5. Its HAI standards, published in December 2001,⁶⁹ include standards of accountability within Health Boards, and Standard 1 in that section states:

“Responsibility for infection control is clearly defined and there are clear lines of accountability for infection control matters throughout the organisation”.⁷⁰

The standards also provided that the Chief Executive of each Health Board was responsible for ensuring a safe, effective and clean physical environment of care in healthcare facilities, and had to be able to account for the overall management of infection control.⁷¹ The Scottish Government⁷² expected this duty to be discharged by the

62 [TRA00970076](#)

63 [TRA00970073](#)

64 [TRA00970073](#)

65 [INQ00820001](#)

66 [INQ00820005](#)

67 [TRA01240055](#)

68 [TRA01240055](#)

69 [GOV00160001](#)

70 [GOV00160028](#)

71 [GOV00160028](#)

72 [TRA00970012](#)

Health Boards putting an effective process of clinical governance into place, and this is examined in Chapter 10. As part of the Scottish Government's annual auditing process of Health Boards, Chief Executives were required to sign a Statement of Internal Control⁷³ as part of the annual accounts to confirm that they had effective processes in place for clinical governance, including appropriate mechanisms in place for HAI.⁷⁴ There was no suggestion in the Statement of Internal Control for the year ending 31 March 2008, which formed part of the annual accounts for NHS GGC, that an effective system of clinical governance was not in place.⁷⁵ The Statement of Internal Control was signed by Mr Tom Divers, the Chief Executive, who was dependent upon information provided to him.

6.4 Health Improvement, Efficiency, Access and Treatment (HEAT) Targets and CDI guidance

Performance targets

Health Improvement, Efficiency, Access and Treatment (HEAT) Targets were performance targets set by the Scottish Government, and in 2007 and 2008 there were approximately 28 HEAT Targets that Health Boards were expected to meet.⁷⁶ Health Boards prepared local delivery plans that included their response to these HEAT Targets, and these delivery plans were submitted to Scottish Ministers for comment and approval.

MRSA

In November 2006 the Scottish Government announced a HEAT Target for *Staphylococcus aureus* bacteraemia (including MRSA and MSSA) of an overall 30% reduction in Scotland. This was to be achieved by 2010, and the reduction figures were to be compared with the levels that were in place from 2005 to 2006.⁷⁷ That target was in fact reached by September 2009, and the trend has continued to be a downward one.⁷⁸

Health Boards were expected to meet the target by having in place effective infection prevention and control methods. This included ensuring that there was local compliance with good practice through their infection prevention and control systems from Board to ward and ward to Board.⁷⁹

There was no dispute in the evidence that there was no HEAT Target for CDI in 2007 and 2008. Professor Martin said in evidence that *C. difficile* was not included as a HEAT Target because in the context of the HEAT Target system it was not then considered to be a "priority"⁸⁰. Dr Woods explained that HEAT Targets were chosen because the Scottish Government wanted there to be a quantitative measure of judging the effectiveness of policy being put into practice in "priority areas".⁸¹ Professor Martin did expect that introducing MRSA as a HEAT Target would have a positive impact on infection prevention and control generally,⁸² and Dr Woods expressed a similar view.⁸³

Reporting of HEAT Target rates

Ms Marie Martin, General Manager, Diagnostics for Clyde, explained how the reporting of MRSA rates was carried out in practice within the Clyde Directorate.⁸⁴ She reported the rates on a quarterly basis to Mrs Deb den Herder, Director, Clyde Acute Services. This information was reviewed by Mr Calderwood,⁸⁵ who reported through NHS GGC to the Scottish Government to enable the HEAT Target to be monitored. Ms Martin suggested that CDI should probably have been included in this system of reporting, but, as Mr Calderwood explained, the CDI rates were not reported in that way because CDI was not then a HEAT Target.⁸⁶

CDI as a HEAT Target

Following on from the report of the Independent Review chaired by Professor William Cairns Smith, Professor of Public Health at the University of Aberdeen, into

73 [TRA01080149](#)

74 [TRA01080150](#)

75 [GGC31970017](#)

76 [TRA01250041-42](#); [WTS00880001](#)

77 [TRA01090039](#)

78 [TRA00980136](#)

79 [TRA01090039](#)

80 [TRA01090042](#)

81 [TRA00970079](#)

82 [TRA01090040-41](#)

83 [TRA00970079-81](#)

84 [TRA01160096-97](#)

85 [TRA01240068-69](#)

86 [TRA01240069-71](#)

CDI at the VOLH between December 2007 and June 2008,⁸⁷ published in August 2008, the Scottish Government set a HEAT Target for CDI in 2009. The target was a reduction of CDI rates of at least 30% by 2011.

Had CDI been a HEAT Target in 2007 and 2008, information relating to the rates of CDI would have been reported in the same manner as rates of MRSA.⁸⁸ That is not, however, to say that any reporting of CDI rates as part of the HEAT Target would have revealed the CDI problem at the VOLH. The HEAT Target system was not designed to be an HAI surveillance system or to replace adequate surveillance systems by NHSGGC. The inclusion of CDI in the HEAT Target might nevertheless have raised awareness of and increased the priority given to the infection.

6.5 The review system

Introduction

The Clinical Standards Board for Scotland (CSBS) was established as a Special Health Board in April 1999. Its remit was to develop and run a national system of quality assurance of clinical services, with the aim of promoting public confidence in NHSScotland.⁸⁹

The standards

Following concern about the rise in the rate of healthcare associated infection, the then Scottish Executive Health Department set up a Working Group⁹⁰ in November 2000, chaired by Mr Richard Carey, Chief Executive of Highland Acute Hospitals NHS Trust. The aim of the Group was to provide guidance to NHSScotland on assessing and managing risks relating to HAI, and its report is considered in more detail in Chapter 7. Following on from the report⁹¹ of the Carey Group of April 2001, in June 2001 the CSBS established the HAI Reference Group⁹² under the Chairmanship of Dr David Old. Its remit was to build upon the work carried out by the Carey Group and finalise HAI related standards.

Following extensive consultation, CSBS first published its standards for HAI Infection Control in December 2001.⁹³ At the heart of the document was an overarching standard to ensure that the risk of infection is controlled.⁹⁴

The 15 standards covered all aspects of infection control and included:

- Accountability at different levels within an NHS Trust
- Processes for planning and development
- Infection Control Programme
- Policies, procedures and guidance/guidelines
- Microbiology services
- Surveillance
- Infection Control report
- Legislation and guidance
- Education
- Monitoring and review
- Internal audit
- Hand hygiene

A revision of these standards was published in March 2008.⁹⁵ The main aims of the standards were to ensure that Trusts and Boards could and did comply with their statutory duty of quality,⁹⁶ and to have in place “a managed environment which minimised the risk of infection to patients, staff and visitors”.⁹⁷

The review process

Following the publication of the standards, CSBS undertook a process of review of all Trusts and Boards. Trusts and Boards were invited to submit self-assessments on how well they were performing against the standards, and thereafter CSBS carried out “peer review” visits⁹⁸ to validate and expand upon the information provided in the self-assessment process. It is important to note that this was not an inspection regime of

87 [GOV00030001](#)

88 [TRA01240068-69](#)

89 [INQ03760005](#)

90 [GOV00160013](#)

91 [GOV00010001](#)

92 [GOV00160015](#)

93 [GOV00160001](#)

94 [GOV00160017](#)

95 [INQ00840001](#)

96 [TRA00970010](#)

97 [GOV00160017](#); [INQ03760009](#)

98 [INQ03760009](#)

individual hospitals. The visit to the Trust or Board involved meeting key personnel of the service under review and speaking with local stakeholders about the services provided, as well as including a visit to ward and departmental areas to learn how infection prevention and control measures were being adopted into clinical practice.⁹⁹

Review of Argyll and Clyde

The operation of this review process can be seen from the way the then Argyll and Clyde Acute Hospitals NHS Trust was reviewed. A review visit took place on 3 July 2002,¹⁰⁰ at which time there were four hospital sites within the Trust:

- Inverclyde Royal Hospital, Greenock
- Lorn and Islands District General Hospital, Oban
- Royal Alexandria Hospital, Paisley
- Vale of Leven District General Hospital, Dumbarton.

Of these, the Review Team only visited a high dependency/intensive therapy unit and a surgical ward, both of them at Inverclyde Royal Hospital.¹⁰¹

In 2002 the Review Team found that the Trust met 24 out of 69 criteria.¹⁰² Of the remaining 45 criteria, 42 were not met and three were “not met (insufficient evidence)”.¹⁰³ Following an update review on 12 May 2004,¹⁰⁴ which involved consideration of a submission made by the Trust, a further three criteria were met. The Trust therefore met 27 out of 69 criteria. No further reviews or assessments took place prior to June 2008.

National overview

In January 2003 CSBS (by then subsumed under NHS QIS)¹⁰⁵ published a National Overview reporting on performance across Scotland against the standards. A number

of key recommendations were made in relation to accountability, infrastructure, monitoring, review and audit. That National Overview concluded that “the real challenge for NHSScotland is to introduce a culture of surveillance and vigilance.”¹⁰⁶

6.6 Healthcare Environment Inspectorate

A planned new approach to scrutiny

In the aftermath of the discovery of the CDI problem at the VOLH the Cabinet Secretary had a number of meetings with families, some attended by Dr Woods.¹⁰⁷ A number of those present made clear to the Cabinet Secretary their view that there needed to be an inspectorate in place¹⁰⁸ which could independently review the actions being taken in hospitals.

Following the publication in August 2008 of the report of the Independent Review, the Scottish Government concluded that, in the context of infection prevention and control, the “quality of the care environment and the application of hygiene and cleanliness standards”¹⁰⁹ required a particular focus. The Cabinet Secretary wanted to put in place a:

“more transparent process of external assurance that will provide reports to the public that the care environment is clean and safe and that processes are in place to prevent, detect and tackle HAI”.¹¹⁰

The Scottish Government Healthcare Policy and Strategy Directorate issued a consultation paper¹¹¹ on 11 November 2008 setting out proposals for the role of the Healthcare Environment Inspectorate (HEI). In this paper the Scottish Government recognised that the “disaggregated nature of the existing approaches”¹¹² did not provide the appropriate level of scrutiny and coherence.

99 [INQ03760087-89](#)

100 [QIS00440016](#)

101 [QIS00440016](#)

102 [QIS00020004](#)

103 [QIS00020004](#)

104 [QIS00020003-04](#)

105 [INQ03760001](#)

106 [INQ03760013](#)

107 [TRA00970104](#)

108 [TRA00970104-105](#)

109 [GOV01010002](#)

110 [GGC16330003](#)

111 [GOV01010001](#)

112 [GOV01010002](#)

A relative's perspective

The first relative to give oral evidence to the Inquiry was a member of the teaching profession. She drew a powerful comparison between the inspection regime faced on the one hand by schools and by care homes, and on the other hand by hospitals.¹¹³ She was able to download from the internet an Inspection report for the local primary school and a local care home. She could access an Inspection report on the VOLH tea bar. She was also able to access the CSBS report of 2002 and the subsequent review, and was “devastated”¹¹⁴ to see that so large a number of standards continued to be described as “not met”.¹¹⁵ Her view was that it was “shocking”¹¹⁶ that a “robust inspection process”¹¹⁷ had not been in place.

Healthcare Environment Inspectorate methodology

The Healthcare Environment Inspectorate (HEI) was established in April 2009¹¹⁸ and was based within NHS QIS, which later became HIS.¹¹⁹ As the HEI Inspection Methodology¹²⁰ discloses, the HEI was to undertake at least one unannounced inspection of all acute hospitals across NHSScotland every three years. Its focus was to reduce the HAI risk to patients through a “rigorous inspection framework”.¹²¹ The aims of the HEI are described as follows:

- To provide public assurance and protection
- To restore public trust and confidence
- To contribute to the prevention and control of HAI
- To contribute to improvement in the healthcare environment including infection control, cleanliness and hygiene, and the broader quality improvement agenda across NHSScotland

An important aspect of the HEI's strategy is the use of an open and transparent method

for inspecting hospitals and the publication of inspection results on its website.

In her evidence¹²² Mrs Susan Brimelow, Chief Inspector for HEI, explained that the HEI was independent of the Scottish Government and of the Health Boards.¹²³ HEI is, however, part of HIS and is not an independent body in the strict sense.

Use of standards

Mrs Brimelow provided some insight into the standards against which hospitals were measured, namely the “Standards - March 2008, Healthcare Associated Infection (HAI)”¹²⁴ published in March 2008. By way of example, standard 3 provides as follows:

“The NHS Board has policies, procedures and guidelines which create a healthcare environment that minimises the risk of infection to patients, visitors and staff, and are based on evidence, best practice and expert opinion”.¹²⁵

Unannounced inspection

Mrs Brimelow explained that an unannounced inspection was one where no notice is given of the proposed inspection. Instead the Inspection Team arrive at the hospital and inform the site manager¹²⁶ that they are there to carry out an inspection. Both announced and unannounced inspections generally took two days to complete but could take longer depending on circumstances.¹²⁷

After the inspection process

Once initial feedback is given by the Inspectors, the Health Board must begin drafting a healthcare improvement plan to address the issues raised. Once the Inspection report is made available to the Health Board, the improvement plan addressing the recommendations made must be developed.¹²⁸ Mrs Brimelow saw this as a very important part¹²⁹ of the process. There

113 [TRA00010080-81](#)

114 [TRA00010083](#)

115 [QIS00020004](#)

116 [TRA00010084](#)

117 [TRA00010084](#)

118 [INQ00880002](#); [TRA01090059](#)

119 [TRA01090058](#)

120 [INQ00880001](#)

121 [INQ00880002](#)

122 [TRA01090058](#)

123 [TRA01090058](#)

124 [INQ00840001](#)

125 [INQ00840014](#)

126 [TRA01090061-62](#)

127 [TRA01090063](#)

128 [TRA01090069](#)

129 [TRA01090069](#)

is then a follow-up process where, 16 weeks after the inspection, and often less than 16 weeks,¹³⁰ the HEI ask the Health Board to disclose what progress has been made. The Inspection report itself is published within six to eight weeks following the inspection, and can be accessed by the public on the HEI website.

Where issues require immediate attention, Mrs Brimelow explained that such issues are often addressed before the Inspection Team leave the hospital in question.¹³¹ A draft Inspection report is made available to the

Chief Executive of the Health Board within four weeks. This is designed to produce a system of “real-time reporting”.¹³²

Healthcare Environment Inspectorate powers

The HEI’s powers include an “escalation” process.¹³³ Table 6.1 sets out the different levels involved. Level 1 is the least serious and level 4 is the most serious. Mrs Brimelow said that it had been necessary in the past to invoke level 1, but level 4 had never been invoked. Between each level there would be ongoing dialogue with the NHS Board.

Table 6.1 HEI Inspection methodology

Level	Issue	Action
1	Improvement Action Plans are not taken forward within the required timeframes.	Regional Inspector will arrange to meet senior staff from the NHS Board with warning of further action.
2	Improvement Action Plans are inadequate and/or not produced within the required timeframe.	Formal written warning of non-compliance sent to NHS Board from Regional Inspector with timeline for resolution, procedure for escalation and sanctions. This document will be publicly available. Chief Inspector informs HIS Board of significant concerns.
3	Improvement Action Plans are not taken forward and this poses a threat to patient safety and public health.	Letter of non-compliance sent by Chief Inspector to the Scottish Government and Cabinet Secretary for Health and Wellbeing supported by requirements for action. This document will be publicly available. The Scottish Government issues a warning to NHS Board with a timeline for resolution.
4	Serious issue identified during inspection.	Formal letter from Chief Inspector, including supporting evidence, sent to the Scottish Government outlining recommendations for action.

130 [TRA01090070-71](#)

131 [TRA01090070-71](#)

132 [TRA01090071](#)

133 [TRA01090067](#); [TRA01090071](#); [INQ00880008](#)

Scope of the inspection regime

An important aspect of the inspection regime is the fact that the inspections are not simply concerned with infection control systems. They inspect patient care and in particular the care being given to patients suffering from an HAI. The medical records are examined to check if appropriate care plans are in place. In the case of a patient suffering from CDI the Inspectors check, for example, to see if a stool chart is being maintained.

The Inspectors also examine the medical records to satisfy themselves about antimicrobial stewardship.¹³⁴ They do not make clinical judgements about whether an antibiotic should or should not have been prescribed, but they do check to see if antibiotics are being managed appropriately.

In so far as systems are concerned, the Inspectors check to see if appropriate inspection systems are in place.

The aspects of the inspection process referred to in the previous three paragraphs are of particular relevance to the manner in which patients suffering with CDI were managed in the VOLH in the period 1 January 2007 to 1 June 2008. As discussed in Chapter 12, an examination of the records of patients who suffered from CDI in the period 1 December 2007 to 1 June 2008, as well as of the records available for the period 1 January 2007 to 30 November 2007, disclosed significant failures in the keeping of written care plans and stool charts.

Between the first inspection on 29 September 2009 and Mrs Brimelow giving evidence to the Inquiry on 22 May 2012 HEI had carried out 101 inspections. Of these, 46 were announced inspections and 43 were unannounced inspections. The remaining 12 had been follow-up inspections, the majority of which were unannounced.¹³⁵

The VOLH influence

Mrs Brimelow explained how what happened at the VOLH influenced the methodology adopted by HEI during inspections.¹³⁶ She had read the transcripts of the evidence given to the Inquiry by patients and families in order to see what their issues were and what their experiences had been, either as patients or as visitors to the VOLH. This resulted in the Inspection Team putting on a “patient’s lens”¹³⁷ when they carried out hospital inspections.

The VOLH inspections

HEI first inspected the VOLH on 10 and 11 August 2011. That was an announced inspection. The report¹³⁸ of that inspection discloses that staff were complying with the relevant HAI standards. Having regard to the evidence gathered by the Inquiry referred to in other Chapters of this Report, had such an inspection been carried out in the period 1 January 2007 to 1 June 2008 the conclusions would have been markedly different.

An unannounced inspection¹³⁹ of the VOLH by HEI took place on 7 June 2012. Overall the Inspection Team found evidence that NHSGGC was complying with the “majority of NHS QIS HAI standards to protect patients, staff and visitors from the risk of acquiring an infection.”¹⁴⁰ The hospital was generally found to be clean and well maintained, and education in infection prevention and control was being well promoted. The inspection did make two requirements that NHSGGC had to comply with, one relating to hand hygiene, where NHSGGC was required to:

“ensure that all staff and volunteers comply at all times with national guidance relating to hand hygiene. This will reduce the risk of infections and cross contamination for patients and the public”.¹⁴¹

Two of the instances giving rise to this requirement were the failure of three doctors

134 [TRA01090073-74](#)

135 [TRA01090082](#)

136 [TRA01090084](#)

137 [TRA01090084](#)

138 [GGC30680001](#)

139 [INQ04450001](#)

140 [INQ04450006](#)

141 [INQ04450012](#)

to practise hand hygiene during a ward round on Lomond ward and the failure of nursing staff in Lomond ward and ward 6 to practise hand hygiene following contact with patients or their environment.¹⁴² NHSGGC was presented with an Improvement Action Plan¹⁴³ containing a specified timescale during which the actions planned were to be met.

Sanctions

The HEI regime does not have an enforcement process of the kind found in other inspection regimes such as the inspection regime employed by the Care Inspectorate (formerly the Care Commission). Under the legislation¹⁴⁴ governing that regime, an improvement notice enforcement procedure can be invoked. Mrs Brimelow did not consider that such an enforcement process was necessary, since experience had shown that when HEI had published reports expressing concern the Scottish Government had acted swiftly in response.

The one area where Mrs Brimelow considered that HEI powers could be improved was if she had the power to stop admissions to a ward.¹⁴⁵ There had been instances where she had concern about the risks to patients and in those circumstances such a power might have been useful to her.

6.7 Conclusion

CDI HEAT target

CDI was only made the subject of a HEAT Target in the aftermath of the discovery of the problem with CDI at the VOLH. To have had this in place from 1 January 2007 to 1 June 2008, it would have been necessary to have adequate data available for comparative purposes, but as discussed earlier in this Chapter the system for mandatory surveillance did not come into operation until September 2006. There was no evidence that in the period prior to 1 June 2008 any consideration was being given to

making CDI a HEAT Target, but in any event only one annual report on the incidence of CDI following upon the introduction of mandatory surveillance was available at that stage. The introduction of CDI as a HEAT Target in 2009 was an appropriate and timely response by the Scottish Government to the disclosure in June 2008 of the CDI problem at the VOLH.

Monitoring

Dr Woods observed that:

“in something as large and complex as the National Health Service there is a limit to what the central administration ... can actually actively monitor day to day”.¹⁴⁶

That is obviously correct. He maintained that a clear message¹⁴⁷ on the importance placed upon combating HAI had been sent to Health Boards. This was a message that had been repeated over and over again because of the importance attached to it. The monitoring that included the annual review process did provide the SGHD with some comfort that appropriate systems were in place for infection prevention and control. Nevertheless, as the Cabinet Secretary's letter¹⁴⁸ of 13 November 2007 disclosed, there was scope for misunderstanding and confusion, for the development of single system working had not been completed across NHSGGC by then.

Although the process or review undertaken by CSBS included an investigatory element, it was not an inspection system. Nonetheless that process did disclose significant failures in infection prevention and control within the Argyll and Clyde Trust in July 2002 against the standards in force at the time. In the main those failures remained unaddressed at the time of the follow-up review in May 2004,¹⁴⁹ almost two years later. Furthermore, as the National Overview report:¹⁵⁰ “Improving Clinical Care in Scotland” discloses, there were significant deficiencies in infection prevention and control in Health Boards

142 [INQ04450008](#)

143 [INQ04450021](#)

144 Regulation of Care (Scotland) Act 2001 (asp 8), s. 10; Public Services Reform (Scotland) Act 2010 (asp 8), s. 62(1)

145 [TRA01090084](#)

146 [TRA00970133](#)

147 [TRA00970069](#)

148 [INQ00820001](#)

149 [QIS0020004](#)

150 [INQ03760001](#)

throughout Scotland. It could be argued that that in itself it should have prompted a more proactive response.

As discussed in Chapter 7, since devolution the SGHD and other agencies have produced a significant amount of policies, instruction and guidelines to Health Boards on HAI, including guidelines on the use of antibiotics. It was the increasing rates of CDI that prompted the introduction of Scotland's national surveillance programme. Professor Martin maintained that CDI "was at the forefront of the thinking of the Task Force"¹⁵¹ in 2006. Against that background, and given the importance placed on HAI in healthcare premises by the Scottish Government and other agencies, consideration needs to be given to whether a regime such as the HEI regime should have been introduced earlier in Scotland.

In September 2007 the Crerar Review on "Regulation, Audit, Inspection and Complaints Handling of Public Services in Scotland"¹⁵² was published. This had been commissioned as part of wider public service reform. It described the core purpose of external scrutiny as including the provision of an "independent assurance that services are well-managed, safe and fit-for-purpose."¹⁵³ The principles of external scrutiny should include independence and transparency. Furthermore, despite the primary responsibility for improvement resting with the Health Board, external scrutiny is seen as a catalyst for improvement by influencing behaviour and culture.¹⁵⁴

In his evidence Professor Martin said that the lack of an inspection system prior to the creation of HEI was "probably a weakness in the system that the Inspectorate has helped to fill".¹⁵⁵ Dr Woods acknowledged that the HEI could have been put in place at any time in the preceding ten years.¹⁵⁶ He explained that the route adopted in Scotland in relation to quality improvement was built on setting

standards, promoting professional review, peer review analysis, the construction of professional consensus and the clinical governance processes developed by Health Boards. The position was different in England and Wales where, since 2001 by virtue of the Health Act 1999¹⁵⁷ and subsequent legislation,¹⁵⁸ there had been a body with an inspection function (now the Care Quality Commission).

Dr Woods was correct in pointing out that despite the existence of an inspectorate in England significant outbreaks of CDI still occurred. These include Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust (2004 and 2005)¹⁵⁹ and Maidstone and Tunbridge Wells (2005 to 2006).¹⁶⁰

Nevertheless, it is regrettable that an effective inspectorate system had not been put in place prior to 1 June 2008. Indeed it is surprising, against the background already noted of how seriously HAI was regarded, that an inspection regime of that kind was not created. This represents a failure on the part of the Scottish Government. There is a real possibility that, if an effective regime of the kind now in place had existed in the period 1 January 2007 to 1 June 2008, the scale of the CDI problem that developed would have been significantly reduced. Its creation would almost certainly have raised awareness of HAI throughout Scotland. If an inspection had been carried out during that period, and the position had been as discovered by the Inquiry, the VOLH would have been subjected to serious criticism and a speedy response from NHSGGC would have been necessary. The swift response in setting up the HEI in the aftermath of the discovery of the problem with CDI at the VOLH was highly appropriate.

The Inquiry does consider that it is vital that there is an effective independent body responsible for hospital inspection and monitoring of standards. As already noted,

151 [TRA01090042](#)

152 [INQ04520001](#)

153 [INQ04520013](#)

154 [INQ04520028](#)

155 [TRA01080148](#)

156 [TRA00970107](#)

157 1999 (c. 8), ss. 19-23, Schedule 2

158 Health and Social Care (Community Health and Standards) Act 2003 (c. 43) and the Health and Social Care Act 2008 (c. 14)

159 [INQ02890001](#)

160 [INQ02870001](#)

the HEI is not a truly independent body, but it is clear that it operates in an independent and transparent way. The Inquiry does not see any need to make any recommendations on the status of the HEI.

It is important that an organisation such as the HEI is given appropriate powers to take proactive action to protect patient safety. Considerable pressure exists on staff and managers within hospitals not to close wards to admissions if they can avoid doing so. The Inquiry recommends that the powers of the HEI should be extended to include a power to close a ward to admissions, following discussion with those on site, if there is a real risk to the safety of patients.

6.8 Recommendations

Recommendation 1: Scottish Government should ensure that the Healthcare Environment Inspectorate (HEI) has the power to close a ward to new admissions if the HEI concludes that there is a real risk to the safety of patients. In the event of such closure, an urgent action plan should be devised with the Infection Prevention and Control Team and management.

Chapter 7

National policies and guidance

Introduction

This Chapter examines some aspects of the national policies and guidance on healthcare associated infection (HAI) in place prior to 1 January 2007. It also reviews aspects of the policies and guidance developed since June 2008 in response to events at the Vale of Leven Hospital (VOLH). The Chapter looks at whether the guidance at the time was generally adequate, and specifically whether there were failures in the provision and implementation of *C. difficile* guidance. Other policy issues are considered in Chapters in which they have particular relevance.

7.1 National guidance on the prevention and control of *C. difficile* before 2008

Background

Concern about the prevention and control of infection is not new. Infection prevention and control was high profile and on the policy agenda for some years prior to the VOLH outbreak. In 1997 to 1998 the House of Lords Select Committee on Science and Technology published a report entitled “Resistance to Antibiotics and other Antimicrobial Agents”.¹ This contained a clear message that infection control should be central to the day to day running of hospitals:

“purchasers and commissioning agencies should put infection control and basic hygiene where they belong, at the heart of good hospital management and practice, and should direct resources accordingly”.²

The “Scottish Infection Manual”,³ produced by the Scottish Office Department of Health Advisory Group on Infection and published in July 1998, set out the roles and responsibilities of Health Boards, Trusts, hospitals and other healthcare providers in relation to infection control. Under reference to the Select Committee, the Manual reinforced the message that infection control should be at the heart of hospital management.

The Scottish Office Department of Health responded to the Select Committee report by issuing a letter to Health Boards and Trusts in May 1999.⁴ In the letter the NHS in Scotland made a commitment to taking action to reduce the emergence and spread of antimicrobial resistance. This was to be achieved through:

- Strengthening infection control processes
- More effective antimicrobial prescribing
- Improving data and surveillance of resistant organisms and antimicrobial usage

The Carey report

In April 2001 a Joint Scottish Executive Health Department (SEHD) and NHSScotland Working Group, chaired by Richard Carey, Chief Executive of the Highland Acute Services NHS Trust, published a report entitled “Managing the Risk of Healthcare Associated Infection in NHSScotland”. Known as the Carey report,⁵ it recommended that there should be a common approach to managing the risk of HAI at local and national level, and that the risk management of HAI should be based on the Australian/New Zealand 4360:1999 model, which is outlined in Figure 7.1.⁶ There are six interrelated processes which involve:

1. Communicating and consulting with relevant stakeholders on risks and related matters
2. Establishing the context for risk management
3. Identifying potential hazards
4. Assessing risks
5. Treating risks
6. Monitoring and reviewing the quality and effectiveness of risk management

1 [INQ04790001](#)

2 [INQ04790067-68](#)

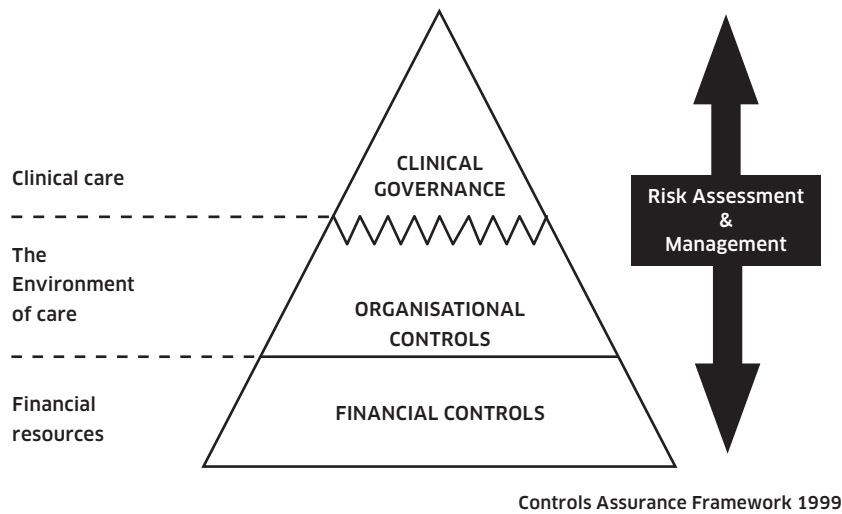
3 [GOV00940001](#)

4 [INQ04540001](#)

5 [GOV00010001](#)

6 [GOV00010015](#)

Figure 7.1 Australian/New Zealand 4360:1999 model



The Carey report recommended that NHSScotland should promote a culture which encourages openness and the sharing of information on risk. It also identified the need for NHS Trusts to review their Infection Control Teams to ensure that they could monitor the risk management of HAI and assess their performance against the standards. In June 2001 the Scottish Executive wrote to all NHS Trusts and the Clinical Standards Board for Scotland (CSBS) requiring them to implement the report's recommendations.⁷

Towards the end of 2004, the HAI Task Force produced a consultation document called "The Risk Management of HAI: a Proposed Methodology for NHSScotland".⁸ The risk based methodology was piloted in NHSScotland under the direction of Health Protection Scotland (HPS) to test how applicable the methodology was and how easy it was to use. The final document was amended as a result of the consultation and the pilot phase. "The Risk Management of HAI: A Methodology for NHSScotland" was then published in November 2008.⁹

The approach of NHS Greater Glasgow and Clyde (NHSGGC) to the risk management of HAI is considered in Chapter 10.

The Watt Group report and Ministerial Action Plan

The Watt Group report has been referred to in Chapter 6. Established following an outbreak of salmonella infection at the Victoria Infirmary in Glasgow in late 2001 and early 2002, the Watt Group had as its remit to make recommendations to help reduce the risk of further outbreaks and to improve the management of such outbreaks. The group, chaired by Dr Brian Watt, a retired Consultant Microbiologist, published its report in 2002, and made 47 recommendations which the Group urged the then Scottish Executive to implement as a whole.¹⁰

A key recommendation was the adoption of a common classification system for outbreaks to be used in deciding the action and communication required during an infection incident. The Watt Group report contains a risk matrix,¹¹ which is a colour-coded method for determining how significant the risk is, and is still in use today. The risks range from high risk to very low risk. Table 7.1 shows a simplified version of the risk matrix.

7 [GOV00060001](#)

8 [INQ03820004](#)

9 [INQ03930001](#)

10 [GOV00130001](#)

11 [GOV00130044](#)

Table 7.1 The risk matrix

	Risk category	Action required	Communications
	Red – High Risk	Implement a Board major incident or outbreak plan	Full communications Scottish Government, HPS and other national bodies
	Orange – Moderate Risk	Implement a Board incident or outbreak plan	Full communications Scottish Government, HPS and other national bodies
	Yellow – Low Risk	Implement a Board incident or outbreak plan	Health Board communications, Scottish Government, HPS
	Green – Very Low Risk	Investigation and monitoring by Infection Control Team	Health Board communications

In response to the Watt Group report, the SEHD published a Ministerial Action Plan.¹² This included the conclusions from the Watt Group report as well as recommendations from an HAI Convention held in Edinburgh in June 2002. The Action Plan: “Preventing Infections Acquired while Receiving Healthcare” was published in October 2002 to cover the period 2002 to 2005.¹³ The newly created Task Force, which is discussed in Chapter 6, was to be led by the Chief Medical Officer and would oversee the implementation of the Watt Group recommendations. Health Boards were asked to consider as a matter of priority how they would best implement these.¹⁴

NHSScotland Code of Practice

One of the first publications of the HAI Task Force, in 2004, was “The NHSScotland Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection”.¹⁵ The Code of Practice includes the following guidance:

“Service users, staff and visitors have a right to, and expect, a safe physical healthcare environment. Key to ensuring this safety at all times is cleanliness of the facilities where healthcare is delivered”.¹⁶

The responsibility of all staff in delivering the Code of Practice is emphasised. Specific responsibilities are outlined for the Infection Control Team, Infection Control Committee, Risk Management Committee and the Senior Manager with overall responsibility for infection control. Professor Martin, Chief Nursing Officer in the Scottish Government, described the Code as the “foundation of modern policy, in terms of the management of HAI in Scotland”.¹⁷

Cleaning

Thorough cleaning and good maintenance of the hospital environment are vital in preventing infection and in controlling the spread of infection where it does occur. A number of policy and guidance documents on cleaning have been made available to NHS Boards over recent years.

In April 2000, Audit Scotland published “A Clean Bill of Health? – A review of domestic services in Scottish hospitals”.¹⁸ This made a number of recommendations on improving cleaning in Scottish hospitals, and highlighted the important role which domestic services play in infection control. CSBS (now Healthcare Improvement Scotland (HIS)) produced standards in cleaning services in June 2002.¹⁹ Audit Scotland then published a follow-up review of cleaning services,

12 [GOV00100001](#)
 13 [GOV00100001](#)
 14 [GOV00070001-02](#)
 15 [GOV00090001](#)
 16 [GOV00090019](#)

17 [TRA01080069](#)
 18 [INQ05160001](#)
 19 [INQ05190001](#)

including performance against the CSBS cleaning standards, in 2003.²⁰

The “NHSScotland National Cleaning Services Specification”²¹ was published in 2004 and set out requirements for:

- Performance management including daily service monitoring
- Staff training and development
- Cleaning services specifications which are detailed descriptions of tasks and quality standards for each area

The Specification was updated in 2009 and included colour coding to indicate what cleaning equipment should be used.²² NHSScotland also published a second version of the monitoring framework for the National Cleaning Services Specification in February 2007,²³ which provided a standard template for the review of systems, policies and procedures.

The Cleanliness Champions Programme

The Cleanliness Champions Programme (CCP) mentioned in Chapter 6 was an important feature of the HAI Task Force. Developed by NHS National Education for Scotland (NES), with expert advice from HPS on the content of the programme,²⁴ it was launched in September 2003 as part of the first HAI Task Force Action Plan.²⁵ It was designed to provide education in the basic principles of infection prevention and control. Hand hygiene was at the heart of the Programme.²⁶

As Professor Martin recalled in his evidence, the SEHD wanted to create a group of staff who were not necessarily clinical or infection control qualified staff:

“They needed to be staff who were willing to participate in the Cleanliness Champions training and to take on the role about promoting good practice and challenging poor practice in and around the health systems”.²⁷

In August 2004, the SEHD introduced a “Framework for Mandatory Induction Training in HAI for NHSScotland”.²⁸ This was designed to complement and strengthen a range of initiatives such as the work of the HAI Cleanliness Champions. The following year, SEHD considered that it would be a good leadership example if all G grade staff (ward sister/charge nurse) were also trained as Cleanliness Champions.²⁹ The Chief Nursing Officer therefore issued a letter dated 18 March 2005 requiring that all G grade nurses undertake the CCP.³⁰ The SEHD later offered funding to Health Boards of £200 for each Cleanliness Champion trained between November 2005 and March 2006. Professor Martin explained that the additional funding was to encourage Health Boards to progress staff through the training rather than use staffing issues as an excuse for not implementing the programme.³¹

It is a computer based programme which when introduced consisted of 11 separate units, including units on “The Chain of Infection” and “the Importance of Hand Hygiene”.³² The programme’s two main themes are safe practice and safe environment.³³ The online learning period was expected to take approximately 16 - 20 hours, and the CCP could be completed in around 16 weeks. Some changes to the programme have been introduced in the current version (version 3).³⁴

Cleanliness Champions Co-ordinators were also created in each Health Board area. They were responsible for driving forward the delivery of the training and ensuring that there were adequate numbers of staff trained across the Board areas. The HAI Task Force received regular updates on implementation from NES, which monitored the numbers of Cleanliness Champions by Board as well as the time taken for completion of the training. NES would ensure that they were supporting Boards to deliver the programme and would look at each Board’s development plans.³⁵

20 [INQ05170001](#)

21 [HFS00070001](#); [HFS00070009-22](#)

22 [HFS00170001](#)

23 [GOV00400001](#)

24 [WTS01830005](#)

25 [NES00240010](#)

26 [TRA00970052-53](#); [NES00240010](#)

27 [TRA01080111-112](#)

28 [GOV00040003](#)

29 [TRA01080112-113](#)

30 [GOV00440011](#)

31 [TRA01080113](#)

32 [INQ01330003](#)

33 [INQ01330003](#)

34 [INQ05390001](#)

35 [TRA01090034-35](#)

Records kept by NES and data reports sent by NES to SEHD allowed for comparisons to be made between Boards' use of the Cleanliness Champions Programme.³⁶ It was noted by NES and SEHD that three Health Boards were falling short of the set targets for Cleanliness Champions uptake. NHSGGC was one of the Boards supported to meet its target.³⁷

NHSGGC had a target of achieving 983 Cleanliness Champions by April 2008.³⁸ The Chairman's self-assessment in the 2008 Annual Review noted that this target was exceeded in March 2008 and stood at 1,193.³⁹

An early evaluation of the programme: "The Cleanliness Champions Programme Evaluation", published in March 2006,⁴⁰ concluded that the CCP had the potential to be one of the most important elements in the range of activities taken forward by the HAI Task Force. It was important in changing culture, and there was a strong argument for further investment in and expansion of the programme. In his expert report⁴¹ Professor Brian Duerden, an infection control expert commissioned by the Inquiry, also noted that the training package had been well implemented and well received throughout Scotland. The implementation of the programme in the VOLH itself is considered in Chapter 15.

National hand hygiene campaign

Professor Martin emphasised in his evidence⁴² the importance of hand hygiene in tackling HAI:

"Hand hygiene is central to any infection prevention and control system or process, no matter the bug or the infection".

In October 2005 Andy Kerr MSP, the Minister for Health and Community Care, took part in the launch of the World Health Organisation Global Patient Safety Challenge. At this event, the Minister launched a National Hand Hygiene Campaign involving NHSScotland

and the general public, and HPS was charged with overseeing the development and delivery of the campaign on behalf of the HAI Task Force. A letter was sent to Health Boards on 18 October 2006 advising that a public media campaign would be launched at the end of January 2007 and would run for four to six weeks.⁴³ Running alongside this would be an awareness campaign aimed at NHS staff, patients and visitors, which would run until March 2008. To support the implementation of the campaign, total funding of around £2 million was made available for each Health Board to employ a Local Co-ordinator until March 2008. In a further letter⁴⁴ the SEHD provided a job description for the Local Co-ordinator role and outlined the funding allocation for each Health Board.

Following publication of the HAI Prevalence Study in July 2007,⁴⁵ Nicola Sturgeon MSP, Cabinet Secretary for Health and Wellbeing, made it clear that she wanted a more intensive programme of work to tackle the rates of HAI.⁴⁶ The National Hand Hygiene Campaign continued as part of the three-year HAI Delivery Plan from 2008 to 2009, but the focus shifted to improving hand hygiene compliance. This was to support the Cabinet Secretary's target of achieving at least 90% compliance with hand hygiene by November 2008. Funding for the Local Co-ordinator posts was to continue until March 2010, with a possibility of extension until 2011.

The Scottish Patient Safety Programme

The Scottish Patient Safety Programme was launched in 2007, and had its origins in some work being promoted by a London based health policy organisation known as the Health Foundation which researches ways to improve healthcare. A programme was introduced in three hospitals across the UK, including Ninewells Hospital in Dundee, and the success of the programme in Ninewells encouraged the SGHD to develop a Patient Safety Programme across acute hospitals in Scotland.⁴⁷

36 [NES00240015](#)

37 [NES00240011](#)

38 [COF00050004](#)

39 [QIS01560052](#)

40 [INQ01900001](#)

41 [EXP02830009](#)

42 [TRA01080106](#)

43 [GOV00420001](#)

44 [GOV00480001](#)

45 [GOV00460001](#)

46 [GGC14430002](#)

47 [TRA00980131-132](#)

The Programme brought together a range of measures to promote patient safety, with the aim of creating an organisational culture of patient safety. Around a quarter of the work streams were concerned with HAI, and the work of the HAI Task Force was aligned with the Programme.⁴⁸ In his evidence Dr Cowan explained that as part of the Scottish Patient Safety Programme Senior Health Board Managers now visit hospital sites along with their Medical Directors.⁴⁹

7.2 The role of Health Protection Scotland in developing guidance on *C. difficile*

An important role

As discussed in Chapter 6, HPS was charged with delivering many aspects of the HAI Task Force Action Plans, and provided expert advice on policy development. Certain aspects of the influence of HPS on the development of surveillance systems have been considered in Chapter 6. HPS also disseminated research and best practice in infection control at a UK and international level. For example, the World Health Organisation Guide, “Prevention of Hospital Acquired Infections”,⁵⁰ was considered by HPS and the HAI Task Force at various points prior to May 2008.⁵¹

Health Protection Scotland weekly reports

HPS and its predecessors have been involved in raising awareness of *C. difficile* in Scotland since 1994.⁵² Since that time Health Boards have provided voluntary reports of *C. difficile* infection (CDI) which have appeared in the HPS weekly reports. In her evidence⁵³ Professor Jacqui Reilly, Head of Group for Healthcare Associated Infection, HPS, explained that CDI was considered to be an organism which caused concern in the broadest sense, but the concern did not have a particular focus. A weekly report in September 2006 demonstrates that there was awareness of the CDI 027 strain,⁵⁴

highlighting research presented at the English Health Protection Agency Conference which showed that only a quarter of the healthcare associated CDIs were caused by the 027 strain. This was the strain which caused most of the outbreaks at the Stoke Mandeville Hospital in England.

Prevalence survey of Healthcare Associated Infections

The HAI Task Force was concerned to ensure that it had good baseline statistics and information on the trends of HAI which would then allow it to assess the impact of the measures introduced. In May 2004 HPS identified the need for more surveillance of HAI, and proposed that it undertake a prevalence survey of all HAI, including CDI. The HAI Task Force agreed to the survey and funding was made available. The survey was carried out by HPS between October 2005 and September 2006, covering all acute hospitals in Scotland as well as a sample of community based hospitals, and the results of the survey were published in July 2007.⁵⁵ It found that 15.4% of HAI patients in acute hospitals acquired gastrointestinal infections. The most frequently occurring organisms where data existed included *C. difficile*, and patients in the Care of the Elderly and General Medicine Specialties accounted for 92% of the CDIs found. *C. difficile* was identified as a priority area for future incident surveillance.

Health Protection Scotland shared website

The HPS shared website was a section on the NHS internal website, established in 2007 as part of the HAI Task Force’s second Delivery Plan. The Project Initiation Document⁵⁶ for Task 14.4: “Develop Programme for Reduction of *C. difficile*” made specific provision for this, and in her evidence⁵⁷ Professor Reilly outlined the purpose of the shared website, which allowed professionals to share research and best practice. There was also a discussion forum which allowed Infection Control Teams in different Health Boards to communicate with each other and with HPS, and a specific network was set up for *C. difficile*. HPS wrote

48 [TRA01100131](#)

49 [TRA01220158](#)

50 [INQ03830001](#)

51 [TRA01100122](#)

52 [TRA01090118](#)

53 [TRA01090118](#)

54 [GOV01110001-04](#)

55 [GOV00460001](#)

56 [HPS00250001-04](#)

57 [TRA01100043-46](#)

to Health Board Infection Control Managers in August 2007 to let them know about the website and inviting relevant staff to register. Registration was on a voluntary basis, and about six staff from NHSGGC were registered on the site. An email alert was sent to registered users to let them know when new information became available.

Awareness of the 027 strain of *C. difficile*

HPS first became aware of the 027 strain in 2006, when a case from Glasgow was ribotyped by the Cardiff Reference Laboratory.⁵⁸ It seemed that this case concerned a patient who had previously been in hospital in England. The next case it became aware of was in 2007. The “Annual report on the Surveillance of *Clostridium difficile* Associated Disease in Scotland” (2007) mentioned both of these cases as the first examples of 027 in Scotland.⁵⁹

The HPS weekly report of 7 November 2007 mentioned a case of 027 from a hospital in the west of Scotland, describing it as the second reported case of 027 in Scotland.⁶⁰ According to Professor Reilly, the purpose of the alert was to increase awareness within Health Boards that 027 was circulating, and to encourage them to send severe cases of CDI related to suspected outbreaks to the Reference Laboratory for ribotyping.⁶¹

The Project Initiation Document for the *C. difficile* Reduction Programme mentioned the emergence of a new hypervirulent strain 027, which was thought to cause more severe disease.⁶² According to the published literature at the time, it was thought that 027 was potentially more transmissible than other ribotypes or strains of *C. difficile*. More recent literature suggests, however, that ribotype 027 is not necessarily more virulent or transmissible than other ribotypes.⁶³

Professor Reilly emphasised that HPS takes a broad approach to infection prevention and control which prepares for all organisms

as they emerge. This is in recognition that “organisms do come and go”.⁶⁴ She also made clear that CDI should be seen as a serious illness regardless of the ribotype.⁶⁵

In May 2008 HPS sent a letter to Infection Control Managers reminding them of the actions to take when there is a suspected case of CDI, regardless of ribotype. It also outlined the necessary steps when dealing with the 027 ribotype.⁶⁶ The letter was prompted by outbreaks related to the 027 strain in Scotland,⁶⁷ which at that time included the emergence of the VOLH CDI problem. In her evidence Professor Reilly said that, had HPS been aware of an earlier outbreak in Scotland, a similar process would have been adopted.⁶⁸

***Clostridium difficile* associated disease care bundle**

HPS published the “*Clostridium difficile* associated disease (CDAD) bundle” (the care bundle) in March 2008. The infection control measures within the care bundle were not new, and would probably have been in local Health Boards’ policies for Infection Control, but the purpose of the care bundle was to focus on these measures and act as a prompt for staff at the point where they were dealing with a patient with CDI.⁶⁹

The care bundle included five measures:⁷⁰

1. Isolating patients until they are at least 48 hours symptom free
2. Stopping inappropriate antibiotics
3. Checking healthcare workers remove gloves and aprons after dealing with each patient
4. Checking that the CDAD patient’s immediate environment has been cleaned with a chlorine based solution
5. Ensuring healthcare workers wash hands with liquid soap and water after leaving a CDAD patient’s room

58 [TRA01100018-19](#)

59 [HPS00310004](#)

60 [INQ03650001](#)

61 [TRA01100024](#)

62 [HPS00250001](#)

63 [TRA01090141](#)

64 [TRA01100021](#)

65 [TRA01100018](#)

66 [HPS00730001](#)

67 [TRA01100023](#)

68 [TRA01100027](#)

69 [TRA01100013](#)

70 [HPS01650001](#)

Professor Reilly explained that in January 2007 SGHD had advised that the Department of Health in England and Wales was looking at implementing high impact interventions for *C. difficile*, and asked if HPS would consider doing something similar. The process began in January 2007 and was built into the Project Initiation Document, which was submitted in the summer of 2007. The CDAD care bundle was tested in a number of Health Boards during 2007, including NHSGGC,⁷¹ before being delivered in March 2008.⁷² All Health Boards had access to the care bundle as it was available on the HPS website from that point.⁷³

Professor Martin confirmed that the CDAD care bundle had been in preparation before the HAI Task Force was aware of the events at the VOLH.⁷⁴ At the HAI Task Force meeting on 27 May 2008⁷⁵ it was agreed that the CDAD care bundle was so important that it should be introduced as quickly as possible, and that it should be co-ordinated with the Scottish Patient Safety Programme to ensure consistency with its care bundle approach.

7.3 Developments from June 2008 onwards

Introduction

A number of *C. difficile* related guidance documents were being developed in the early part of 2008, but not finalised by June 2008, at which point SGHD and other national bodies became aware of the outbreak at the VOLH. Production and dissemination of some key guidance documents were accelerated as a result of the VOLH experience.

Checklist for preventing and controlling *C. difficile* associated disease

HPS developed a checklist⁷⁶ for preventing and controlling *C. difficile* associated disease to ensure adequate governance of *C. difficile* at all levels within Health Boards. According to Professor Reilly, the checklist was being discussed early in 2008 by the HPS internal

C. difficile Infection Team in response to some of the lessons learnt from the *C. difficile* outbreaks in England.⁷⁷ It was produced earlier than planned in light of the outbreak at the VOLH and was tested with NHSGGC. The final version was published in September 2008 and shared with all NHS Boards. The creation of the checklist is examined in greater detail in Chapter 18.

Information for patients

The NHS Quality Improvement Scotland (QIS) (now Health Improvement Scotland (HIS)) HAI standards⁷⁸ require Health Boards to provide patient information, so that there was an expectation that patient leaflets would be available within Health Boards. Despite this, the lack of information provided to relatives regarding the washing of patients' clothing was highlighted in the August 2008 report of the Independent Review into the outbreak of *C. difficile* at the VOLH,⁷⁹ and Professor Reilly told the Inquiry that HPS was subsequently asked in the light of the Independent Review to produce a template for a patient laundry leaflet and share it across Boards to strengthen existing information.⁸⁰

Root Cause Analysis tool

Root Cause Analysis is a structured technique used within the NHS to analyse serious adverse events and establish what went wrong. The General Action Plan for HAI,⁸¹ developed for Health Boards in June 2008, included the introduction of a *C. difficile* Root Cause Analysis Tool to investigate adverse outcomes, including death. Professor Martin agreed that such a tool was not being used routinely in Scotland at the time of the VOLH outbreaks, nor had a policy been issued to Health Boards at this time,⁸² although a *C. difficile* Tool had been introduced in England as a result of the Maidstone and Tunbridge Wells report.⁸³ It was then decided that as part of the response to the VOLH outbreaks HPS should develop a similar tool in Scotland.

71 [TRA01090143](#)

72 [TRA01100006](#)

73 [TRA01100010](#)

74 [TRA01080134-135](#)

75 [GOV00740009](#)

76 [HPS01590002-03](#)

77 [TRA01090149](#)

78 [INQ00840012](#)

79 [GOV00030012](#)

80 [TRA01100041](#)

81 [GGC14470006](#)

82 [TRA01080136-138](#)

83 [INQ02870001](#)

The Quality Strategy

A more recent development in Scotland is the Quality Strategy,⁸⁴ launched in 2010. It promotes safe, effective, person-centred care and builds on the theme of creating a quality culture within the NHS. Safe care is defined as avoiding “injury or harm to people from healthcare they receive” and providing an “appropriate clean and safe environment” for the delivery of healthcare at all times. Professor Reilly explained that the HAI Task Force philosophy fits with this strategy. It reflects best practice for infection control as outlined by the World Health Organisation and European requirements for infection control.⁸⁵

7.4 Was the guidance on HAI adequate?

Range of guidance

A range of guidance on HAI was in place at the time of the VOLH outbreak. Indeed, Scotland was considered to be a leader in tackling infection control. Dr Woods recalled a conference in 2005 where the World Health Organisation’s leading Infection Control Expert, Professor Pittet, said that Scotland was at the forefront of infection control measures in Europe in tackling HAIs.⁸⁶ The HAI Task Force was seen as being unique in taking a countrywide approach to tackling HAI.

Dr Woods’ letter of 27 June 2008

On 27 June 2008,⁸⁷ shortly after the outbreak at the VOLH, Dr Woods wrote to Health Board Chief Executives reminding them of their responsibilities. The Appendix to Dr Woods’ letter lists guidance relevant to HAI, and that list extends to six pages, a clear indication of the extent of the information available.

Dr Woods considered that a clear message was being provided to Boards in relation to the management of HAI. As he said:

“it was a message that was repeated over and over again because of the importance we attached to it”.⁸⁸

This consistent message spanned different political administrations.⁸⁹ The repetition of the message did not necessarily reflect dissatisfaction with the Boards. Instead:

“it reflected a determination to make sure that it remained very firmly at the front of the leadership of these organisations’ minds”.⁹⁰

The Inquiry is satisfied that there was adequate guidance on HAI available to Health Boards.

7.5 The provision of *C. difficile* guidance

Pre 2008 *C. difficile* guidance

In her evidence Professor Reilly explained that guidance on standard infection control precautions was in place from February 2006.⁹¹ This covered all organisms of concern including *C. difficile*. Prior to this, there was UK guidance produced by the Department of Health in 1994⁹² which was relevant to Scotland. Additionally, HPS published transmission-based precautions which focused specifically on *C. difficile*. These outlined the additional measures which should be put in place when dealing with a patient who was known or thought to have CDI.⁹³

The 2008 *C. difficile* guidance

Professor Reilly explained in her evidence that HPS was represented on a European working group developing the first European guidance focusing on the specific topic of CDI.⁹⁴ The plans to produce Scottish guidance were outlined in the Project Initiation Document mentioned in Section 7.2, which was sent to the HAI Task Force in 2007, and which contained a two-year programme of work including the development of *C. difficile* specific guidance.⁹⁵ The European guidance was due to be produced in 2008, and the publication of the Scottish guidance was planned for 2009. HPS expected to

84 [GOV01460001](#)

85 [TRA01100131](#)

86 [WTS01200002-03](#)

87 [GOV00200001](#)

88 [TRA00970069](#)

89 [TRA00970077](#)

90 [TRA00970078](#)

91 [TRA01090135](#)

92 [INQ01700001](#)

93 [HPS00330001](#)

94 [HPS01090137](#)

95 [HPS00250001](#)

review the European guidance following its publication to check that there was sufficient evidence to support the recommendations and to adapt it to the Scottish context, ensuring that Scottish policies on infection control were referred to.

The guidance was actually published in October 2008. Professor Reilly explained that its publication was brought forward at the request of the Scottish Government as a result of the emerging O27 outbreaks which were reported to HPS in May 2008.⁹⁶ Production of the guidance in a shorter timescale meant that the normal consultation process which would take place was reduced, and following production of the guidance in October 2008 a fuller consultation took place to ensure that it was fit for purpose. The guidance was revised in light of the consultation and re-issued in September 2009.⁹⁷ The changes made were minor, and the guidance did not change significantly from the earlier version.

The equivalent guidance in England was published by the Health Protection Agency in January 2009.⁹⁸

7.6 The monitoring of the implementation of guidance

Additional resources

Professor Martin explained in his evidence that the HAI Task Force could release additional resources to support Health Boards in implementing new work.⁹⁹ Funding for Infection Control Managers, Nurse Consultants and Hand Hygiene Co-ordinators was an example of such support. A sum of £40,000 was provided to each of the mainland Scottish Health Boards and £20,000 to each of the island Health Boards to support the appointment of dedicated Infection Control Managers.¹⁰⁰

How was the implementation of policy and guidance monitored?

Chapter 6 outlines the accountability systems in place in 2007 and 2008. Dr Woods described the process for the monitoring of policy,¹⁰¹ in which monthly meetings were held with Chief Executives which covered current performance, future policy and the experience of putting policy into practice. The Chief Nursing Officer held monthly meetings with the Nurse Directors within each Health Board, and these would include discussion on HAI.¹⁰² As part of this ongoing dialogue between Government and Health Boards, complementary meetings were held between the Scottish Government and Chairs of the Health Boards. HAI issues formed part of these discussions. For example, at the meeting on 26 November 2007, Ministers made clear that HAI was a top priority for Government.¹⁰³

The annual review process introduced by the then Minister for Health and Community Care, Andy Kerr MSP, provides a formal process for asking Health Boards what they are doing to deliver their responsibilities. HAI has been an agenda item under both political administrations. Nevertheless, Professor Martin thought that the SGHD would only become aware that a policy had not been put in place if they specifically asked the question at the time of the annual review.¹⁰⁴ Dr Woods, on the other hand, explained that there were sources of intelligence for the SGHD to monitor compliance with standards. If they became aware of a deficiency, this would be flagged as an issue and followed up at the next review.¹⁰⁵

As discussed in Chapter 6, Health Improvement, Efficiency, Access and Treatment (HEAT) targets cover a range of areas relating to efficiency improvements and patient access to treatment, and Health Boards are measured against these targets. The HEAT target for *C. difficile* was not introduced until April 2009.¹⁰⁶

96 [TRA01100016](#)

97 [INQ03600001](#)

98 [INQ02440001](#)

99 [TRA01080068](#); [TRA01080093](#)

100 [GOV00440001](#)

101 [TRA00970075-76](#)

102 [TRA01090036](#)

103 [WTS01200006](#)

104 [TRA01080096](#)

105 [WTS01200007-08](#)

106 [GOV01430001](#)

Inadequate implementation tools

Although there was a range of guidance available at a national level, the persisting CDI problem in the VOLH over the period January 2007 to June 2008 shows that not enough attention was paid to the implementation of such guidance on *C. difficile*. At the meeting of the HAI Task Force on 4 July 2008,¹⁰⁷ after the events at the VOLH, members raised concerns that, although good guidance was in place across Scotland, the tools for implementation were not always in place.

In his witness statement¹⁰⁸ Professor Martin noted that: “there was a shift from policy development to supporting policy delivery in the second plan”. The SGHD would not become too involved in delivery issues, as this was not their responsibility, but they could provide levers such as additional resources to effect change. In contrast, the SGHD took a prescriptive approach to NHSGGC in response to the Independent Review report of the VOLH outbreak. They issued a specific action plan with timescales for completion and a more general action plan for all Health Boards to respond to. Professor Martin explained that an unusually firm line was taken, and the language used by him in his evidence reflected this: “No more excuses, just get on and get this done”.¹⁰⁹ This was not a specific response to reluctance on the part of NHSGGC, but arose from a general observation that policies were difficult to implement across Scottish Health Boards.

In his evidence, Dr Woods acknowledged that although there was a lot of guidance available prior to events at the VOLH, something still went wrong. In his view it is important that good processes are in place to ensure that guidance is implemented at a local level. It can be achieved through:

- Training
- Review processes
- Clinical leadership
- Early warning system
- External review¹¹⁰

The suggestion is that guidance and tools were fragmented and were not easily accessible in one place.

7.7 Conclusion

There was a considerable range of policies and guidance on HAI and *C. difficile* available from the mid 1990s onwards. Scottish Government and national organisations such as HPS took the threat of HAIs seriously.

The challenge for Health Boards is to ensure that policies are put into place every day for every patient. NHS staff should be aware of policies on infection control and *C. difficile* and understand how they relate to their day to day work. Staff should also be actively involved in the review of policies and ongoing improvement.

Although a number of monitoring systems were in place, as explored in Chapter 6, there was inadequate external scrutiny of HAI until the creation of the Healthcare Environment Inspectorate in April 2009. This was a weakness in the system.

The introduction of policies and guidance on HAI should be adequately policed by or on behalf of the Scottish Government.

Policies and guidance relevant to *C. difficile* were in place and available to Health Boards in 2007 and 2008. Specific Scottish guidance on *C. difficile* was not pulled together in one place until October 2008, when HPS produced guidance on the prevention and control of *C. difficile*.

The production of the 2008 *C. difficile* guidance is fully examined in Chapter 18. The production of the checklist, as discussed in Chapter 18, should have occurred earlier than it did. This, however, does not diminish NHSGGC’s responsibility to take the threat of *C. difficile* seriously. NHSGGC did, after all, have their own *C. difficile* policy within the Infection Control Manual.

During the Inquiry’s oral evidence, it was suggested by legal representatives of patients and relatives that Health Boards might benefit from a local HAI Task Force,

107 [GOV01420003](#)

108 [WTS01670004](#)

109 [TRA01080132](#)

110 [WTS01200009](#)

with links to the national HAI Task Force.¹¹¹ Professor Martin was very responsive to this idea, and said that if a local Task Force reflected the membership of the national Task Force and included representatives from local communities it could be a very positive development for Scotland. The Inquiry supports this suggestion. A local HAI Task Force could provide reassurance to the general public that HAI is a priority within their Health Board area.

7.8 Recommendations

Recommendation 2: Scottish Government should ensure that policies and guidance on healthcare associated infection are accompanied by an implementation strategy and that implementation is monitored.

Recommendation 3: Health Boards should ensure that infection prevention and control policies are reviewed promptly in response to any new policies or guidance issued by or on behalf of the Scottish Government, and in any event at specific review dates no more than two years apart.

Recommendation 4: Scottish Government should develop local Healthcare Associated Infection (HAI) Task Forces within each Health Board area.

111 [TRA01090019-20](#)

Chapter 8

Changes in services at the
Vale of Leven Hospital
from 2002

Introduction

Chapter 9 examines the process of integration of NHS Argyll and Clyde with Greater Glasgow. It is important to be aware, however, that significant developments took place at the Vale of Leven Hospital (VOLH) in the years before and after that integration. As an introduction to a review of the integration process, the Inquiry has found it helpful to set out these developments, since they serve to place in context certain events which the Inquiry has examined in the course of its investigations and which are directly related to matters within the Inquiry's Terms of Reference.

8.1 Prolonged uncertainty

Background

In 2002 the Vale of Leven District General Hospital (this is its full title) was one of the smaller hospitals in the NHS in Scotland delivering a broad range of acute hospital services. The hospital's "front door" was an Accident and Emergency (A&E) Department which dealt with well over 20,000 attendances each year. The Lead Clinician was an Associate Specialist. The A&E Department provided the triage (the process of determining priority of treatment for patients) for the Acute Medical and Acute Surgical receiving units, whose specialties included an inpatient gynaecology unit. The hospital also had an inpatient Maternity unit, with a small specialist Medical Paediatric unit operating in support.¹ The VOLH was used for placement of nurses in training, although the extent of this has not been explored by the Inquiry.

Even by 2002, however, concerns had arisen about the sustainability of such a range of services at the VOLH. Attempts had been made for a number of years to develop "a sustainable strategy"² for the VOLH. A project known as the Vale of Leven Project was undertaken from 1999 to 2001 to consider how best to develop the VOLH and its clinical services, and this identified key issues in relation to each of the specialties provided at the hospital. The conclusion arrived at was that important services provided at the VOLH were no longer viable, primarily because of

a lack of medical staff. By December 2002, surgical services at the VOLH were close to total collapse because it was not possible to recruit surgeons to replace those who left to take up other positions or who retired.³

Reduction in services

Between 2002 and 2004 a significant service reconfiguration took place in NHS Argyll and Clyde involving, in particular, the VOLH and the Royal Alexandria Hospital (RAH). This was to address the challenge of providing sustainable and safe specialist Acute Clinical services for the local population. Surgery and urology services were transferred from the VOLH to the RAH in 2003.⁴ Following upon a major review of maternity services in NHS Argyll and Clyde in 2003, consultant-led obstetric and gynaecology services for the VOLH catchment area were also transferred to the RAH, while a community midwifery service was developed at the VOLH.⁵ In January 2004 A&E services were transferred to the RAH, although other unscheduled medical admissions were maintained for the time being, as was a separate minor injuries unit.⁶ These changes occurred without public consultation or being put to the Scottish Government.⁷

Impact upon anaesthetic services

The reconfiguration of services meant that the level of activity at the VOLH was significantly reduced. That reduction in activity meant that the anaesthetic service was not sustainable beyond the short-term. This in turn cast doubt upon the sustainability of the remaining unscheduled medical admissions to the VOLH.⁸ In June 2004 Dr Geoffrey Douglas, Clinical Director for Anaesthetics, wrote to the Chief Operating Officer of NHS Argyll and Clyde and to the then Minister for Health and Community Care, Malcolm Chisholm, informing them that the anaesthetic service could not be sustained beyond the short-term because of the impact of the reconfiguration of the former service provision at the VOLH.⁹ The reason for this was that:

1 [GGC32180003](#)

2 [GGC18250021](#); [TRA00980003](#)

3 [GGC18250021](#)

4 [GGC03430001](#)

5 [GGC03430001](#)

6 [GGC03430001](#)

7 [TRA00980039](#)

8 [QIS01190052](#); [GGC03430001](#)

9 [QIS01190052](#)

“there was simply not the volume of work that would allow anaesthetists to maintain their skills base or provide adequate training workload to sustain training accreditation”.¹⁰

8.2 Shaping the Future

The consultation process

In 2004 the NHS Argyll and Clyde Board produced a public consultation paper entitled “Shaping the Future”.¹¹ The consultation period was initially intended to run from 14 June to 17 September 2004, although it appears to have continued into 2005.¹² The central theme of that paper was the development of the RAH as the major acute hospital for Argyll and Clyde. The key proposals for the VOLH included the transfer of geriatric and dementia beds from other hospitals to the VOLH,¹³ the retention of the midwife-led maternity service, and a renal dialysis service.¹⁴

There were two proposed options for future services at the VOLH. The first option was that the VOLH could become an Ambulatory Care and Diagnostic Centre for non-inpatient activity,¹⁵ provided by NHS Greater Glasgow, which was to include a nurse-led minor injuries service. All inpatient services would be in Glasgow. The second option was the development of an intermediate hospital which integrated ambulatory care with intermediate care beds and services.¹⁶ Patients who required major acute inpatient care would be transferred to the RAH.

The consultation paper proposed significant changes not only at the VOLH but across the whole Argyll and Clyde area, including the closure of hospitals.¹⁷ It was proposed that the reconfiguration of services would be substantially completed by the end of April 2007.¹⁸

10 [GGC18220106](#)

11 [INQ05340001](#)

12 [GGC03430002](#)

13 [INQ05340041](#)

14 [INQ05340042](#)

15 [INQ05340046](#)

16 [INQ05340046](#)

17 [INQ05340041](#)

18 [INQ05340049](#)

These options proved to be highly controversial, however, and no final strategy was concluded before the proposed dissolution of NHS Argyll and Clyde was announced in May 2005.

8.3 Lomond Integrated Care Model

A new approach to admissions

Some 6,000 unscheduled admissions continued to take place at the VOLH every year through the Medical Assessment Unit (MAU). The fragility of the anaesthetic service led to steps being taken to devise a model of care, known as the Lomond Integrated Care Model (the Care Model), that would allow such unscheduled medical care to be retained at the VOLH in the absence of on-site anaesthetic support.¹⁹ This model had been developed by the Lomond Integrated Care Steering Group, a group that included care physicians, nurses, allied healthcare professionals (AHPs), and members of the public.²⁰ The Care Model had four key elements:

1. An assessment and scoring system enabling patients likely to require intensive or anaesthetic care to be identified and **either** bypass the VOLH and be admitted direct to RAH **or** be rapidly transferred from the VOLH to the RAH
2. A nurse practitioner “hospital at night” team, which could safely and effectively provide cover out of hours with medical input from a primary care physician
3. A retrieval service to ensure that patients requiring a more acute level of care than could be provided at VOLH could safely be transferred to RAH
4. The early transfer to VOLH of patients living in the catchment area, for ongoing care and rehabilitation, after an acute episode of care in another hospital²¹

In essence, this model of care used general practitioners (GPs) with additional skills and training as primary care physicians at VOLH to manage emergency admissions without

19 [QIS01190053](#)

20 [GGC18220101](#)

21 [GGC03800101](#)

the support of anaesthetists. It was partially implemented in January 2006, with the focus on testing elements 1 and 3 of the care model. At this stage, however, the Care Model depended on the presence of a senior house officer (SHO) working overnight with the primary care physician, as well as on-call and on-site anaesthetic cover. The anaesthetic cover was dependent in turn upon input from three long-term Consultant Locum Anaesthetists who could have left with only one month's notice.

At the heart of the Care Model was the desire to retain a significant number of unscheduled medical admissions at the VOLH.²² Under this model it was anticipated that 85% to 88% of such admissions would continue. The rapid retrieval service referred to in element 3 of the model was to support the transfer from the VOLH of those patients requiring anaesthetic input. The introduction of the model was to be phased, and initially on-site anaesthetic cover was to be retained, the intention being that cover would subsequently move to on-call, off-site cover.²³

By the time NHS Argyll and Clyde was dissolved, the Care Model had been launched as a pilot at the VOLH,²⁴ but it had not been fully implemented and on-site anaesthetic cover was still available.

On-site anaesthetic cover

At the date of the dissolution of NHS Argyll and Clyde (1 April 2006), NHSGGC was intent on fully implementing the Care Model.²⁵ The next stage of the model was to involve the withdrawal of the on-site, out-of-hours anaesthetic cover for the VOLH.

At a meeting with VOLH consultants in July 2006,²⁶ significant issues were raised concerning the clinical safety of moving to the next stage of the model without anaesthetic cover. The conclusion arrived at was that the model was not sustainable without cover from the wider group of physicians at the RAH. Further discussion

took place involving the RAH consultants in August 2006, and the clear consensus was that providing unscheduled care at the VOLH without anaesthetic cover was not a safe system of work.²⁷ This inevitably meant that the Care Model could not proceed as originally conceived.

At a meeting on 21 September 2006²⁸ it was reported to the Minister for Health and Community Care that the model developed was not safe without anaesthetic input. The anaesthetic input at the VOLH was fragile, being based on the use of locum doctors and without any possibility of recruiting permanent consultants to the posts.²⁹ At the end of that meeting the Minister appeared to accept that the anaesthetic cover was not sustainable. Nevertheless, at a subsequent meeting on 2 October 2006 attended by Dr Woods and by Mr Alastair Brown, Head of Performance Management at the Scottish Executive Health Department (SEHD), Mr Divers was told that NHSGGC must carry out a full option appraisal of the change before embarking on a public consultation. A health needs assessment was also to be carried out for the population of West Dunbartonshire.³⁰ No decision on the future of unscheduled medical care at the VOLH could therefore be taken until the outcome of these was known.³¹

8.4 A new strategy

The NHS Greater Glasgow and Clyde proposal

NHSGGC established a substantial planning and community engagement process to consider the future of services in the Clyde area.³² By June 2007 that process had been completed and an NHSGGC paper, "Clyde Health and Service Strategies: Outcome of Reviews and Proposals for Consultation",³³ was presented to the NHSGGC Board at its meeting on 26 June 2007.³⁴ Those proposals consisted of an extensive programme for

22 [TRA00980006](#)

23 [QIS01190053](#)

24 [GGC18220099](#); [QIS01190053](#)

25 [GGC18220099](#)

26 [GGC18220103](#)

27 [GGC18220104](#)

28 [GGC32180009](#)

29 [GGC32180009](#)

30 [TRA00970144](#)

31 [GGC32180010](#)

32 [GGC18220004](#)

33 [GGC01720005](#)

34 [GGC01720001](#)

change, including the withdrawal of the Care Model at the VOLH and the transfer of unscheduled medical care to the RAH. The Board approved the proposals as the basis for formal public consultation and for external review.³⁵

With the change in administration following elections in May 2007, Nicola Sturgeon came into post as Cabinet Secretary for Health and Wellbeing. Her health policy included the delivery locally of as many services as possible and extensive consultation when changes were being proposed.³⁶ She also wanted to pursue a policy of independent scrutiny for proposals of the kind being put forward by NHSGGC.³⁷ The reason for that approach was a widespread feeling in parts of Scotland, reflected in comments made in the Scottish Parliament, that Health Boards were not good at consulting with communities over major service changes.³⁸ That, therefore, was the background to the NHSGGC Board's decision at its meeting on 26 June 2007 to embark upon public consultation and external review.

The Independent Scrutiny Panel

The proposals accepted by the Board at its meeting on 26 June 2007 were thereafter reviewed by the Independent Scrutiny Panel, chaired by Professor Angus Mackay.³⁹ The Panel's report records that the Panel was created by the Cabinet Secretary for Health and Wellbeing:

“to consider and report on the options prepared for public consultation by NHS Greater Glasgow and Clyde with respect to the future health provision in the Clyde area, including those services provided at the Vale of Leven (VoL) Hospital in Alexandria”.⁴⁰

In its report, published on 30 November 2007,⁴¹ the Panel raised questions about NHSGGC's methodology in arriving at its conclusions, and in particular NHSGGC's

failure to take greater steps to convince stakeholders of the benefits of its preferred option.⁴² While not challenging the conclusion that anaesthetic services at the VOLH were in the long-term unsustainable, the report recommended the development, appraisal and presentation of the following options for public consultation:

1. The status quo
2. The status quo for a specified period with continuance of anaesthetic support to permit evaluation of the predictive scale (to identify patients for transfer to RAH)
3. The transfer of unscheduled medical admissions to RAH
4. The transfer of unscheduled medical admissions to another Glasgow hospital

The Panel summarised its position in the following way:

“The Panel feels that more effort could have been made to provide a vision for the Vale of Leven in the medium to longer term”.⁴³

As Dr Woods explained, the Panel was not convinced NHSGGC had done enough to explore the options that might be available for the VOLH.⁴⁴

NHS Greater Glasgow and Clyde's response

The conclusions of the Independent Scrutiny Panel were considered by the Board at its meeting on 18 December 2007, and a motion in favour of following the Panel's recommendation was heavily defeated.⁴⁵ The Board concluded that the Panel was sending conflicting messages,⁴⁶ especially as the Panel agreed with NHSGGC's conclusion that current anaesthetic provision was unsustainable.⁴⁷ The Board decided that in fact the Panel's clinical conclusions supported NHSGGC's proposals on integrated care and unscheduled medical admissions at the VOLH,⁴⁸ and that plans should be developed

35 [GGC01720011](#)

36 [TRA00980027](#)

37 [TRA00980028](#)

38 [TRA00980028](#)

39 [GGC18240072](#)

40 [GGC18240026-27](#)

41 [GGC18240026-27](#)

42 [GGC18240055](#)

43 [GGC18240054](#)

44 [TRA00980018](#)

45 [GGC01750007](#)

46 [GGC01750010](#); [TRA00980024](#)

47 [GGC01750009-10](#)

48 [GGC01750010](#)

to transfer unscheduled medical admissions from the VOLH to the RAH.⁴⁹ Following meetings between NHSGGC officials and the Scottish Government, however, and a direct instruction from the Cabinet Secretary,⁵⁰ the Board's position changed. At its meeting on 22 January 2008, the Board was presented with,⁵¹ and accepted, a recommendation to reverse its earlier decision and initiate a period of public consultation as soon as possible.⁵²

Over the following five months NHSGGC embarked on a public consultation process on service areas in Clyde other than unscheduled medical care at the VOLH.⁵³ In relation to unscheduled medical care, NHSGGC had discussions with the Independent Scrutiny Panel on how best to proceed with this aspect of the consultation process.⁵⁴ As at February 2008 material was being drafted in liaison with the Scottish Health Council in anticipation of the public consultation that was to be held.⁵⁵ That drafting process was still going on in April 2008.⁵⁶ At a public meeting held on 18 June 2008, when challenged about the future of all services at the VOLH, Mr Divers made a commitment that NHSGGC would publish a public consultation document on all services in autumn 2008.⁵⁷

The anaesthetic review

In June 2008, while NHSGGC was preparing for that consultation, the Cabinet Secretary for Health and Wellbeing commissioned an Independent Review into the sustainability of anaesthetic services at the VOLH. The Review Team, chaired by Professor Chris Dodds of Aberdeen University, produced a report entitled the "Independent External Clinical Review of Anaesthetic Services at the Vale of Leven Hospital",⁵⁸ which concluded that the continued provision of anaesthetic services at VOLH was unsustainable in the short,

medium or long term. In contrast to NHSGGC's previous proposal that all unscheduled medical admissions should go to the RAH, however, this review concluded that the optimal solution was the retention of selected unscheduled admissions at the VOLH, with all other unscheduled medical admissions diverted to a suitably equipped hospital such as RAH.⁵⁹

8.5 The Vision for the Vale

The uncertainty resolved

In September 2008 NHSGGC approved and published its consultation document "Vision for the Vale of Leven Hospital",⁶⁰ with the consultation period running from 31 October 2008 to 30 January 2009. This followed a period of pre-consultation engagement during which emerging plans were shared with stakeholders. The Vision for the Vale document in effect incorporated the recommendations of the Independent Review as the model for unscheduled medical admissions.⁶¹

A meeting of the NHSGGC Board was held on 24 February 2009 to consider the recommendations that came out of the consultation process.⁶² The Board approved the conclusion that the level of anaesthetic service required to support the current model of unscheduled medical care was unsustainable. It also approved the development of alternative arrangements that would maintain about 70% of the current level of unscheduled medical admissions without anaesthetic cover. This was in line with the conclusion in the Vision for the Vale consultation document that unscheduled medical admissions could continue at the VOLH at that level. It is to be noted that this differs substantially from NHSGGC's proposal in 2006 and 2007, which was effectively to transfer all such admissions to the RAH.⁶³ Figure 8.1 sets out the impact on unscheduled medical care recommended and adopted by NHSGGC.

49 [GGC01750010](#)

50 [GGC01760011](#)

51 [GGC03860001](#)

52 [GGC01760013](#)

53 [GGC32180013](#)

54 [GGC01770008](#)

55 [GGC01770008](#)

56 [GGC01780004](#)

57 [GGC32180013](#)

58 [INQ04500001](#)

59 [INQ04500029](#)

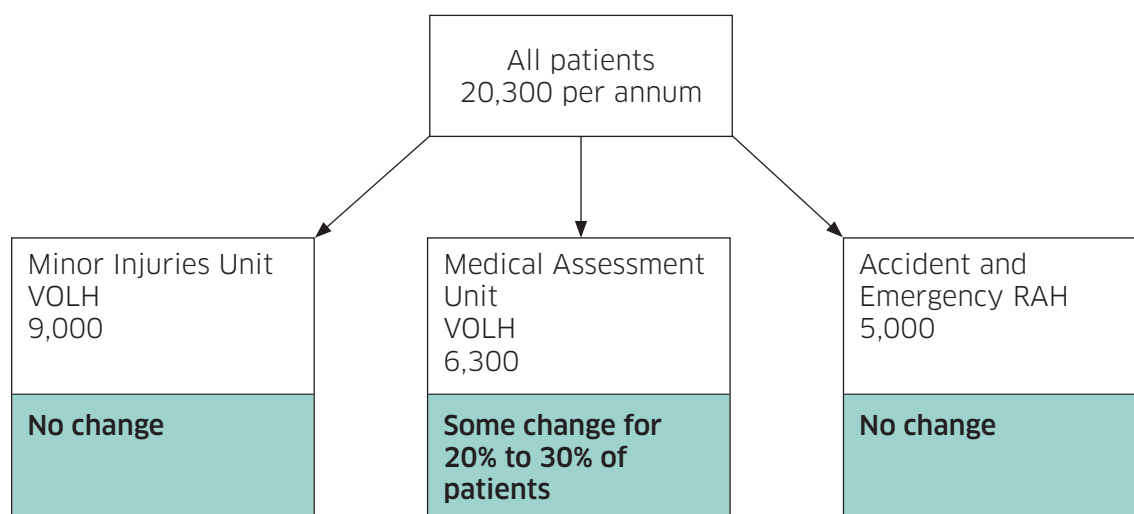
60 [QIS01190001](#)

61 [GGC02450001](#)

62 [QIS01170006](#)

63 [TRA00980036-38](#)

Figure 8.1 Impact on unscheduled medical admissions



The uncertainty surrounding the level of unscheduled medical care (and the services required to support that) was therefore finally resolved after many years.

Microbiology and infection control services

From 2002 onwards there was continuing difficulty in maintaining microbiology and infection control services in Clyde Area. In the course of 2002, Dr Stephanie Dancer, Consultant Microbiologist at the VOLH, resigned, and NHS Argyll and Clyde was unsuccessful in filling the post, which remained vacant. In addition, Dr Anne Eastaway, Consultant Microbiologist at the RAH, left in 2005. This left two of the five Consultant Microbiologist posts in the Clyde area vacant. The impact on microbiology and infection control services at the VOLH is examined in Chapter 15.

Impact of changes

Tables 8.1 to 8.3 record the range of inpatient services and the number of beds available at VOLH in 2002,⁶⁴ 2008⁶⁵ and 2012.⁶⁶ The psychiatric wards (Fruin and Christie wards) are not included in the Tables.

**Table 8.1: VOLH:
Bed complement at 31 March 2002**

Specialty	Bed Numbers
General medicine	70
General surgery (including gynaecology)	51
Obstetrics	19
Medical paediatrics	6
Geriatric medicine	88
Total	234

**Table 8.2: VOLH:
Bed complement at March 2008**

Specialty	Bed Numbers
Emergency medicine (including CCU)	52
Surgery/anaesthetics	20
Rehabilitation assessment	64
Total	136

**Table 8.3: VOLH:
Bed complement at April 2012**

Specialty	Bed Numbers
Emergency medicine (including CCU)	39
Surgery/anaesthetics	10
Rehabilitation assessment	41
Total	90

64 [GGC32180003](#)

65 [GGC11320005](#); [TRA00900045](#); [GGC32180005](#)

66 [GGC32180003-05](#)

A comparison between Table 8.1 and Table 8.2 shows that the changes introduced by NHS Argyll and Clyde described previously had a profound impact on the nature of services delivered from the hospital and on its bed complement. There was a marked reduction in the number of acute beds by the point in 2008 at which the public consultation paper on unscheduled medical care was being developed.

8.6 Conclusion

Prolonged uncertainty over the range of services to be provided at the VOLH, the future of anaesthetic cover, and the future of the hospital itself, had a damaging effect on recruitment, on staff morale, and on the physical environment of the hospital.

This state of affairs should not have been permitted to continue for as long as it did.

In addition to, and perhaps due to, this broad uncertainty over the provision of services at VOLH, unsuccessful recruitment led to uncertainty over provision of microbiology and infection control services at VOLH, with only temporary arrangements in place.

It may well be that a change of political administration in 2007 caused additional delay in a final decision being reached. The new administration decided to subject the proposed changes to independent scrutiny and extensive consultation. It is regrettable that this scrutiny and level of consultation did not take place at an earlier stage. Nevertheless, the result of that whole process was ultimately the development of the “Vision for the Vale” and the retention of the VOLH as a hospital that could perform an important role for the local community.

8.7 Recommendations

Recommendation 5: Scottish Government should ensure that where any uncertainty over the future of any hospital or service exists, resolution of the uncertainty is not delayed any longer than is essential for planning and consultation to take place.

Recommendation 6: Scottish Government should ensure that where major changes in patient services are planned there should be clear and effective plans in place for continuity of safe patient care during the period of planning and change.

Chapter 9

The creation, leadership and
management of the Clyde
Directorate

Introduction

The intention in this Chapter is to consider some limited aspects of the integration process that impact upon the Inquiry's Terms of Reference following upon the dissolution of NHS Argyll and Clyde. It will also examine the approach taken to management and leadership within what became known as the Clyde Acute Directorate, often referred to as the Clyde Directorate.

9.1 The dissolution of NHS Argyll and Clyde

The dissolution decision

The Scottish Parliament Audit Committee's Report on the NHS Argyll and Clyde 2003-04 Annual Accounts,¹ published on 16 March 2005, was highly critical of NHS Argyll and Clyde and its Board. Indeed it was also critical of the then Scottish Executive Health Department (SEHD). On 19 May 2005 the Minister for Health and Community Care, Malcolm Chisholm, announced in a statement to the Scottish Parliament that NHS Argyll and Clyde was to be dissolved. The administrative boundaries of NHS Greater Glasgow (Greater Glasgow Health Board) and NHS Highland were to be changed to allow them to take over responsibility for managing the delivery of health services in the relevant areas of Argyll and Clyde.²

A public consultation took place on what the new administrative boundaries for NHS Greater Glasgow and NHS Highland should be, but not on the actual decision to dissolve.³ Following this, dissolution occurred on 1 April 2006 with the coming into force of the National Health Service (Constitution of Health Boards) (Scotland) Amendment Order 2006.⁴ From that date Greater Glasgow Health Board (GGHB) took over a significant part of NHS Argyll and Clyde's responsibilities. GGHB has since used the descriptive name of NHS Greater Glasgow and Clyde (NHSGCC).

There is no doubt that the process before and after dissolution was a highly complex one. It involved the application of considerable expertise by many of those in senior management positions within NHSGCC.

9.2 Integration

The financial crisis

As explained in the paper prepared for the Inquiry by Mr Thomas Divers, the Chief Executive of NHSGCC from 2001 to 2009, the financial problems of NHS Argyll and Clyde had developed over several years and were acute by the date of dissolution.⁵ In 2004 to 2005 NHS Argyll and Clyde had exceeded its revenue resource limit by almost £30 million, representing 6% of its annual revenue. Health Boards were at that time required to live within their revenue limit, with any expenditure in excess of the limit to be paid back to the SEHD from the following year's allocation. NHS Argyll and Clyde had been unable to pay back sums of overspend, and in four years the cumulative deficit had reached £82 million.

The Minister for Health and Community Care agreed to write off that part of the debt, and asked GGHB to develop a recovery plan to return expenditure in Argyll and Clyde to a balanced position within three years of 1 April 2006. Some further transitional funding was provided to allow time for preparation of a recovery plan and to avoid adverse impact on services to patients during this period.

The integration process up to 30 March 2006

GGHB produced a paper on 14 November 2005 entitled "Integrating Argyll and Clyde: NHS Greater Glasgow Proposals".⁶ It contained a recommendation that all acute services within the Argyll and Clyde areas that were to become the responsibility of GGHB be initially incorporated as a single Directorate of the Acute Division of Greater Glasgow.⁷ The position of this new Clyde Acute Directorate within the overall structure is illustrated by the Acute Services Division Management Structure for November 2007.⁸

1 [INQ05310001](#)

2 [GOV00870007](#)

3 [GOV00870005](#)

4 [INQ05320001](#)

5 [GGC32180002](#)

6 [GGC21480001](#)

7 [GGC21480003](#)

8 [GGC02700001](#)

Mr Divers discusses the options in his paper at paragraph 4.7.⁹ On the one hand, immediate full integration would complete the restructuring process. This would bring with it the perceived benefits of the Greater Glasgow model in ensuring equality of care and resource use. On the other hand, a major programme of restructuring was already being implemented in Greater Glasgow. There was a risk that adding any further restructuring to that might prove unmanageable. In addition, the structured recovery plan that was envisaged in order to achieve “a balanced position”¹⁰ in Clyde would be easier to implement if the budgetary resources of Greater Glasgow and of Clyde were not rolled together in one set of accounts. It was thought too that this arrangement would maintain organisational stability through existing local relationships. The objective was to achieve full integration within three years. Any reference to integration taking place on 1 April 2006 (in the sense that NHS Argyll and Clyde ceased to exist from 1 April 2006) should therefore be understood in that light.

The Transition Steering Group

A group known as the Transition Steering Group was formed in August 2005. The main role of that group, outlined in the minute of its initial meeting on 30 August 2005, was to lead on the development of a Transition and Migration Plan¹¹ to take the existing organisation towards the implementation of the new organisational arrangements. The group was chaired by Mr Divers and met regularly from mid 2005 to mid 2006.

Elizabeth Anne Hawkins was appointed Transition Project Director with effect from 1 November 2005, although by the time of her appointment the project and planning work had been under way for some time.¹² Her principal responsibility was that of staffing arrangements and the reorganisation of managerial posts. She remained with the project until the summer of 2006, but after 1 April 2006 each Directorate was responsible for its own area.¹³

The Inquiry has had sight of a significant number of documents including check lists,¹⁴ plan updates¹⁵ and board papers.¹⁶ These all formed part of an ongoing analysis of the potential effects of integration and the preparation for integration. It is clear, in brief, that extensive and careful preparation was carried out prior to the transition date.

The soundness of the creation of the interim Clyde Acute Directorate

The Inquiry finds that the interim creation of a Clyde Acute Directorate was a sound decision in the circumstances. In his report, Mr Alex Smith, an NHS management expert commissioned by the Inquiry, agreed that it had “obvious merit”.¹⁷ The objective was to identify early opportunities for consolidation of management arrangements across the new Health Board. In the interim, however, this arrangement allowed the newly constituted NHSGGC to address staff concerns and uncertainties following the dissolution of NHS Argyll and Clyde. It also provided an opportunity to consider fully future organisational arrangements.

The integration process from 1 April 2006

As explained previously, NHS Argyll and Clyde was dissolved on 1 April 2006, and the areas identified for incorporation into GGHB became the responsibility of that Board with effect from that date. But the integration process was not then complete, indeed it was not intended to be complete for a further three years, and the Clyde Acute Directorate had only been created as an interim measure. The Clyde Acute Directorate was also in a somewhat anomalous position within the Acute Division as a geographically based directorate, whereas the other directorates within the Division were service based.

The Transition Steering Group continued to meet formally until 23 May 2006.¹⁸ A meeting scheduled for 20 June 2006 did not take place,¹⁹ although by then a separate group was established, known as the Clyde

9 [GGC32180008](#)
10 [GGC32180008](#)
11 [GGC21280001](#)
12 [WTS01800002](#)
13 [WTS01800004](#)

14 [GGC21520001](#); [GGC21920001](#); [GGC21910001](#)
15 [GGC21490001](#)
16 [GGC21890001](#); [GGC18170001](#)
17 [EXP02800006](#)
18 [GGC21970001](#)
19 [GGC21970003](#)

Transition Review Group, which first met on 25 April 2006. NHSGGC have suggested that the Transition Steering Group “became”²⁰ the Transition Review Group, with an emphasis on “service strategies”²¹ and any remaining human resource issues. This was also chaired by Mr Divers, and membership included most of those who had been members of the Transition Steering Group. The minutes of the meeting of 25 April 2006 record its purpose as one of ensuring that:

“all integration matters were managed during the transition period and that a corporate view was taken on the many inter-linked issues which would need to be considered over the coming weeks and months”.²²

At that first meeting on 25 April 2006 the plan appears to have been that there would be five further meetings over the next five months,²³ but in fact the group met on only three further occasions, on 25 May, on 22 June, and finally on 14 September 2006. The agenda for the meeting of 14 September 2006 did raise as an issue the requirement for further meetings,²⁴ although in the minutes it has been noted that a further meeting “should take place late November early December”.²⁵ Apparently such a meeting did take place on 28 November 2006, although no minutes were taken.²⁶ By then of course Mrs den Herder had taken up her position as Director, Clyde Acute Services, NHSGGC, which included chairing the Clyde Acute Senior Management Team.²⁷

It is apparent from the minutes of those three meetings²⁸ of the Clyde Transition Review Group that much of the focus was upon such issues as management, finance and staffing, although by the time of the final meeting many operational matters and patient services issues were also coming under discussion. At the meeting of 25 May 2006

it was noted that the reporting arrangements for infection control nurses had been established through Ms Marie Martin, General Manager, Diagnostics for Clyde.²⁹

Absence of audit

Mr Smith notes the absence of a formal post-implementation independent audit or review. He considers that this would be expected given the extensive transitional arrangements in place for such a major organisational change.³⁰ An internal audit did take place, but the scope of this was limited to:

“an independent high level information gathering exercise to assist management in determining areas of potential for releasing savings within non-clinical areas”.³¹

In essence it was an audit of the cost reduction and efficiency savings programme adopted as part of the recovery plan referred to earlier in this Section.

9.3 Impact of integration on the Vale of Leven Hospital (VOLH)

Consequences for management of infection control

The establishment of the Clyde Acute Directorate meant that infection prevention and control management within that Directorate initially remained separate from infection prevention and control management in the rest of Greater Glasgow. As part of the continuing process of integration, however, in September 2007 the Rehabilitation and Assessment areas of the Clyde Acute Directorate were integrated into the NHSGGC Rehabilitation and Assessment Directorate (RAD).

As a result, from that point Ms Anne Harkness, Director of RAD, became responsible for wards 14, 15 and F at the VOLH.³² Mrs Elizabeth Culshaw, who had been General Manager for Rehabilitation and Assessment within the Clyde Acute Directorate since April 2006, ceased to

20 [GGC33050001](#)

21 [GGC33050001](#)

22 [GGC21990001](#)

23 [GGC21990006](#)

24 [GGC22040001](#)

25 [GGC22050004](#)

26 [GGC33050001](#)

27 [GGC22530001](#)

28 [GGC22010001](#); [GGC22030001](#); [GGC22050001](#)

29 [GGC22010005](#)

30 [EXP02800007](#)

31 [GGC22630009](#)

32 [TRA01180090](#)

be responsible to Mrs den Herder and instead reported to Ms Harkness.³³ Staff in the remaining parts of the Clyde Acute Directorate remained under the management of Mrs den Herder. Included among these was Ms Martin, who had responsibility for infection prevention and control and was also line manager for Dr Elizabeth Biggs, the Infection Control Doctor for the Clyde Sector. It is to be noted that Ms Martin therefore retained the role of line manager for infection prevention and control in the Rehabilitation and Assessment wards.

The Clyde Acute Directorate Infection Control Team remained under separate line management up to Directorate level, but above that level responsibility rested with Mr Robert Calderwood as the Chief Operating Officer of NHSGGC. Furthermore, with the integration into the RAD on 1 September 2007, Ms Harkness had ultimate professional responsibility for infection prevention and control throughout the newly expanded directorate despite not having actual line management responsibility for infection prevention and control staff.³⁴

Implications for infection prevention and control with earlier integration

The problems with infection prevention and control existed long before integration was contemplated. The Inquiry detected no signs that NHS Argyll and Clyde managers had attempted to address in any systematic way the issues raised in either the Clinical Standards Board for Scotland (CSBS) report of 2002,³⁵ published in January 2003, or the follow-up report of 2005.³⁶ These issues are fully considered in Chapter 15, and for present purposes it is sufficient to note that significant failures were identified in 2002 and remained unaddressed in 2005. It is also of note that the Dissolution and Integration Checklist and Risk Log maintained by NHS Argyll and Clyde³⁷ makes no specific mention of infection prevention and control, but does refer to governance issues. Under governance

issues (for the periods both before and after 31 March 2006) it does list:

“loss of control over business as usual (to 31/03/06): – Managers become distracted by requirements of dissolution/integration process”.³⁸

Dr Brian Cowan, Medical Director of the Acute Division of NHSGGC, agreed in his evidence to the Inquiry with the proposition that the establishment and maintenance of a separate Clyde Acute Directorate contributed to the outbreaks going undetected. He said:

“I think....if we had had the Glasgow management team of Isabel Ferguson (General Manager for Laboratory Medicine NHSGGC), Annette Rankin, working as a team, as a group, together with the co-ordinating infection control doctor, looking after the whole of Glasgow and Clyde, that some of the abnormal behaviour, if I could classify it as that, of Dr Biggs and possibly some of the failures to identify raised incidences of *C. difficile* would have been spotted”.³⁹

Dr Cowan believed that full integration at an earlier stage would have resulted in earlier recognition that the Clyde infection prevention and control system was defective. There is little doubt that that is so. Nevertheless, this does not lead the Inquiry to conclude that the decision to establish a separate Clyde Acute Directorate was wrong. Neither was this Dr Cowan’s view, for he agreed with the view expressed by Mr Smith and by Mr Divers that there were sound reasons for it.⁴⁰ So if the establishment of the Clyde Acute Directorate was an acceptable measure in principle, the reasons for the failure in infection prevention and control practices and surveillance must lie elsewhere.

33 [TRA01170008](#)

34 [TRA01180098-99](#); [TRA01160158](#)

35 [QIS00010001](#)

36 [QIS00020001](#)

37 [GGC21520001](#)

38 [GGC21520004](#)

39 [TRA01230016](#)

40 [TRA01230016](#); [GGC32180008](#)

9.4 Leadership of the Clyde Directorate

Experienced leadership

As Mr Smith remarks, the new Clyde Acute Directorate required highly experienced leadership and strong management over a considerable time frame in order to achieve successful integration.⁴¹ In the light of this it was unfortunate that the recruitment process for the Director was delayed. Mrs den Herder was not interviewed until 19 June 2006,⁴² and only took up post formally on 1 October 2006,⁴³ although she chaired at least one Directorate meeting in September 2006.⁴⁴ To fill the gap, Ms Karen Murray was appointed interim Director from 1 April 2006, but she departed to a new post on 31 July 2006.

Karen Murray

Ms Murray was well acquainted with the issues surrounding service provision at the VOLH from previous roles within NHS Argyll and Clyde. In 2003 she became the Divisional Director for Lomond and Argyll, a post which gave her line management responsibility for the hospital manager at the VOLH.⁴⁵ She had a sound understanding of the issues surrounding service provision at the VOLH, having prepared a paper on the future of anaesthetic services there for NHS Argyll and Clyde in 2004.⁴⁶

On 25 July, prior to her departure, Ms Murray provided a detailed list of handover issues to Mr Calderwood.⁴⁷ She also provided an updated document the following month.⁴⁸ The list covers 28 issues, some broken down into separate sections. These include staffing, management processes, financial planning, and performance management. A number of issues are directly concerned with patient care, such as the Lomond Integrated Care Pilot and waiting times, although infection prevention and control does not feature as a specific item on the list. The Lomond Integrated Care Pilot is discussed in Chapter 8.

Item one on the handover list records that seven reports had been completed for Clyde. On 9 January 2006, Dr Elizabeth Jordan, then Medical Director, NHS Argyll and Clyde, produced an end of year report on the work of the NHS Argyll and Clyde Healthcare Governance Committee.⁴⁹ The intention of the report was to provide an end of year position statement to NHS Greater Glasgow and NHS Highland on the Healthcare Governance position within NHS Argyll and Clyde.⁵⁰ It explained that the Healthcare Governance Committee discharged its function in 2005 to 2006 in terms of national guidance, and effectively operated as a committee of assurance for the NHS Argyll and Clyde Board.⁵¹ The report also noted that responsibility for Healthcare Governance accountability would pass to the new organisation, and set out priority transitional work plans for this process.⁵² Mr Smith described this report as a:

“summary of activities over the year; risk registers, key ongoing issues/work and issues to be considered for inclusion in the future work programme”.⁵³

He saw this handover as intended to ensure “safe and comprehensive continuity of governance and accountability with effect from 1 April 2006”.⁵⁴

Following Ms Murray’s departure, no further interim Director was appointed in her place. Instead, responsibilities were passed to individual Directorate General Managers, who reported direct to Mr Calderwood.⁵⁵ This meant that continuity of leadership was missing during this period of transition.

9.5 The leadership of Mrs den Herder

According to Mr Calderwood, no formal documented handover to Mrs den Herder took place on her appointment.⁵⁶ He used the document supplied by Ms Murray to brief

41 [EXP02800005-06](#)

42 [TRA01240032](#)

43 [TRA01240047](#); [TRA01240033](#)

44 [GGC32820001](#)

45 [WTS01960002](#)

46 [WTS01960002](#)

47 [GGC21860001](#)

48 [GGC21860008](#)

49 [GGC21570001](#)

50 [GGC21570003](#)

51 [GGC21570003](#)

52 [GGC21570006](#)

53 [EXP02800011](#)

54 [EXP02800011](#)

55 [TRA01240034](#)

56 [TRA01240048](#)

Mrs den Herder, as Mrs den Herder herself confirms.⁵⁷ It appears that Ms Murray may also have participated in a brief handover.⁵⁸ As part of her induction to the organisation, it does appear that Mrs den Herder would in addition have had meetings with Directors and other key staff to discuss their roles and responsibilities.⁵⁹ She would also have had available to her the reports on Clyde including Dr Jordan's end of year report and the minutes of the Transition Steering and Review Groups.

Furthermore, at the meeting of the Clyde Acute Operational Management Group on 24 August 2006⁶⁰ (referred to erroneously in the action notes as the meeting of 29 August 2006) the items in the Clyde handover list of issues were considered individually and updated. This group became the Clyde Acute Senior Management Team after Mrs den Herder was in post. Mrs den Herder chaired the next meeting of the group on 21 September 2006, at which the action notes from the meeting of 24 August 2006 were considered.⁶¹

Mrs den Herder's concerns

According to Mrs den Herder, she was aware of the risk to patient safety at the VOLH even before she took up post, through attendance at a number of meetings.⁶² She certainly lost no time in identifying the need for effective management at the VOLH, because the minutes of the second meeting she attended as Chair of the Clyde Acute Senior Management Team, on 19 October 2006, record that she:

“indicated that there is a need for more concentrated Senior Management Team representation on VOL site”.⁶³

Mrs den Herder later became sufficiently concerned to present a paper in February 2008 to the Acute Management Team: “The Vale of Leven Hospital – Maintaining Patient

Safety”,⁶⁴ in which she articulated a number of live concerns over staffing and patient safety. This led to the establishment of the Vale of Leven Governance Group,⁶⁵ which met monthly from April 2008.⁶⁶ The concerns expressed by Mrs den Herder, however, related to levels of staffing – both medical and nursing – and to patient care, particularly in relation to the range of services available and the transfer of patients. They did not extend to infection prevention and control issues.

The restricted range of Mrs den Herder's concerns is reflected in the notes of the new Governance Group itself.⁶⁷ Only two meetings of that group took place prior to June 2008,⁶⁸ and the subject of infection prevention and control does not appear to have featured at those meetings, although mention is made of the outbreak in the action notes for the meeting of 20 June 2008.⁶⁹ Indeed in both her letters to the Inquiry of 22 June 2012⁷⁰ and later on 13 September 2012⁷¹ Mrs den Herder makes clear that the principal issue for senior managers at the time was that of the safety of medical receiving arrangements for unscheduled medical care.

It is surprising that, despite such concerns and her specific observations about a senior management presence, Mrs den Herder herself was not often at the VOLH.⁷² Mr Calderwood expected that she would attend the VOLH “on a relatively regular basis”.⁷³ On the other hand, she had a wide range of responsibilities, and there was other management presence there. Ms Martin, for example, was normally there once a week, at least until her secondment.⁷⁴

57 [INQ04960003](#)
58 [WTS01960004](#)
59 [GGC33060001](#)
60 [GGC22950001](#)
61 [GGC32820001](#)
62 [INQ04960001](#)
63 [GGC22530006](#)

64 [GGC04520001](#)
65 [INQ04480001](#)
66 [GGC04490002](#)
67 [GGC30420001](#); [GGC30430001](#); [GGC30440001](#)
68 [GGC30420001](#); [GGC30440001](#)
69 [GGC30430002](#)
70 [INQ04240003](#)
71 [INQ04960005](#)
72 [GOV00890120](#)
73 [TRA01240046-47](#)
74 [TRA01160007](#)

Ms Harkness said this of a manager's responsibilities:

"I think, as a director responsible for a service as large as mine, the degree to which I can get out and about at individual ward level is inevitably limited, but I would accept it is something I would expect managers to do. They should be out proactively talking to staff and they should be picking up issues, both through informal and formal structures, and the formal governance and committee structure is very much that: it is formal, it is about making sure actions have been taken and noting that. You would expect that to be enhanced by operational discussions".⁷⁵

Mrs den Herder mentions in her letter of 22 June 2012 that she first received statistical data about infection rates in May 2008.⁷⁶ She does not suggest that she had sought such information previously. Nor had she sought any audit of infection prevention and control systems.⁷⁷

Within a number of months of taking up post Mrs den Herder should have been fully cognisant of the critical issues within the Clyde Acute Directorate. She had certainly recognised one of these – the need for effective management – at an early stage. Later she recognised the risks to patient safety at the VOLH. Although it did not happen until early 2008, she took appropriate steps in instigating the establishment of the VOLH Governance Group to monitor these. It concentrated on issues such as the safety of the Lomond Integrated Care Model referred to in Chapter 8 and on transfer to other hospitals.

Failures in leadership

Why Mrs den Herder did not afford greater priority to infection prevention and control remains without a satisfactory answer. Her performance plan for 2006 to 2007 does make reference to healthcare acquired infection (HAI), although this is in the context of ensuring that action plans are in place following outbreaks and environmental audits

and of monitoring the overall incidence of HAI within surgical areas.⁷⁸ Perhaps more significantly, her Personal Objectives for 2007 to 2008 include the following objective:

"Reinforce surveillance arrangements within Clyde to reduce the number of patients acquiring HAI with particular emphasis on tackling the incidence of MRA bacteraemia throughout the year".⁷⁹

There is no evidence that any action was taken in response to that objective in the VOLH prior to the introduction of Statistical Process Control (SPC) charts in April/May 2008.

The role of the Infection Control Manager for NHSGGC within the Clyde Acute Directorate is examined in Chapter 15. As discussed in Chapter 10, however, Mrs den Herder retained responsibility for infection prevention and control within her Directorate, and was answerable to Mr Calderwood.⁸⁰ Despite that, she had no apparent awareness of infection prevention and control issues, or the management of these, or of the steps being taken to monitor infection levels. She describes the "managerial focus on the large financial deficit and the projects intended to address this...".⁸¹ She did of course identify the importance of certain patient safety issues to the extent of establishing the Vale of Leven Governance Group, but its focus was not infection prevention and control. The Inquiry notes too that infection prevention and control issues, other than staffing issues, do not feature prominently in the letters it received from Mrs den Herder. These letters do not suggest that wider infection control issues were a high priority for her. She was, for example, unaware that the Clyde Infection Control Support Group (the Support Group) had ceased to meet.⁸²

There is no doubt that, in this as well as in other aspects of her work, Mrs den Herder was let down by other members of her management team, who should have noted the failure of the Support Group. But

75 [TRA01180112-113](#)

76 [INQ04240004](#)

77 [INQ04960003](#)

78 [GGC21930006](#)

79 [GGC24320014](#)

80 [TRA01240052-53](#)

81 [INQ04960005](#)

82 [INQ04960006](#)

given her responsibilities she should have exercised greater scrutiny of the structures in place. She should have been in a position to identify the fact that crucial meetings had ceased to take place. She should have identified the critical state of affairs in infection prevention and control.

Unfortunately, Mrs den Herder's limited engagement with infection prevention and control also meant that she did not have a full grasp of the impact of Dr Biggs' behaviour on infection prevention and control and patient safety within the Clyde Acute Directorate. As she explained in her letter of 13 September 2012, the "key failures" were not known to her.⁸³ Again in this she was let down by others, but she had ultimate responsibility for infection prevention and control in the Directorate. Had she taken a greater interest in infection prevention and control matters she would have had a better grasp of the true position.

This limited engagement with infection prevention and control is likely to have contributed to a failure on the part of Mrs den Herder to ensure that Ms Martin's infection prevention and control duties continued to be carried out to the full during her secondment. The circumstances surrounding that secondment are fully explained in Chapter 15. Mrs den Herder wrote on 8 October 2007 to "all staff, Clyde Laboratory Services" concerning the secondment, and in that letter she intimates that Ms Martin had agreed to lead the implementation of the Picture Archiving and Communications System (PACS) within Clyde. She continues:

"I recognise that Marie will require to be supported in various aspects of her management role to provide sufficient time to enable her to undertake the PACS work".⁸⁴

Despite this, no evidence was produced to the Inquiry to suggest that the necessary level of support was forthcoming. Mrs den Herder must have been aware that the solution – that Ms Martin should retain responsibility for infection control issues in

the absence of cover from elsewhere – was an unsatisfactory one. It required careful management. It was a matter which, as Director, she should have kept under careful scrutiny in order to reassure herself that infection control issues were accorded the attention they needed. In this case she owed a particular duty to Ms Martin and to others in the Clyde Acute Directorate to set out in writing which responsibilities remained with Ms Martin and who would undertake those of which she had been relieved. That is to be expected of a competent senior manager.

As Mrs den Herder points out,⁸⁵ and as Mr Calderwood accepts,⁸⁶ the Clyde Acute Directorate was not directly comparable with other Directorates within NHSGCC. Because it was geographically defined rather than service based, the range of services for which she was responsible, and the targets introduced in relation to some of these, proved a considerable burden. Mr Calderwood acknowledges that, whereas other Directors would be accountable for a restricted number of HEAT Targets, she was responsible for all such targets within Clyde.⁸⁷ Indeed he likened her role with its range of clinical services to his own position at that time as Chief Operating Officer.⁸⁸

The Inquiry finds it unnecessary to express a view on whether Mrs den Herder's post was overloaded with responsibility. But as Mr Calderwood concedes, Mrs den Herder was "carrying a significant responsibility".⁸⁹ This was against the following background:

- The disadvantages faced by Mrs den Herder coming into post six months after the dissolution of NHS Argyll and Clyde
- Demands placed on Mrs den Herder in relation to a multiplicity of targets
- The outstanding issues over VOLH services
- Failure by a number of other managers within Clyde Directorate reporting to Mrs den Herder to give infection prevention and control issues the level of attention required

83 [INQ04960003](#)

84 [GGC32630001](#)

85 [INQ04240003](#)

86 [TRA01240049](#)

87 [TRA01240049-50](#)

88 [TRA01240043](#)

89 [TRA01240050](#)

It is therefore perhaps unsurprising that Mrs den Herder did not **initially** give priority to infection prevention and control at the VOLH. But she had the opportunity over a number of months to identify and familiarise herself with the critical issues facing the Clyde Acute Directorate. She should therefore have been in a position in the course of 2007 to acquaint herself with the outstanding deficiencies in the management of infection prevention and control and to tackle them.

Mrs den Herder resigned her post in July 2008 at least in part because of “stress and burnout”.⁹⁰ Mr Calderwood confirmed in evidence that Mrs den Herder told him in April 2008 that she wanted to leave her post earlier than had originally been envisaged,⁹¹ and that stress was one of the reasons why she wanted to leave.⁹² Inevitably such stress levels would have had an effect upon her performance as Director of the Clyde Acute Directorate.

9.6 Other managers in the Clyde Directorate

Marie Martin’s management role

The working relationship between Ms Martin and Dr Biggs in particular is considered in greater detail in Chapter 15. This Chapter seeks only to examine certain aspects of Ms Martin’s management role.

Ms Martin reported to Mrs den Herder. She was responsible for laboratories and radiology, and her remit included infection prevention and control.⁹³ She was line manager for Ms Annette Rankin, Head Infection Control Nurse for NHSGGC. On her own admission, Ms Martin was clearly heavily reliant upon Infection Control Doctors and Nurses alerting her to any problem. In her own words, “they were the people who really understood”.⁹⁴ An example of this is that she was not aware of any problem over wash-hand basins until Dr Linda Bagrade took up post as Infection Control Doctor at the VOLH in February 2008, because no one had previously brought it to her attention.⁹⁵

Ms Martin was also line manager for Dr Biggs from April 2006,⁹⁶ and would see Dr Biggs once or twice a month. Yet she was unaware that Dr Biggs had no job description as Infection Control Doctor until September 2007.⁹⁷ The background to this is explored in Chapter 15.

In her evidence Ms Martin explained that she thought that Dr François de Villiers, Consultant Microbiologist at the IRH, had responsibility as Infection Control Doctor at the VOLH. This again is considered in greater detail in Chapter 15, but it was not the case. Her lack of understanding of this area of responsibility, despite also being line manager for Dr de Villiers, is a matter of concern.

While Ms Martin had some awareness of the monitoring of infection carried out by Infection Control Nurses, and knew of the T-card system and database described in Chapter 15,⁹⁸ she was not aware of how *C. difficile* cases were recorded at ward level or how they were monitored.⁹⁹ To a degree that may reflect the fact that there was no requirement to report such figures upwards through the management structure (as was the case with MRSA).¹⁰⁰ Nevertheless, it remains of concern to the Inquiry that the General Manager with responsibility for infection prevention and control had such a limited grasp of monitoring arrangements. It is worthy of note that included in her Personal Objectives for 2007 to 2008 was the following objective:

“Provide audit information on Hospital Surveillance across Clyde and action plan required to address Hospital acquired infection rates ...”¹⁰¹

Melanie McColgan

The Clinical Service Manager for Clyde Acute Directorate from January 2008 was Ms Melanie McColgan. While not based at the VOLH, she attended there regularly, usually one day a week. Her responsibilities

90 [INQ04240005](#)

91 [TRA01240050](#)

92 [TRA01240051-52](#)

93 [TRA01160001](#)

94 [TRA01160018](#)

95 [TRA01160077](#)

96 [TRA01160033](#)

97 [TRA01160033](#)

98 [TRA01160106](#)

99 [WTS00810009](#)

100 [TRA01160102-103](#)

101 [GGC24360010](#)

encompassed wards 3, 6 and the Critical Care Unit (CCU).¹⁰² Her job description included responsibility:

“for ensuring robust and auditable systems are in place to enable the successful monitoring of performance and the early identification of problem areas within the Directorate”.¹⁰³

She saw her responsibilities for infection control as part of her wider governance responsibilities. She would have taken action had any issues been brought to her attention.¹⁰⁴

Infection prevention and control was not on the agenda of operational meetings Ms McColgan attended.¹⁰⁵ She did not know who the Infection Control Doctor was during her early period at the VOLH.¹⁰⁶ She was concerned about norovirus rates, because these were brought to her attention, but she took no steps to check infection rates for CDI or to check that proper infection prevention and control systems were in place.¹⁰⁷ She believed they were, because she was receiving information about norovirus. She did not visit the Infection Control Team office, and did not know what she would have found there.¹⁰⁸ From June 2008 she received infection prevention and control audits.¹⁰⁹

As pointed out, Ms McColgan took up her post in January 2008. It is clear she took much at face value in the period initially following this, and relied upon systems being in place. At that stage she had little alternative, and the Inquiry does not criticise her for adopting that approach. Had she been longer in post, however, the Inquiry would have expected her to be more familiar with systems in place and to have identified issues of concern, and to place less reliance on being told what was wrong when it went wrong.

Elizabeth Culshaw

Mrs Culshaw was General Manager for the Rehabilitation and Assessment areas within the Clyde Acute Directorate from April 2006. Responsibility for this area of work passed to RAD in September 2007, and Mrs Culshaw then reported to Ms Harkness rather than to Mrs den Herder,¹¹⁰ but her job did not change.

Mrs Culshaw had responsibilities across five hospital sites within Clyde, including wards 14, 15 and F at the VOLH.¹¹¹ Among the responsibilities set out in her job description was to:

“ensure the delivery of high quality patient care, taking account of standards and guidance including hospital acquired infection”.¹¹²

Mrs Culshaw was not based at the VOLH, and her direct contact with wards there was through Ms Elizabeth Rawle, Lead Nurse for the Rehabilitation and Assessment Directorate.¹¹³ Mrs Culshaw explained during her evidence that her duty was to be aware of underlying issues or trends, but that her responsibilities for infection prevention and control were “indirect”.¹¹⁴ She had no contact with the Infection Control Team. She only became involved if and when there was an issue. Infection prevention and control was not a standing item on the agenda of the RAD Senior Management Team prior to June 2008.

Mrs Culshaw was aware of cases of CDI, but she took no active steps to ascertain the level of the problem because it was not highlighted to her as an issue by anyone else.¹¹⁵ Her “understanding” was that the reporting systems were not in place and data were unavailable.¹¹⁶ She was unaware that the data were in fact available at the VOLH.¹¹⁷

Mrs Culshaw unfortunately relied simply on being told that there was a specific problem over infection prevention and control. Even

102 [TRA01170018](#)

103 [GGC30240003](#)

104 [TRA01170019](#)

105 [TRA01170021](#)

106 [TRA01170035](#)

107 [TRA01170028-29](#)

108 [TRA01170051-52](#)

109 [TRA01170043](#)

110 [TRA01160128](#)

111 [TRA01160129](#)

112 [GGC30280003](#)

113 [TRA01160131](#)

114 [TRA01160140-142](#)

115 [TRA01160149-150](#)

116 [TRA01160144-145](#)

117 [TRA01160145](#)

when she was informed, her response was limited. On 15 March 2007, in the context of an outbreak of CDI in ward 7 at the RAH, she was alerted by Dr Syed Ahmed, Consultant in Public Health Medicine and Clinical Consultant in the Public Health Protection Unit, NHSGGC,¹¹⁸ to an audit report that “basic infection control principles are not being followed rigorously.” She in turn alerted managers at that hospital, but did not think to check the position at the VOLH. Asked to explain her reasons, she provided the following explanation:

“Because this was highlighting a particular issue in a particular ward, that there had been an outbreak of *C. difficile*, so I addressed the issues there rather than on other sites”.¹¹⁹

Unfortunately the Inquiry heard evidence of another instance, this time at the VOLH, where Mrs Culshaw did not pursue the matter beyond the immediate issue in question. When dealing with a letter of complaint in January 2008 involving a patient suffering from CDI at the VOLH, she did not raise the question of whether there were other cases at the same time. Her explanation for this during her evidence was that no one mentioned other cases to her.¹²⁰

The Inquiry would have expected a competent manager with the responsibilities of Mrs Culshaw to make further enquiries in both instances, particularly since one of the objectives in her list of Personal Objectives for 2007 to 2008 was to “Ensure robust measures [were] in place to prioritise HAI within Clyde RAD”.¹²¹ The absence of data in itself should have been a warning to Mrs Culshaw of potential problems. But she did not pursue this further, and made no enquiry to ascertain the number of cases involved. She did not take active steps to inform herself. Had she done so she would have discovered that such data could in fact be found on the computer system.

Elizabeth Rawle

Ms Rawle was Clinical Services Manager/Lead Nurse in RAD, based at the VOLH. She had a clinical responsibility to deliver rehabilitation services.¹²² She was quite regularly on the wards. She was aware of raised rates of CDI, and in particular of a cluster of cases in January or February 2008, but she was told by Sister Laura Gargaro, Senior Charge Nurse in ward F, that this was “explainable”.¹²³ Ms Rawle did not know who the Infection Control Doctor at the VOLH was in 2007 to 2008 and had never met her.¹²⁴ She saw no reason to discuss CDI with Mrs Culshaw because, as she said in her evidence, “there was *C. difficile* in all of the hospitals”.¹²⁵

Had Ms Rawle been better informed, or had she pursued matters further by posing certain pertinent questions, the outbreak at VOLH early in 2008 might well have been identified sooner. But her limited understanding of the seriousness of CDI led her not to challenge Sister Gargaro, and gave her no reason to involve Mrs Culshaw. Her attitude reflected a general approach to infection prevention and control that placed exclusive reliance on the Infection Control Nurses. It is worth recalling here that the “Annual Infection Control Report 2007/08” for NHSGGC contains the following statement:

“Good practice in Infection Prevention and Control clearly does not rest solely within the domains of our Infection Control Committees and Teams. Everyone has Infection Prevention and Control responsibilities”.¹²⁶

Management and Dr Biggs

The role of Dr Biggs is examined in detail in Chapter 15 and is only considered here in relation to the managers with whom she interacted professionally.

It was apparent to a number of managers that Dr Biggs was discontented with her position as Infection Control Doctor. More importantly, it should have become apparent that she was

118 [GGC15450001](#)

119 [TRA01170005-06](#)

120 [TRA01160154](#)

121 [GGC24370011](#)

122 [TRA00890086-87](#)

123 [TRA00890106](#)

124 [TRA00890101](#)

125 [TRA00890104](#)

126 [COF00030003](#)

not fulfilling that role. With the departure of Dr Geoffrey Douglas, Consultant Anaesthetist and Clinical Lead at the VOLH, in April 2006 there was no Clinical Director to exercise oversight of her as he had done.¹²⁷ Line management responsibility remained with Ms Martin,¹²⁸ but due to her lack of attention to infection control matters she did not play an effective role. Dr Biggs' attempts to raise the issues which she thought affected her role as Infection Control Doctor were largely unsuccessful.

As discussed in Chapter 15, Dr Biggs' position was clearly a dysfunctional one. The period from April 2006 onwards was a critical one for Clyde, and management systems needed to be in place and fully functioning to address any problems. This was a key issue for infection prevention and control, and it was not dealt with effectively by management over an extended period.

9.7 Conclusion

The integration process

It is impractical, even with the benefit of hindsight, to conclude with any certainty that specific aspects of the integration process were crucial to the outbreaks of CDI at the VOLH or to the failure to identify them.

There is little doubt that in certain respects the integration process was carefully planned and that the necessary management structures were in place. The Inquiry accepts the views of Mr Divers¹²⁹ and Dr Cowan,¹³⁰ that the decision to establish a separate Clyde Acute Directorate as part of the integration process was, in principle, a sound one. These are views supported by Mr Smith's report to the Inquiry.¹³¹

The Inquiry endorses the view expressed in Mr Smith's report that a post-implementation audit or review by an independent party would have been desirable.¹³² What the outcome of any such review would have

been in late 2006 cannot be ascertained, as the Inquiry has not scrutinised the infection prevention and control position in the VOLH prior to January 2007. Nonetheless it is at least possible that the CSBS report of 2002 (published in January 2003)¹³³ and the follow-up report of 2005,¹³⁴ both of which highlighted glaring deficiencies in infection prevention and control in Argyll and Clyde, would have prompted some further investigation.

Leadership

What is clear is that the Clyde Acute Directorate suffered from a lack of continuity of leadership through its initial stages. In his report Mr Smith remarks upon the significance of the leadership of the Directorate in terms of the new organisational arrangements.¹³⁵ The appointment of an interim director, and the lack of any individual in that post for two months during August and September 2006 after Ms Murray's departure, are matters that were not conducive to strong leadership. Mr Smith identified the need for:

“highly experienced leadership and strong management in the Clyde Directorate over a considerable time frame reflecting the complexity, sensitivity and challenge of the transition”.¹³⁶

It is unfortunate that the permanent Director for Clyde was not in place at least from 1 April 2006.

Had a permanent Director been in place earlier, then it is at least possible that clinical governance and infection prevention and control issues would have come to the attention of the Director and to other senior managers at an earlier stage. It is by no means certain that these issues would have been recognised at an early stage by Mrs den Herder, given her failure to identify them in the months after she took up post. Even so, the lack of continuity in management was a failure in the integration process after 1 April 2006, particularly since, as Mr Calderwood

127 [TRA01160014-15](#)

128 [TRA01260045](#)

129 [GGC32180007-08](#)

130 [TRA01230016](#)

131 [EXP02800006](#)

132 [EXP02800007](#)

133 [QIS00010001](#)

134 [QIS00020001](#)

135 [EXP02800008](#)

136 [EXP02800005](#)

acknowledged, the post was one where Mrs den Herder was “carrying a significant responsibility”.¹³⁷ This included achieving certain targets in a number of different areas because her directorate was a geographical one in contrast to other directorates, which were service based.

As discussed earlier in this Chapter, it is evident that Mrs den Herder failed to afford sufficient priority to infection prevention and control issues after she became Director of the Clyde Acute Directorate. The infection prevention and control system broke down with a failure of the committee structure and a dysfunctional Infection Control Doctor. These were issues Mrs den Herder should have become aware of and dealt with.

Role of other managers

The managerial role played by Ms Martin in relation to infection prevention and control, and her failures in that role, are considered in Chapter 15.

A number of other managers had infection prevention and control responsibilities at the VOLH. Unfortunately, as evidenced earlier in this Chapter, in many instances managers in Clyde did not see infection control as an issue with which they should be routinely engaged. They tended to wait to be told that a problem existed. They did not understand surveillance systems and did not take the steps to be reasonably expected of a manager to inform themselves. They had a limited understanding of infection prevention and control issues.

This management approach to infection prevention and control is but a further manifestation of a culture that viewed infection prevention and control as being of low priority, notwithstanding NHSGGC’s statement in the 2007/08 Annual Infection Control Report that everyone had infection prevention and control responsibilities. Ultimately, the Board of NHSGGC has to bear responsibility for the development of this culture.

Had these managers been more knowledgeable, and had they been more proactive within their own spheres of responsibility, it is likely that they would have found that CDI rates were indicative of a CDI problem in the VOLH. They might have also discovered that essential infection prevention and control measures were not in place.

9.8 Recommendations

Recommendation 7: In any major structural reorganisation in the NHS in Scotland a due diligence process including risk assessment should be undertaken by the Board or Boards responsible for all patient services before the reorganisation takes place. Subsequent to that reorganisation regular reviews of the process should be conducted to assess its impact upon patient services, up to the point at which the new structure is fully operational. The review process should include an independent audit.

Recommendation 8: In any major structural reorganisation in the NHS in Scotland the Board or Boards responsible should ensure that an effective and stable management structure is in place for the success of the project and the maintenance of patient safety throughout the process.

137 [TRA01240050](#)

Chapter 10

Clinical governance

Introduction

This Chapter examines what is involved in the term “clinical governance” by reference to national policy and policy developed by NHS Greater Glasgow and Clyde (NHSGGC), and considers the impact of NHSGGC’s approach to clinical governance upon the occurrence and rates of *C. difficile* infection (CDI) at the Vale of Leven Hospital (VOLH).

10.1 National policy

The concept of clinical governance

A natural starting point is to examine what is said on clinical governance in national policy. In October 2005 NHS Quality Improvement Scotland (NHS QIS) published a document entitled “Clinical Governance and Risk Management: achieving safe, effective, patient-focused care and services”.¹ One of the purposes of this publication was to set national standards for clinical governance for Health Boards across Scotland, a matter for which NHS QIS was responsible.² Clinical Governance is defined in this document as:

“the system through which NHS organisations are accountable for continuously monitoring and improving the quality of their services and safeguarding high standards of patient-focused care and services”.³

The NHS QIS publication also provides the following explanation by way of background:

“The concept of clinical governance was introduced to NHSScotland in the Scottish Executive white paper *Designed to Care* (SEHD, 1997) to ensure that quality of care is given the same prominence as other key drivers such as finance and staffing. It has been described as “corporate accountability for clinical performance” and is the system for making sure that healthcare is safe and effective, and that patients and the public are involved”.⁴

Quality assurance

The NHS QIS document makes the need for monitoring clear. The standards for clinical

governance and quality assurance set out there include the following requirement:

“There are effective organisational systems and processes for monitoring and reporting on the effectiveness of quality assurance and improvement processes at individual, team, operational unit/ service (i.e. community health partnership, divisions) and corporate levels”.⁵

Policing the standards

NHS QIS introduced a review process that consisted of a number of key parts. First, there was to be local self-assessment by Boards. Second, a pre-visit analysis report was produced by NHS QIS after the self-assessment had been received, and given to the particular Board for comment. Third, once the analysis report had been agreed, that report was sent to an external peer review team (the review team) together with the self-assessment and supporting evidence.⁶ Thereafter, the review team visited the Board and spoke to local stakeholders, for example staff, about the services provided.

The review team combined several separate areas of expertise and was led by an experienced reviewer. The team included healthcare professionals and members of the public. Team members had no connection with the Board under review.

NHSGGC was reviewed in the second half of 2006, with a Review visit taking place on 27 September 2006,⁷ and the NHS QIS report of the findings of the peer review was published in April 2007.⁸ Overall, in its assessment of assurance and accountability, the review team saw evidence of much work under way “to drive the clinical governance and quality assurance agenda”.⁹ It did, however, note that at the time of the visit:

“clinical governance and quality assurance systems and processes were not monitored throughout the Board area”.¹⁰

1 [INQ04970001](#)

2 [INQ04970009](#)

3 [INQ04970008](#)

4 [INQ04970009](#)

5 [INQ04970018](#)

6 [INQ04970007](#)

7 [QIS02560032](#)

8 [QIS02560001](#)

9 [QIS02560014](#)

10 [QIS02560025](#)

10.2 Clinical governance in NHS Greater Glasgow and Clyde

NHS Greater Glasgow and Clyde policy

In December 2006 NHSGGC produced a Clinical Governance Framework document setting out its main commitments, general policy requirements and organisational arrangements on clinical governance.¹¹ In this, clinical governance was defined and the concept explained in the following terms:¹²

“By ‘clinical governance’ we basically mean putting in place effective arrangements to improve public and staff confidence in the safety and quality of the health care that we provide. At NHS Greater Glasgow and Clyde...we will show that improving the safety and quality of the care we provide is an important concern for all our staff and everyone who works with us”.

The Clinical Governance Framework document went on to emphasise the importance of putting and keeping in place monitoring arrangements in order to improve the quality of health care provided.¹³

Clinical governance is not part of operational management. Ms Anne Harkness, Director of the Rehabilitation and Assessment Directorate, was asked in the course of her evidence at the Inquiry’s public hearings to distinguish the two. She explained:

“We would use the term ‘governance’ to describe the kind of high-level systems and processes that you would have in place to check that actions were being taken and to report that back as part of a routine process”.¹⁴

She went on to explain that operational management would include the day to day involvement with patients, and in the context of cases of CDI the monitoring of the number of cases in a ward.¹⁵

In summary, then, the underlying aim of clinical governance is patient safety and good

quality care. In practical terms it is about systems – systems of monitoring and of reporting.

Accountability

The Clinical Governance Framework document also sets out responsibility for the delivery of clinical governance in the following way:

“The Chief Executive has overall responsibility for making sure that we deliver clinical governance and will carry out this responsibility by delegating to our general managers”.¹⁶

A committee known as the Clinical Governance Committee (CG Committee) was to be integral to the delivery of clinical governance. It was to be that Committee’s responsibility to oversee the Clinical Governance Framework and assure the NHSGGC Board that it was working effectively. The Committee was also to ensure that appropriate systems were in place for monitoring the clinical governance arrangements.¹⁷ Further details on the CG Committee’s role is set out in the next Section (10.3).

The key role to be played by management was described as follows:

“Clinical governance responsibilities are a specific part of the role of our senior staff, directors and other general managers. These specific responsibilities are set out clearly in their job descriptions”.¹⁸

More detailed policy

Along with the Clinical Governance Framework document NHSGGC published a more detailed policy in December 2006 in a document entitled the Clinical Governance Strategy and Framework.¹⁹ This was described as:

“the policy and guidance that our organisation will use to meet the requirements of our clinical governance framework”.²⁰

11 [GGC18510001](#)

12 [GGC18510001](#)

13 [GGC18510001](#)

14 [TRA01190001](#)

15 [TRA01190004-05](#)

16 [GGC18510002](#)

17 [GGC18510002](#)

18 [GGC18510002](#)

19 [GGC18460001](#)

20 [GGC18510001](#)

The scheme of accountability set out there was more detailed. That document repeated that the Chief Executive was charged with overall responsibility for the delivery of clinical governance, while within the Acute Services Division accountability for the delivery of clinical governance rested with the Chief Operating Officer.²¹

The document also emphasised that responsibility for clinical governance was to be an explicit component of the role played by senior staff, with that responsibility clearly defined in job descriptions.²² While responsibility in the first instance lay with general management, this was to be supplemented by the Clinical Governance Implementation Group (the CG Implementation Group), linked to the oversight role of the CG Committee, and assurance provided using the following means:

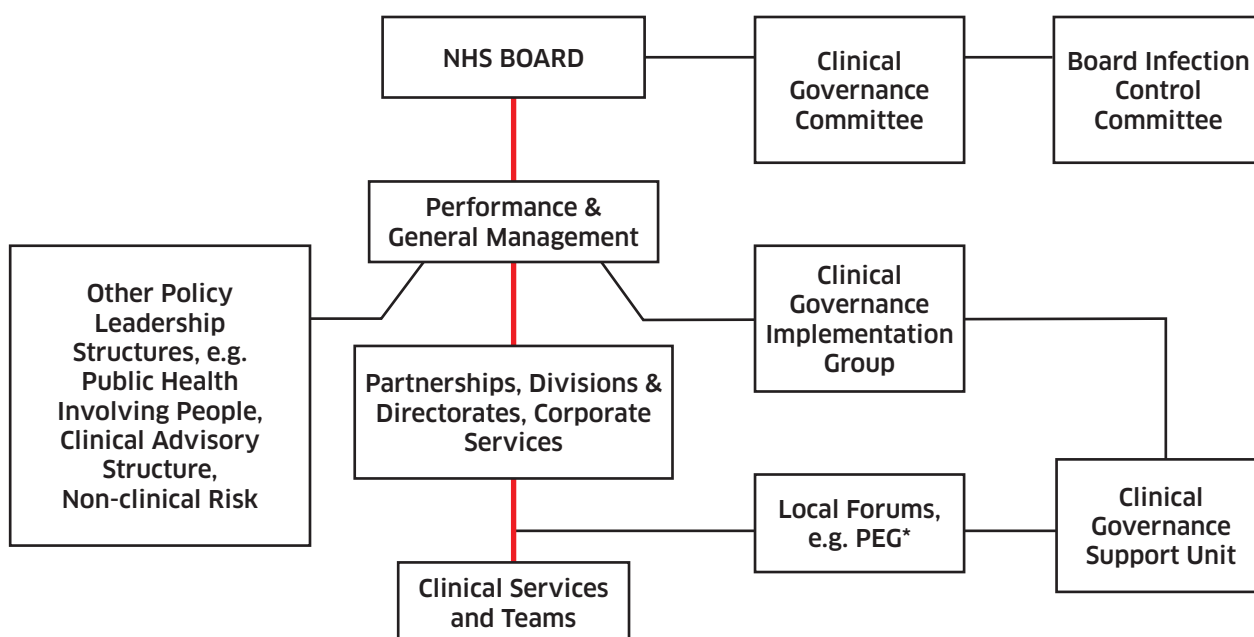
- The CG Implementation Group and CG Committee would obtain assurance on the standards of clinical quality through reports from clinical services and their supports

- Monitoring reports reviewing progress against local clinical governance development plans would be co-ordinated through the CG Implementation Group
- The Acute Services Division and Partnerships were to ensure regular reports reflecting progress and clinical governance activity were published
- A variety of other internal and external mechanisms would be used to monitor and review the effectiveness of clinical governance²³

A Clinical Governance Support Unit was charged with providing specialist advice and practical support in the development of safer and more effective care. This group was to work closely with clinical services.²⁴

Figure 10.1 has been derived from the “Clinical Governance Strategy and Framework”²⁵ document to display the structure.

Figure 10.1 Clinical Governance Structure



*PEG – Professional Executive Group

21 [GGC18460007](#)
 22 [GGC18460007](#)

23 [GGC18460010](#)
 24 [GGC18460008](#)
 25 [GGC18460006](#)

Figure 10.1 expresses the primary line of accountability for quality of care through general management arrangements. This is represented here by the red line. The Clinical Governance Strategy and Framework document describes this as the “core structure of accountability”, but one supported by “extended structures”.²⁶

10.3 Clinical governance structures at divisional level

Number of directorates

Responsibility for the Clyde Acute Directorate and the Rehabilitation and Assessment Directorate lay within the Acute Services Division of NHSGGC of which they formed part. In 2007 to 2008 there was a total of nine directorates in the Acute Services Division.²⁷

The Clinical Governance Committee (CG Committee)

The CG Committee was a formal committee of the NHSGGC Board, with a membership consisting of non-executive directors who were also members of the NHSGGC Board, and met every two months. Its objectives were set out in the “Clinical Governance Strategy and Framework” document in the following terms:

“The purpose of the Clinical Governance Committee is to assist the NHS Board to deliver its statutory responsibility for the quality of healthcare that it provides. In particular, the Committee will seek to provide assurance to the Board that an appropriate system for monitoring and development is in place, which ensures that clinical governance and clinical risk management arrangements are working effectively to safeguard and improve the quality of clinical care. This includes affirming that NHS Greater Glasgow and Clyde:

- Has established clear lines of responsibility and accountability for the overall quality of care that it provides or commissions

- Has in place a soundly based clinical governance framework including strategy and local development plans
- Has in place reporting arrangements which ensure that the Board and Clinical Governance Committee are fully informed on the development of clinical governance
- Is taking all reasonable steps to prevent, detect and rectify irregularities or deficiencies in the quality of care provided or in the clinical governance framework
- Is doing its reasonable best to meet its objectives of improving health and tackling inequalities whilst protecting patients, staff, the public and other stakeholders against risks of all kinds”.²⁸

As set out in the Clinical Governance Strategy and Framework document its remit was to:

“provide an independent judgement on how the Board as a whole is managing the issues of strategy, performance and stewardship of public resources as they relate to the safety and quality of clinical care”.²⁹

It also had broad powers to:

“operate as necessary in order that it is confident that clinical governance and clinical risk management arrangements are working effectively to safeguard and improve the quality of clinical care”.³⁰

According to Mr Calderwood, the role of the CG Committee was to assure the Board of the effectiveness of the clinical governance arrangements in place.³¹ And as Dr Brian Cowan, Board Medical Director and Medical Director of the Acute Division, explained:

“It is a scrutiny committee, in the sense of non-executives at that committee can hold people like myself and the Chief Executive to account for what is happening in the organisation, and the committee... one of

26 [GGC18460006](#)

27 [GGC02700001](#)

28 [GGC18460015](#)

29 [GGC18460016](#)

30 [GGC18460016](#)

31 [TRA01240006](#)

the ways it went about its work was to bring the directors and the associate medical directors to the committee, in turn, to describe issues and problems they were having directly to the committee”.³²

Clyde representation on the Clinical Governance Committee

The membership list of the NHSGGC Clinical Governance Committee for 25 April 2006³³ records that a member for Clyde had still to be appointed and that a vacancy existed for a lay member. The Internal Audit report of 2007 to 2008 on Clinical Governance Committee Reporting Arrangements, published in March 2008,³⁴ notes that there is no designated non-executive Board representative from Clyde. It recommends that the need for such a post be reviewed.³⁵ The Inquiry has found no evidence to indicate that such a review took place, and no appointment was ever made.

Mr Alex Smith, an NHS management expert commissioned by the Inquiry, in his report to the Inquiry, records that:

“Given the strong case for the retention of Clyde as a distinct directorate from 1 April 2006 and the challenge of the transition, a non-executive appointment on the Greater Glasgow and Clyde Board Clinical Governance Committee with a Clyde focus would have been desirable for the key period through to full integration”.³⁶

Mr Calderwood was asked about this observation in the course of his evidence at the Inquiry’s public hearings. He provided the following answer:

“I don’t think you need someone who has a geographical residence within former Clyde to discharge the non-executive director responsibility of clinical governance”.³⁷

Dr Cowan did say, however, that, in contrast to the other Board sectors, the Associate Medical Director of Clyde was invited to attend every meeting of the CG Committee. This was because at the time of the dissolution of Argyll and Clyde in April 2006 it was acknowledged that he (Dr Cowan) and others on the CG Committee would not be as familiar with clinical governance issues in Clyde.³⁸ That practice is evident from the minutes of the CG Committee.³⁹

The Clinical Governance Committee’s performance of its role – 2007 to 2008

At the CG Committee meeting of 20 February 2007⁴⁰ Mr Andrew Crawford, the Head of Clinical Governance, submitted a detailed paper reporting on developments and issues associated with the management of clinical governance in NHSGGC.⁴¹ That paper confirms to the CG Committee that the key groups in the clinical governance structure were in place through which clinical governance objectives and priorities were “set, monitored and reported”.⁴² Reference is made to the key groups, including the Clinical Governance Forum in each directorate.

Clinical Governance Committee and infection prevention and control

There was a reporting line from the infection prevention and control committee structure to the CG Committee. The Board Infection Control Committee (BICC) reported to the CG Committee.⁴³ This was an important link in connection with monitoring infection prevention and control issues. As discussed in Chapter 15, the Acute Control of Infection Committee (ACIC) for the Clyde Sector reported to the BICC, and was in a position to alert the BICC of any problems with CDI, and in particular the existence of an outbreak.

32 [TRA01220082](#)

33 [GGC21540001](#)

34 [QIS00900001](#)

35 [QIS00900009](#)

36 [EXP02800013](#)

37 [TRA01240042](#)

38 [TRA01220109](#)

39 [GGC18370001](#); [GGC29060001](#); [GGC28400001](#); [GGC28370001](#); [GGC28360001](#); [GGC28350001](#); [GGC18320001](#)

40 [GGC18370001](#)

41 [GGC18370005](#)

42 [GGC18490001](#)

43 [TRA01130013](#)

Reports and presentations to the Clinical Governance Committee

At the CG Committee's meeting of 20 February 2007 the minutes of the BICC were received together with a summary paper highlighting key issues.⁴⁴ The minutes of the CG Implementation Group were also received, again with a paper on key issues.⁴⁵ The receipt by the CG Committee of the minutes of the BICC and the CG Implementation Group accompanied by papers on key issues occurred at every meeting of the CG Committee in the period January 2007 to June 2008.

At the CG Committee meeting of 17 April 2007⁴⁶ Dr Robin Reid, who at that time was the Associate Medical Director in the Diagnostics Directorate, provided a detailed presentation on the structure of clinical governance within that Directorate.⁴⁷ At that same meeting Mr Tom Walsh, Infection Control Manager, and Ms Sandra McNamee, the NHSGGC Infection Control Nurse Consultant, submitted for consideration a draft of the Annual Infection Control Programme for 2007 to 2008.⁴⁸

At the CG Committee's meeting of 26 June 2007⁴⁹ Mr Crawford is noted to have reported that the Clinical Governance Support Unit had received around 20 Annual Clinical Governance Reports from individual directorates and partnerships.⁵⁰ It was decided that in view of the volume of material the reports would be placed on a CD Rom and distributed to members, with each report to be reviewed by two members, an allocation that was to be organised by Mr Crawford.⁵¹

The Infection Control Annual Report for 2006 to 2007 was presented by Mr Walsh to the CG Committee meeting of 21 August 2007.⁵²

At the CG Committee meeting of 18 December 2007 presentations were provided on Clinical Governance in the Clyde Acute Directorate and in the Rehabilitation and Assessment Directorate (RAD). By this time Clyde Rehabilitation and Assessment had been integrated into the Greater Glasgow RAD. The presentation on behalf of the Clyde Acute Directorate was given by Dr John Dickson, the Associate Medical Director for Clyde. Among the challenges identified by him were the range of specialities to be covered within the geographical area and finding the means of supporting even prioritised audits.⁵³ The presentation on behalf of the RAD was given by Dr Margaret Roberts, then the Associate Medical Director in the RAD. She advised that Clinical Governance was a standing item at monthly Directorate meetings. Among the challenges identified by her was the incorporation of Clyde.⁵⁴

This pattern of Clinical Governance presentations being given to the CG Committee was repeated at meetings of the CG Committee in 2008.⁵⁵

In his report⁵⁶ Mr Smith took as an example of the role of the CG Committee the minutes of the meeting of 5 February 2008.⁵⁷ In his view the minutes reflected a well attended meeting of non-executives with several senior clinical staff in attendance. He thought that the agenda was comprehensive and covered, by rotation, major directorate reviews.⁵⁸ He concluded that in terms of clinical governance, NHSGGC had:

“developed a comprehensive framework, through its Clinical Governance Committee and Chief Executive's general management arrangements to maintain the safety and quality of the healthcare provided”.⁵⁹

The management arrangements are considered below.

44 [GGC18370006](#)

45 [GGC18370006](#)

46 [GGC29060001](#)

47 [GGC29060002](#)

48 [GGC29060005](#)

49 [GGC28400001](#)

50 [GGC28400005](#)

51 [GGC28400005](#)

52 [GGC29040001](#); [GGC29040006](#)

53 [GGC28370003](#)

54 [GGC28370002](#)

55 [GGC28360001-03](#); [GGC28350001-04](#); [GGC18320001-04](#)

56 [EXP02800001](#)

57 [GGC28360001](#)

58 [EXP02800012](#)

59 [EXP02800025](#)

The Clinical Governance Implementation Group

The Clinical Governance Implementation Group (CG Implementation Group) met every two months and reported to the CG Committee. It was responsible:

“on behalf of the Chief Executive, for developing policy and establishing decisions on strategic priorities deemed essential to clinical governance and the attainment of its goals”.⁶⁰

Among the items expected to feature in the agenda of its meetings was:

“receipt of appropriate information from committees/groups underpinning clinical governance”.⁶¹

In practice, then, the role of the CG Implementation Group was largely to facilitate the CG Committee’s fulfilment of its remit. For example, the presentations made to the CG Committee on 18 December 2007 on clinical governance had been arranged by the CG Implementation Group at its meeting on 14 November 2007.⁶²

Dr Cowan, who chaired the CG Implementation Group, explained that infection prevention and control was not a regular topic for discussion. This was because infection prevention and control, unlike many of the other services, had its own Board Infection Control Committee (BICC). This is discussed further in Chapter 15. The BICC reported directly to the CG Committee,⁶³ and prior to June 2008 it provided an annual report to the CG Committee.⁶⁴

There was some reference to infection prevention and control at the CG Implementation Group meeting of 14 March 2007,⁶⁵ but, so far as the Inquiry can ascertain, there was no further specific reference at any meetings prior to June 2008.

Dr Cowan usually attended the CG Committee meetings. He also saw the minutes of the BICC and the Acute Control of Infection Committee (ACIC).⁶⁶

Senior management groups

Whereas the role of the CG Committee was to provide assurance to the Chief Executive and the Board that appropriate systems were in place to deliver the clinical governance agenda of ensuring that healthcare was safe and effective, it was the role of management to put in place systems that were operating effectively. Within the Acute Services Division at the senior management level the two groups discussed below had responsibilities for clinical governance. Mr Calderwood chaired both groups and was in a position to report from them to the Chief Executive on any issues of concern that he considered he himself could not handle.⁶⁷

The Acute Operational Management Group

At divisional level the Acute Operational Management Group was, according to its terms of reference:

“responsible for ensuring the arrangements are in place within the directorates for the implementation of strategy and policy within the Acute Services Division”.⁶⁸

In defining the group’s purpose, the terms of reference provide that:

“The Operational Management Group will focus its work plan around the key issues for the Division in terms of:

- Corporate Governance
- Clinical Governance
- Staff Governance
- Financial Governance
- Service Development”

60 [QIS02360001](#)

61 [QIS02360001](#)

62 [GGC32790001](#); [GGC32790003](#)

63 [TRA01220103](#)

64 [WTS01890008](#)

65 [GGC32770001](#); [GGC32770003](#)

66 [TRA01220104](#)

67 [TRA01220106](#)

68 [GGC31860001](#)

They go on to say that:

“operational implementation will be delegated to the Directorate Management Teams or an individual Member of the Operational Management Group”.⁶⁹

Dr Cowan explained that the primary focus of the Acute Operational Management Group was on managerial issues rather than clinical issues.⁷⁰ As already mentioned, this group was chaired by Mr Calderwood, with a membership made up mainly of senior managers.⁷¹ It did not report to any other body.⁷² There is evidence of clinical governance issues being discussed at meetings in the second half of 2007 and in 2008,⁷³ and there was some reference to infection prevention and control issues at the meetings of 8 March 2007,⁷⁴ 11 October and 13 December 2007,⁷⁵ but otherwise infection prevention and control was not mentioned at meetings in the period January 2007 to 1 June 2008.

The Acute Strategic Management Group

According to its terms of reference the Acute Strategic Management Group (Acute SMG) was:

“responsible for the development of strategy and policy for the Acute Service Division within the framework of NHS Board policy and strategy”.

It was “a management Group/Committee and (had) no reporting relationship to any other Committee”.⁷⁶ It had a responsibility to:

“ensure that strategies, plans and policies are developed locally in such a way as to ensure, within the Division, effective and efficient....Clinical Governance”.⁷⁷

The Acute SMG was also chaired by Mr Calderwood. In contrast to the Acute Operational Management Group, it did have a specific clinical focus,⁷⁸ with a membership consisting of managers (Directors) and Associate Medical Directors,⁷⁹ and was the senior management group in the Acute Division. Mrs Deborah den Herder, Director Clyde Acute Services and Ms Anne Harkness, Director of Rehabilitation and Assessment, Acute Services, were members, as was Dr Cowan.

Infection prevention and control issues were considered by the Acute SMG. Quarterly reports on infection prevention and control were presented by Dr Reid as Chairman of the ACIC.⁸⁰ In his report to the Acute SMG meeting of 27 September 2007,⁸¹ Dr Reid raised as an issue the need to gather consistent data across the whole of NHSGGC and then “provide it in a meaningful manner”.⁸² At the Acute SMG meeting of 24 April 2008⁸³ Dr Reid reported that Statistical Process Control charts were being “circulated to wards”.⁸⁴ There is no reference to CDI until the meeting of 26 June 2008.⁸⁵

Clinical governance reports were presented on a regular basis to the Acute SMG, a number of them by Dr Cowan.⁸⁶

In summary, the Acute Operational Management Group, and in particular the Acute SMG, did hold some responsibility for the development and operation of clinical governance. It did not, however, form part of a formal reporting chain on clinical governance arrangements that involved either the CG Committee or the CG Implementation Group.⁸⁷

69 [GGC31860007](#)

70 [TRA01220107](#)

71 [GGC02650001](#)

72 [TRA01220107](#)

73 [GGC02630004](#); [GGC02170004](#); [GGC02120005](#); [GGC02010003](#); [GGC02040006](#); [GGC02030005](#); [GGC02160005](#); [GGC02080004](#); [GGC02680005](#); [GGC02090004](#)

74 [GGC02620001](#)

75 [GGC02170001](#); [GGC02120001](#)

76 [GGC31860001](#)

77 [GGC31860002](#)

78 [TRA01220107](#)

79 [GGC01390001](#)

80 [TRA01220105](#); [GGC01430005](#); [GGC02380005](#)

81 [GGC01430001](#)

82 [GGC01430005](#)

83 [GGC02380001](#)

84 [GGC02380005](#)

85 [GGC02390002](#)

86 [GGC01390005](#); [GGC01380002](#); [GGC01150005-06](#); [GGC01360004-05](#)

87 [TRA01180101-103](#)

Clinical governance at divisional level

It is clear that, because of the reporting link between the BICC and the CG Committee, at divisional level NHSGGC had appropriate structures in place to obtain assurance that effective systems were in place for the management of infection prevention and control. What is also clear from the analysis in Chapter 15 is that at the level of the Clyde Sector there were system and personal failures that resulted in the infection prevention and control system becoming dysfunctional for the VOLH, unbeknown to the ACIC, the BICC and the CG Committee.

10.4 Clinical governance in the Clyde Acute Directorate

As set out in Chapter 9, although the integration process was not intended to be completed for a further three years after 1 April 2006, Clyde Rehabilitation and Assessment was integrated into the Glasgow Rehabilitation and Assessment Directorate on 1 September 2007. From that date the clinical governance reporting lines at directorate level changed. One line led to Mrs den Herder as the Director of the Clyde Acute Directorate and the other to Ms Harkness as Director of the Rehabilitation and Assessment

Directorate (RAD). As Ms Harkness acknowledged, from 1 September 2007 she and Mrs den Herder had parallel but separate responsibilities within the VOLH for different wards.

The respective job descriptions for Mrs den Herder⁸⁸ and Ms Harkness⁸⁹ placed identical responsibilities for clinical governance upon them in the following terms:

“Lead the clinical governance agenda within the Directorate to ensure highest possible quality of patient care is achieved including issues such as Hospital Acquired Infection [HAI] and compliance with standards and guidelines”.⁹⁰

This Section will explore to what extent they fulfilled that duty.

The Clyde clinical governance structures

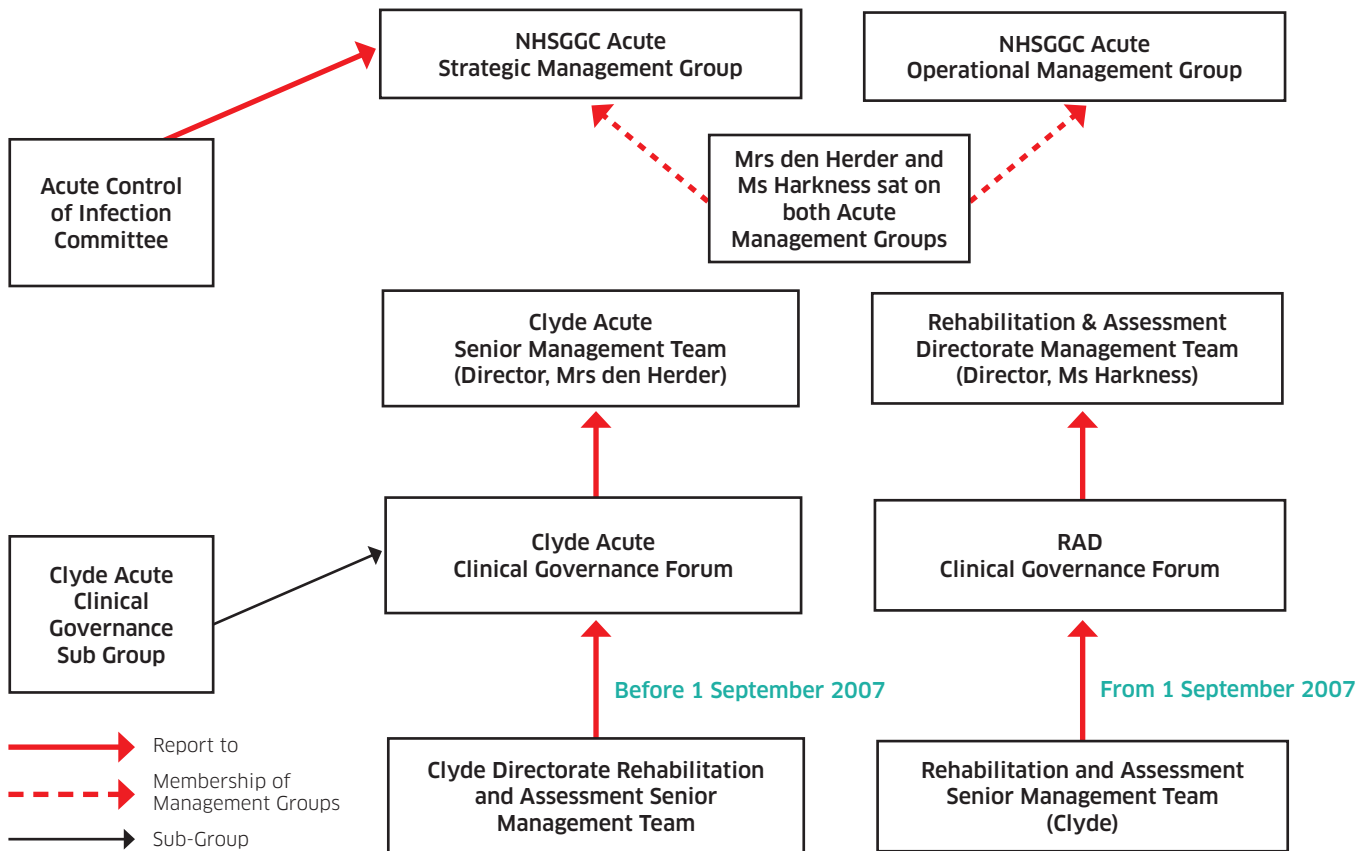
Figure 10.2 sets out the clinical governance structures within Clyde. Because from 1 September 2007 the reporting lines ended at the two separate director levels, the clinical governance structure appears to be a complicated one with separate reporting lines for the Clyde Acute Directorate, chaired by Mrs den Herder, and for the RAD, chaired by Ms Harkness.

88 [GGC33030001](#)

89 [GGC18570001](#)

90 [GGC33030003](#); [GGC18570003](#)

Figure 10.2 Flow of Clinical governance information in Clyde 2007-2008



Clyde Clinical Governance Framework meeting

A Clyde Clinical Governance Framework meeting was held on 11 July 2006 (the Framework meeting). This appears to have been an *ad hoc* meeting attended by senior clinicians and managers, and its stated purpose was to discuss the way forward for clinical governance in the Clyde Acute Directorate,⁹¹ which at that time included Rehabilitation and Assessment. Dr Elizabeth Jordan, then the Associate Medical Director, chaired the meeting and explained the clinical governance structure put in place across NHSGGC. In particular, she informed the meeting that, while a Clinical Governance Committee had been formed at Board level,⁹² it was up to directorates and specialty groups to devise clinical governance structures below this. It had been decided that one Clinical Governance Forum should be formed for the Clyde Acute Directorate.⁹³

Dr Jordan identified the key role of the group as:

“to ensure that things that go wrong in other organisations aren’t (happening) and can’t happen in Clyde”.⁹⁴

It was agreed at this meeting that clinical directors and general managers should be members of the Forum. A draft Clyde Acute Clinical Governance Plan was circulated⁹⁵ to members, and a decision was taken to circulate the draft for wider consultation in the Clyde Acute Directorate.⁹⁶

A group known as the Clyde Acute Clinical Governance Forum in fact already existed prior to the meeting of 11 July 2006. It had met on 27 March 2006,⁹⁷ apparently not for the first time, since the minutes of

91 [GGC19880002](#)

92 [GGC19880003](#)

93 [GGC19880003](#)

94 [GGC19880003](#)

95 [GGC19880002](#)

96 [GGC19880002](#)

97 [GGC19860001](#)

that meeting make reference to an earlier meeting. It met again on 19 June 2006.⁹⁸ Many who attended those meetings were also at the Framework meeting.

The reconstituted Clyde Acute Clinical Governance Forum

A meeting of the reconstituted Clyde Acute Clinical Governance Forum (Clyde Acute Forum) took place on 29 August 2006,⁹⁹ and at that meeting Dr Jordan tabled the Clyde Acute Forum draft constitution. It was agreed that the Clyde Acute Forum would report to the Clyde Acute Senior Management Team (SMT), chaired by Mrs den Herder, rather than to the Associate Medical Director.¹⁰⁰

The draft constitution

The draft constitution of this reconstituted body (the version provided to the Inquiry is designated a “final draft” dated 21 September 2006) lists among its aims:

“(to) ensure that safe and appropriate systems are in place to deliver high quality, safe and effective care and services”.¹⁰¹

Specific objectives of the Clyde Acute Forum included:

- Providing assurance to the Board that systems are in place for promotion and support of clinical governance within the Clyde Acute Directorate and to monitor the performance of these systems
- Alerting the Associate Medical Director of issues of concern that cannot be resolved locally
- Reviewing and ensuring compliance with national standards¹⁰²

The fundamental role of the Clyde Acute Forum was said to be:

“to seek assurances, monitor performance and offer support on all governance matters in the Directorate”.¹⁰³

Under the draft constitution, responsibility for the delivery of clinical governance within Clyde Acute Directorate lay with the associate medical director and general managers.¹⁰⁴ The terms of the draft constitution also reflect the decision noted previously that the Clyde Acute Forum was to report to the Clyde Acute SMT (referred to in the draft constitution as “the Clyde Acute Management Group”).¹⁰⁵

The draft constitution also listed those who were to be the “core membership”¹⁰⁶ of the Clyde Acute Forum, and included an infection control representative. Those key members of the Clyde Acute Forum were expected to attend every meeting or “send a deputy”.¹⁰⁷

Reporting lines are laid down in the draft constitution for reporting from the different clinical directorates. At that time Rehabilitation and Assessment was still within the reporting structure of the Clyde Acute Directorate. Mrs Elizabeth Culshaw, General Manager for the Rehabilitation and Assessment Directorate, chaired the Rehabilitation and Assessment (Clyde) Senior Management Team meetings, and was identified as the person responsible for reporting on behalf of that Senior Management Team.¹⁰⁸

Provision was also made in the draft constitution for reports to be made available to the Clyde Acute Forum on nine issues. Included in the nine reports to be provided to the Clyde Acute Forum was an Infection Control report by an “Infection Control Representative”¹⁰⁹ who was not identified. The persons responsible for the other reports were identified.

The functioning of Clyde Acute Clinical Governance Forum

In 2007 the Clyde Acute Clinical Governance Forum (Clyde Acute Forum) was normally chaired by Miss Aileen White, Consultant Surgeon at RAH. It was to meet on a quarterly

98 [GGC19870001](#)

99 [GGC19890001](#)

100 [GGC19890002](#)

101 [GGC18450002](#); [GGC29150002](#); [TRA01000039](#)

102 [GGC18450002](#)

103 [GGC18450002](#)

104 [GGC18450002](#)

105 [GGC18450003](#)

106 [GGC18450003](#)

107 [GGC18450003](#)

108 [GGC18450006](#)

109 [GGC18450006](#)

basis.¹¹⁰ As already mentioned, an Infection Control report was among the standing items on its agenda.¹¹¹

The first meeting of the Clyde Acute Forum for 2007 was on 27 March 2007.¹¹² In the minutes for that meeting it has been noted that there was no update for infection prevention and control. An “Infection Control Representative [was] to be invited to attend future meetings”.¹¹³ This repeated identical notes made in minutes of meetings of the Clyde Acute Forum in 2006.¹¹⁴ The note is again repeated in the minutes for the meeting of 19 June 2007,¹¹⁵ although at that meeting Ms Marie Martin, General Manager, Diagnostics, did provide an infection prevention and control update¹¹⁶ to the effect that infection prevention and control had been fully integrated “in terms of Acute Services”¹¹⁷ and that Ms Annette Rankin had been appointed Head Nurse for Infection and Control. Ms Rankin attended the following meeting of the Clyde Acute Forum on 18 September 2007, and presented the infection prevention and control report.¹¹⁸ That was the first infection prevention and control report presented. Ms Rankin attended the meeting of 11 December 2007¹¹⁹ and again presented the infection prevention and control report.¹²⁰

At the next meeting of the Clyde Acute Forum on 11 March 2008 Ms Rankin was not in attendance, and intimated her apologies for her non-attendance. In her absence there was no update for infection prevention and control, despite the draft constitution envisaging that in such circumstances a deputy would attend. That meant that in the year March 2007 to March 2008 only two infection prevention and control reports were presented by a key member of the Infection Control Team.

In Chapter 15 the point is made that the Clyde Infection Control Support Group (the

Support Group) chaired by Dr Elizabeth Biggs, the Infection Control Doctor, had stopped meeting after its meeting on 10 July 2007.¹²¹ A meeting planned for 9 October 2007 did not take place. Nor did any further meetings take place until May 2008, when Dr Linda Bagrade, the replacement Infection Control Doctor for the VOLH, arranged a meeting.¹²² Ms Rankin did not, for example, raise the fact that the Support Group had ceased to meet at the meeting of the Clyde Acute Forum she attended on 11 December 2007.¹²³ Furthermore, as discussed more fully in Chapter 15, neither did Mrs Catherine MacGillivray, Head of Nursing for Clyde Acute, who was a member of the Clyde Acute Forum and also the Support Group, who was aware that the Support Group had ceased to meet and who, like Ms Rankin, attended the Clyde Acute Forum meeting on 11 December 2007.¹²⁴

When the Internal Investigation described in Chapter 17 took place Miss White explained to the Internal Investigation Team that the Clyde Acute Forum had requested minutes of local infection control meetings. What is significant is that according to the notes of her interview she was not aware that “the IC Committee” had ceased to meet. Although the Clyde Acute Forum was not receiving minutes from that committee, members assumed that meetings were continuing to take place.¹²⁵

The Inquiry concludes from the foregoing narrative that until September 2007, when Ms Rankin first attended the Clyde Acute Forum and reported on infection prevention and control, there was a protracted period of time when there was no Infection Prevention and Control Team representative in attendance at the Clyde Acute Forum meetings. Infection prevention and control was not viewed as a high priority among those involved in clinical governance.

The Clyde Acute Forum meetings were generally not well attended.¹²⁶

110 [GGC18450004](#)

111 [TRA01000041](#)

112 [GGC20740001](#)

113 [GGC20740007](#)

114 [GGC19860007](#); [GGC19870006](#)

115 [GGC29260001](#); [GGC29260006](#)

116 [GGC29260001](#)

117 [GGC29260003](#)

118 [GGC03780009](#)

119 [GGC15400001](#)

120 [GGC15400005](#)

121 [GGC20940001](#)

122 [GGC13390002](#)

123 [TRA01000039-41](#)

124 [GGC15400001-08](#)

125 [GOV00890126](#)

126 [GGC20740001](#); [GGC29260001](#); [GGC03760001](#)

The Clyde Acute Clinical Governance subgroup

The draft constitution envisaged that between the meetings of the Clyde Acute Forum a subgroup of the Forum would meet at six-weekly intervals.¹²⁷ This was also chaired by Miss White.¹²⁸ The draft constitution did not specify that infection prevention and control would be a standing item.¹²⁹

From January 2007 and prior to June 2008 there were ten meetings of the subgroup. Infection prevention and control did not become a standing item on the agenda until a decision was made to that effect on 17 July 2007.¹³⁰ Before then the only reference to infection prevention and control had been at the subgroup's meeting of 29 May 2007,¹³¹ and related to infection within Surgery and Anaesthetics.¹³² At the meetings of 28 August 2007,¹³³ 20 November 2007,¹³⁴ and 29 January 2008,¹³⁵ Mrs Jean Murray, interim Lead Nurse for Infection Control, did provide verbal reports on infection prevention and control issues, but *C. difficile* infection is not mentioned. By the date of the subgroup's meeting of 29 April 2008¹³⁶ Mrs Murray had retired and there was no infection prevention and control report presented.¹³⁷

There is no suggestion in the minutes that the subgroup at any time enquired as to the adequacy of infection prevention and control systems in place at the VOLH. Nor is there any suggestion that it became aware of the failure in the infection prevention and control committee structure and lack of input from the Infection Control Doctor.

For a significant number of the subgroup meetings there was poor attendance.¹³⁸

127 [GGC18450004](#)

128 [GGC03670001](#)

129 [GGC18450006](#)

130 [GGC03630001](#); [GGC03630006](#)

131 [GGC03640001](#)

132 [GGC03640003](#)

133 [GGC03620001](#); [GGC03620004](#)

134 [GGC03600001](#); [GGC03600003](#)

135 [GGC16970012](#); [GGC16970015](#)

136 [GGC15410001](#)

137 [GGC15410001-05](#)

138 [GGC03630001](#); [GGC03620001](#); [GGC03610001](#);
[GGC03600001](#); [GGC16970003](#); [GGC16970012](#);
[GGC15410001](#)

Clyde Acute Senior Management Team

The Clyde Acute Senior Management Team (Clyde Acute SMT) met monthly, and was normally chaired by Mrs den Herder. Some members of the Clyde Acute Forum, for example, Ms Martin, Dr Jordan and Mrs MacGillivray, were also members of the Clyde Acute SMT,¹³⁹ and Dr John Dickson became a member in September 2007 after he became Associate Medical Director.¹⁴⁰ The Clyde Acute SMT discussed clinical governance issues such as patient safety, waiting times, child protection and blood transfusion,¹⁴¹ but none related to infection prevention and control until the meeting of 5 June 2008, just after the CDI problem at the VOLH was identified.¹⁴² One important qualification to that is the fact that action notes after September 2007 up until the meeting on 3 April 2008 are missing and were not available for scrutiny.¹⁴³

As noted earlier, the Clyde Acute Forum reported to the Clyde Acute SMT.¹⁴⁴ In the action notes of the Clyde Acute SMT meeting of 20 February 2007 it has been noted, under reference to clinical governance, that "Liz will bring minutes of quarterly CG Forum to this meeting".¹⁴⁵ That is a reference to Dr Jordan and the minutes of the Clyde Acute Forum, and although subsequent action notes do not make any reference to the minutes of the Clyde Acute Forum there is no reason to conclude that the minutes were not produced. The cross-membership of the Clyde Acute Forum and Clyde Acute SMT also provided an informal route for the passage of information.

The lack of infection prevention and control input disclosed by the action notes of the Clyde Acute SMT suggests that it did not recognise infection prevention and control as an integral part of clinical governance. The minutes of the Clyde Acute Forum should have made apparent to the SMT the extent to which infection prevention and control matters were not receiving the attention they required.

139 [GGC32140001](#)

140 [GGC04550001](#)

141 [GGC04630003](#); [GGC04640002-03](#)

142 [GGC04620002](#)

143 [GGC32110001](#)

144 [GGC18450003](#)

145 [GGC32140002](#)

In the action notes of the Clyde Acute SMT's meeting of 20 September 2007¹⁴⁶ it has been noted that Mr Walsh was to attend the next meeting set for 18 October 2007 "to discuss National HAI Prevalence Study".¹⁴⁷ The action notes of the meeting of 18 October 2007 are missing and have not been seen by the Inquiry. Those action notes do, however, appear to have been available to the Internal Investigation Team, which extracted from them the information that Mr Walsh and Ms

Rankin had attended and had discussed the HAI prevalence study.¹⁴⁸ The role played by the Internal Investigation Team is considered in Chapter 17.

Table 10.1 is a revised version of a Table contained in the Internal Investigation report. Under the heading of clinical governance it highlights that only the action notes of 18 October 2007 had a reference to infection prevention and control.¹⁴⁹

Table 10.1 Clyde Acute Senior Management Team action notes

Date	Note in action notes
1/5/08	<ul style="list-style-type: none"> • Child Protection • Blood TAG Compliance
3/4/08	<ul style="list-style-type: none"> • VoL Governance Group established (no reference to VoL control of infection issues) • Child Protection • Paediatric Minor Injuries • Unscheduled Care • Dermatology • Blood Tag Compliance
18/10/07	Tom Walsh, control of Infection Manager and Annette Rankin, Head of Nursing for Infection Control, attended the meeting to discuss the HAI prevalence study, which reported that hospitals in Clyde had generally been around or below the national average.
21/8/07	Modernising Medical Careers
26/6/07	Consent Policy Child Protection
24/5/07	Clinical Governance Annual report Child Protection
19/4/07	Child Protection
15/3/07	Nil to report
20/2/07	Incidents Production of minutes
18/1/07	Exception Reporting Absence figures

146 [GGC04550001](#)

147 [GGC04550007](#)

148 [GGC00610006](#)

149 [GGC00610006](#)

In summary, ten sets of action notes of the Clyde Acute SMT meetings have been reviewed in the period covered by the Inquiry remit. One had a reference to infection prevention and control specifically linked to the National Prevalence Study results.

Mrs den Herder's responsibility

Mrs den Herder's duty to lead the clinical governance agenda with a particular focus on HAI, as set out in her job description, has already been described in this Chapter. That duty reflected the clinical governance structure set out in the Clinical Governance Strategy and Framework document, in which the delivery of clinical governance was to be achieved through general management.¹⁵⁰ Subject to the qualification already mentioned that not all the action notes are available, there appears to have been little attention paid to infection prevention and control as an aspect of importance to clinical governance at the Acute SMT meetings chaired by Mrs den Herder. Furthermore, the repeated references made in the minutes of the Clyde Acute Forum about the lack of infection prevention and control input should have been identified by her. That position should have been remedied long before Ms Rankin first attended a meeting of that group in September 2007. In the later part of 2007 and early 2008 there was some infection prevention and control input provided by Mrs Murray at the meetings of the subgroup, but there is no evidence of any real focus at any level, and particularly at Mrs den Herder's level, on the operation of the infection prevention and control systems, particularly insofar as they affected the VOLH.

10.5 Clinical governance in the Rehabilitation and Assessment Directorate

Full integration

Clyde Rehabilitation and Assessment was fully integrated with NHS GGC in September 2007, and Ms Harkness, who had been director of the Greater Glasgow directorate since October 2005, became the director of

the extended Rehabilitation and Assessment Directorate (RAD).¹⁵¹ At the VOLH, wards 14, 15 and F were in the new RAD. The Senior Management Team for Rehabilitation and Assessment (Clyde) therefore reported to the Clyde Acute Forum until September 2007 and thereafter to the RAD Clinical Governance Forum.¹⁵²

The Rehabilitation and Assessment Senior Management Team

Mrs Culshaw chaired the Rehabilitation and Assessment Senior Management Team (SMT) meetings and was a member of the Clyde Acute Forum until September 2007. The Rehabilitation and Assessment SMT tended to meet at least monthly.¹⁵³

In the period from January 2007 up to September 2007 during which the SMT reported within the Clyde Acute Directorate structures, the action notes available of the SMT meetings disclose that occasionally issues relating to infection prevention and control did feature. In March 2007 there were outbreaks of MRSA and CDI identified in ward 7 of the RAH. The concern expressed by Dr Syed Ahmed, Consultant in Public Health Medicine and Clinical Consultant in the Public Health Protection Unit, NHS GGC, in his email of 15 March 2007 to Mrs Culshaw and her inadequate response to that email have already been discussed in Chapter 9. That outbreak had been referred to at the meeting on 13 March 2007¹⁵⁴ and again on 11 April 2007.¹⁵⁵ As previously mentioned in Chapter 9, Mrs Culshaw said in evidence that there had been a discussion at the meeting in March about the outbreak.¹⁵⁶ Having become aware of the failures in the RAH, Mrs Culshaw did not check to see if there were infection prevention and control issues at the VOLH. Mrs Culshaw's position was that she had raised the profile of this infection prevention and control issue within the Senior Management Team.¹⁵⁷ She believed that as she had raised the RAH issue at the meeting,

151 [TRA01180087-88](#)

152 [GGC03780001](#); [GGC03780003](#); [GGC15400003](#)

153 [GGC19320001](#); [GGC19340001](#)

154 [GGC19260001](#); [TRA01170005](#)

155 [GGC19280001](#)

156 [TRA01170005](#)

157 [TRA01170006](#)

150 [GGC18460006](#)

the manager responsible at local level, in this instance Ms Elizabeth Rawle, Lead Nurse for the Rehabilitation and Assessment Directorate, would be aware there was an issue at other sites within the Clyde Sector. Ms Rawle had not in fact attended the meeting of 13 March 2007.¹⁵⁸

Although infection control was listed on the agenda for the meeting of the Rehabilitation and Assessment SMT held on 25 May 2007, the action notes for the meeting do not refer to infection prevention and control. Nor do the action notes of SMT meetings after April 2007 disclose any references to infection prevention and control as a topic that had been discussed¹⁵⁹ until the meeting of 7 August 2007, when there was some discussion in connection with the Cleanliness Champions Programme.¹⁶⁰ It is to be noted that some of the action notes of meetings are missing, although the agendas for some of these meetings have been made available.

After the integration of Clyde Rehabilitation and Assessment with Greater Glasgow RAD in September 2007, Mrs Culshaw's group became the Rehabilitation and Assessment Directorate SMT (the RAD SMT) and reported to the RAD Clinical Governance Forum,¹⁶¹ of which she became a member.¹⁶² The role played by that group is discussed later in this Chapter.

There appear to have been infection prevention and control issues discussed at the meeting of the RAD SMT on 25 September 2007,¹⁶³ and again at the meeting held on 9 October 2007.¹⁶⁴ Thereafter until the meeting of 10 June 2008,¹⁶⁵ when the CDI problem at the VOLH had become public, there appears to have been little focus on infection prevention and control at the meetings of this group.

It is perfectly apparent that there was no system of management in place at this level

that could monitor adequately that infection prevention and control was being properly managed in the VOLH. Mrs Culshaw accepted in evidence that, had appropriate reporting systems been in place, she would have become aware of the scale of CDI at the VOLH sooner than she did. She, like a number of others, was relying on the introduction of the Statistical Process Control (SPC) Charts described in Chapter 15 to produce data on the number of CDI cases.¹⁶⁶ As discussed in other Chapters, Mrs Culshaw was unaware that the data on numbers of patients who contracted CDI at the VOLH were available. She should have made herself aware of the actual position.

Rehabilitation and Assessment Directorate Clinical Governance Forum

The RAD Clinical Governance Forum (the RAD Forum) met every two months, and was chaired by Dr Roberts.¹⁶⁷ Minutes of meetings of that group are available from 22 August 2007, and a further four meetings took place prior to June 2008. Ms Harkness did not attend the RAD Forum, but the group she chaired, the RAD Management Team, did receive the minutes of the RAD Forum.¹⁶⁸

There is some reference in the minutes of the meeting of 17 October 2007 to HAI, and to CDI in particular, concerning the collection of data on CDI.¹⁶⁹ There is no reference to infection prevention and control in the minutes of the next meeting, which took place on 12 December 2007, but at the meeting after that, on 13 February 2008,¹⁷⁰ a number of infection prevention and control issues were discussed, including local infection control audits and CDI SPCs.¹⁷¹ The following observations have been recorded in the minutes:

“It was agreed there would be discussion as to how more meaningful information could be achieved and how this would be taken forward”.¹⁷²

158 [GGC19260001](#)

159 [GGC19300001](#); [GGC19320001](#); [GGC19340001](#)

160 [GGC19360001](#)

161 [TRA01160128](#); [TRA01160139-140](#)

162 [GGC02740001](#); [GGC02750001](#)

163 [GGC19390001](#)

164 [GGC19410001](#)

165 [GGC19630001-02](#)

166 [TRA01160144-146](#)

167 [GGC02780001](#)

168 [TRA01180104](#)

169 [GGC02760001](#); [GGC02760003](#)

170 [GGC02740001](#)

171 [GGC02740003](#)

172 [GGC02740003](#)

HAI was also discussed at the following meeting held on 16 April 2008,¹⁷³ with a particular focus on the Annual Infection Control Programme.¹⁷⁴ At that meeting Dr Roberts is noted as advising the meeting that the Vale of Leven Governance Group had been formed and would provide regular reports to the RAD Forum.¹⁷⁵

It is clear that by February 2008 the RAD Forum had realised the importance of infection prevention and control issues to clinical governance. This recognition simply highlights the previous general lack of monitoring of the reporting systems in place. It implies ignorance of whether the systems were sufficiently effective to comply with NHSGGC's stated policy on clinical governance.

In contrast to the meetings of the Clyde Acute Forum, the meetings of the RAD Forum were generally well attended.¹⁷⁶

Rehabilitation and Assessment Directorate Management Team

Ms Harkness chaired the RAD Management Team meetings after integration on 1 September 2007. These meetings were normally held monthly.¹⁷⁷ The membership included Mrs Culshaw, the Chair of the RAD Senior Management Team meetings, and Dr Roberts, the Chair of the RAD Forum,¹⁷⁸ although Mrs Culshaw may not have attended until early 2008.¹⁷⁹

In her evidence Ms Harkness said that the RAD Management Team meetings were a forum for discussion on infection prevention and control prior to April 2008.¹⁸⁰ She drew attention to the minutes of the meeting of 19 September 2007, and to the record made there of a briefing provided by Ms Rankin on the HAI Prevalence Survey¹⁸¹ that was

published in July 2007.¹⁸² At that September meeting there was some discussion in connection with the standardising of information regarding HAI. It was noted that regular charts were being produced for the North Sector of NHSGGC.¹⁸³ It has been noted that the ACIC would be asked to produce a standard set of reports on HAI.

The history of the development and production of the SPC Charts is discussed in Chapter 15. Suffice to say at this point that it was only in May 2008 that Ms Harkness first received a standard infection prevention and control report.¹⁸⁴ This included matters such as details of environmental audits, an update on the numbers who had completed the Cleanliness Champions Programme, information on hand hygiene, and SPC Charts.¹⁸⁵

As discussed in Chapter 15, SPC Charts were not available in the VOLH until May 2008.¹⁸⁶ Information on the rates of infection was available, however, as was information on the other issues contained in that first infection prevention and control report. SPC Charts, as explained in Chapter 15, present a retrospective picture. They are not a substitute for monitoring patients in real time. Somewhat tellingly Ms Harkness said that after June 2008 not only was the retrospective situation considered at the RAD Management Team meetings but the current situation was also checked.¹⁸⁷

There was some discussion about infection prevention and control at the RAD Management Team meeting of 31 October 2007 in connection with ward closures¹⁸⁸ and the need for guidance from the Infection Control Team for staff entering closed wards.

Ms Harkness accepted that infection prevention and control did not feature in the minutes of the RAD Management Team meeting from November 2007 until

173 [GGC02750001](#)

174 [GGC02750002-03](#)

175 [GGC02750006](#)

176 [GGC02730001](#); [GGC02740001](#); [GGC02750001](#)

177 [GGC02420001](#); [GGC02520001](#)

178 [GGC02520001](#); [GGC02760001](#)

179 [GGC02740001](#)

180 [TRA01180104](#); [GGC32070001](#)

181 [GOV00460001](#); [GOV00510001](#)

182 [GOV00460002](#)

183 [GGC32070002](#)

184 [TRA01180106](#)

185 [TRA01180107](#)

186 [TRA01180144](#)

187 [TRA01190019](#)

188 [GGC02420002](#)

28 May 2008.¹⁸⁹ Four meetings of the RAD Management Team had taken place over that six to seven month period.

The RAD Management Team minutes for the meeting of 28 May 2008 provide an example of good clinical governance of infection prevention and control. The issue under review was that of patients suffering from MRSA infection in a ward in the RAH. An action plan was discussed, and a decision was made that the RAD Clinical Governance Group was to monitor the implementation of the action plan and report back.¹⁹⁰ This was before Ms Harkness was aware of the CDI problem at the VOLH.¹⁹¹

A similar approach is evident from the minutes of the RAD Management Team meeting of 30 July 2008,¹⁹² after the VOLH CDI problem had been made public. At that meeting infection prevention and control reports were considered, with decisions made on monitoring action plans and implementing policy.¹⁹³

The approach to clinical governance in relation to infection prevention and control evident at the RAD Management Team meetings of 28 May 2008 and 30 July 2008 is not apparent in the minutes of earlier meetings of that group.

Ms Harkness' responsibility

Ms Harkness did receive the minutes of the ACIC,¹⁹⁴ but certainly prior to June 2008, as discussed in Chapter 15, there was nothing in those minutes to alert her to the failures at the VOLH. She was not made aware prior to June 2008 of the CDI problem in the VOLH.¹⁹⁵

Ms Harkness was an impressive witness and gave her evidence with commendable clarity. Nonetheless, Ms Harkness, as the director of the RAD, was right in accepting that she should have been made aware of the CDI levels in wards for which she

had responsibility.¹⁹⁶ She was also right in accepting some responsibility after 1 September 2007 for the failure to identify outbreaks of CDI at the VOLH.¹⁹⁷ In her favour is the fact that she had only been responsible for the rehabilitation and assessment wards in the VOLH for a relatively short period before the outbreaks came to light.

The clinical governance arrangements within the RAD, for which she has to bear ultimate responsibility, were not sufficiently effective to ensure the "highest possible quality of patient care"¹⁹⁸ in relation to HAI, and in particular CDI Ms Harkness was perfectly candid in accepting that the absence of the provision of routine infection prevention and control information was a "gap"¹⁹⁹ in the governance arrangements for her as the director of the RAD.

10.6 Reporting from the Clyde Sector

Separate lines of reporting

As mentioned earlier in this Chapter, after 1 September 2007 the Clinical Governance Forums for the Clyde Acute Directorate and for the Rehabilitation and Assessment Directorate reported separately to the Management Team meetings for these two directorates chaired respectively by Mrs den Herder and Ms Harkness.

Lack of formal reporting

There was no formal reporting line from the Clyde Acute SMT or the RAD Management Team to the Acute Strategic Management Group (Acute SMG) or the Acute Operational Management Group, although Mrs den Herder and Ms Harkness were members of the Acute SMG and the Acute Operational Management Group. The Acute SMG in particular was a forum where clinical governance issues, including infection prevention and control, were discussed.

NHSGGC has maintained that the Clinical Governance Implementation Group (CG Implementation Group) received reports

189 [TRA01180105; GGC02540001](#)

190 [GGC02540001-02](#)

191 [TRA01180132-133](#)

192 [GGC08550036](#)

193 [GGC08550036](#)

194 [TRA01180119](#)

195 [TRA01180110](#)

196 [TRA01180110](#)

197 [TRA01190015-16](#)

198 [GGC18570003](#)

199 [TRA01190020](#)

from each Clinical Governance Forum, and mentioned the Clyde Acute Forum as an example of this line of reporting.²⁰⁰ The minutes of the CG Implementation Group do not refer to such reports. Furthermore, as discussed earlier in this Chapter, the draft constitution of the Clyde Acute Forum specified that the group would report to the “Clyde Acute Management Group”²⁰¹ which seems to be a reference to the Management Team meetings chaired by Mrs den Herder.

Ignorance of system failures

It will be evident from the discussion in this Chapter of the roles played by the Clinical Governance Committee (CG Committee) and the Clinical Governance Implementation Group (CG Implementation Group) that those groups were unaware of the system failures for the VOLH. Ms Harkness was a member of the CG Implementation Group, as was the Associate Medical Director for the Clyde Acute Directorate, but those links did not serve to inform the CG Implementation Group because of the lack of focus on infection prevention and control as an integral aspect of clinical governance within the Directorates.

10.7 The Clinical Governance Committee and NHS Greater Glasgow and Clyde

As Medical Director in 2007/08,²⁰² Dr Cowan was responsible for providing advice to the Chief Executive and Chief Operating Officer, with a particular focus on clinical governance.²⁰³ He oversaw the clinical governance system and attended the CG Committee meetings.²⁰⁴ He first became aware of the CDI problem at the VOLH on 9 June 2008. He was “horrified at the news”²⁰⁵ because he was told that there had been “an outbreak going on for six months” which “at least no-one above Clyde had known about.”²⁰⁶ Dr Cowan made the point that the previous week he had attended a “Clyde Governance” meeting and that no issue

had been raised in connection with infection prevention and control or *C. difficile*.²⁰⁷ His reaction was expressed in the following manner:

“...we were no longer going to just encourage people to implement infection control measures, we were going to tell them to implement them and monitor them more effectively”.²⁰⁸

The oversight role of the CG Committee for effective clinical governance has already been described. As observed at the beginning of this Chapter, this group required confirmation that there was an:

“appropriate system in place for monitoring and developing our clinical governance and risk management arrangements”.²⁰⁹

The clinical governance committee structures themselves were in place and cannot be criticised. The CG Committee had an important reporting line to infection prevention and control from the BICC and received other forms of infection prevention and control input as set out earlier in this Chapter. Had the relevant information on the VOLH CDI problem reached the ACIC, the BICC and the CG Committee, NHSGGC and its Board would have been in a position to respond. The infection prevention and control failures that deprived the ACIC and the BICC of that information are discussed in Chapter 15. Had the clinical governance arrangements at directorate level functioned effectively, the problem would have become apparent, and again the CG Committee and the Board would have become aware of the CDI problem at the VOLH.

In this connection Dr Cowan provided a rather telling insight. He was asked what the main lessons were for him, the Board and senior management from what happened at the VOLH. In his reply Dr Cowan included as a lesson learned never to underestimate the effects of “two massive mergers”.²¹⁰ The “merger” with Clyde is considered in Chapter 9. The other merger he had in mind was the restructuring that had occurred in Glasgow

200 [GGC33100001](#)

201 [GGC18450003](#)

202 [TRA01220078](#)

203 [TRA01220080](#)

204 [TRA01220081-82](#)

205 [TRA01220094](#)

206 [TRA01220094](#)

207 [TRA01220094](#)

208 [TRA01220095](#)

209 [GGC18510002](#)

210 [TRA01220156](#)

in 2005.²¹¹ A second lesson that Dr Cowan identified was:

“never to think that your safety margin is the fact that people will carry on doing what they have been doing and that that will keep you going until you can get your new reporting systems up and running, and that is where I think we got caught ... in Clyde”²¹²

Another point made by Dr Cowan was that NHSGGC was:

“caught out as an organisation, in not realising with the huge changes that a number of ... reporting systems were relying on the old systems that had been there ... and (the) new amalgamated reporting systems were taking longer ... to come onstream”.²¹³

He went on to say that NHSGGC:

“missed just how things were being delayed, simply because of the massive number of things we were trying to deal with because of the amalgamation”.²¹⁴

Of course when he gave his evidence Dr Cowan was speaking with the benefit of hindsight, but he nevertheless identified how important aspects of infection prevention and control had gone badly wrong in relation to the VOLH.

Dr Cowan gave his evidence with commendable candour and it was obvious that he had been “shocked”²¹⁵ when he discovered in June 2008 that:

“an infection could rage away for as long as six months and no-one would report it up the system”.²¹⁶

The reference to six months is explained by the fact the focus then was on the period December 2007 to May 2008. In fact, as discussed in this Report, the CDI problem in the VOLH had emerged much earlier in 2007 and remained undetected within the clinical

governance structure for much longer than the six months mentioned by Dr Cowan.

Dr Cowan’s commitment to the proper management of infection prevention and control was obvious. Furthermore, the Inquiry can sympathise with the nature of the workload undertaken by NHSGGC. The role played by the dissolution of Argyll and Clyde and the integration process, discussed in Chapter 9, was an important one, and having effective systems in place to manage infection prevention and control in the Clyde Sector inherited by NHSGGC would take time. Nonetheless the clinical governance arrangements in place within Clyde itself so far as the VOLH was concerned were not sufficiently effective to provide the responsible directors, Mrs den Herder and Ms Harkness, with the necessary assurances that the infection prevention and control arrangements were operating effectively.

Inevitably with such a large organisation as NHSGGC the information made available to the CG Committee was limited to the issues deemed to be of importance. The CG Committee did have infection prevention and control input provided to it but, as it turned out, that input did not alert it to the VOLH CDI problem to allow it to perform its scrutinising role effectively. That is why the Inquiry endorses the changes made to the processes after June 2008, which established infection prevention and control as a standing agenda item at every meeting of the CG Committee and reporting by the BICC to the CG Committee at each of its meetings.²¹⁷

10.8 Changes in clinical governance since 2008

The Head of Clinical Governance at NHSGGC, Mr Andrew Crawford, has explained certain changes in reporting practices since the VOLH CDI problem emerged. For example, infection prevention and control is now a standing item on the CG Committee agenda, and the BICC now reports to the CG Committee at each meeting instead of annually.²¹⁸

NHSGGC has in addition provided the Inquiry with certain information on changes in

211 [TRA01220152](#)

212 [TRA01220156-157](#)

213 [TRA01220151](#)

214 [TRA01220151](#)

215 [TRA01220094](#)

216 [TRA01220095](#)

217 [WTS01890008](#)

218 [WTS01890008](#)

clinical governance since 2008. In 2009 the Acute Division established an acute clinical governance committee to consider issues of clinical risk and patient safety, including infection prevention and control. The purpose of establishing this committee was to allow more time and debate on these issues than before.²¹⁹ A report of issues from the acute clinical governance committee is made to the CG Implementation Group. The Inquiry welcomes the changes made by NHSGGC as representing a more effective focus on issues of infection prevention and control.

10.9 No non-executive director for Clyde

There was no designated non-executive director for Clyde on the CG Committee. It appears from the membership list that the intention was to make such an appointment, and the reasons for not doing so are unknown. But the Inquiry finds that Mr Calderwood's response – that geographical residence is not essential to carrying out the duties of non-executive director – misses the point on two counts. The first of these is that the Clyde Acute Directorate was unique in NHSGGC in being a geographically defined directorate. The second is that for Mr Smith the particular issue of concern was not geographical residence; it was that there was no non-executive director on the CG Committee with an identifiable **specific interest in or responsibility for** Clyde during a period of organisational change. The Inquiry considers that to be a justified concern. It cannot be said with any certainty that the presence of such a person would have led to more questions being raised about the effectiveness of clinical governance within the Clyde Sector, but the absence of a member with a particular Clyde remit undoubtedly reduced the probability that such questions would be asked.

10.10 Conclusion

This Chapter is concerned with clinical governance issues alone, with a particular focus on the CDI problem at the VOLH. The question of whether infection prevention and

control structures should have identified the CDI problem at the VOLH, and the extent to which they did not do so, is considered in Chapter 15.

In relation to infection prevention and control at the VOLH, the Inquiry finds that NHSGGC's clinical governance system was not operating effectively. It is clear to the Inquiry that, had the clinical governance system been operating effectively, it would have identified the CDI problem in the VOLH. It is inconceivable that an effective clinical governance system would have failed to identify the inadequate input from the Infection Control Doctor, the failure of the infection prevention and control committee structure, and the failures to declare outbreaks of CDI discussed in Chapter 15. The level of reporting and monitoring necessary to identify the sort of failings that led to the levels of CDI at VOLH, was simply not in place. This meant that the Clinical Governance Committee and ultimately the Board remained in ignorance of the system failures within the Clyde Sector.

Had the clinical governance structures at directorate level been effective, the problems with infection prevention and control relating to the VOLH would have come to the attention of senior personnel both within the Acute Directorate and latterly the RAD. It is worth repeating that from 1 September 2007 there were two parallel directorates in the VOLH, and the fact that senior management in both directorates did not identify the CDI problem does emphasise that infection prevention and control was not regarded as integral to clinical governance. Appropriate monitoring within the Acute Directorate should have identified problems by mid-2007 at the latest. The precise impact of earlier detection cannot of course be measured, but it is reasonable to conclude that had action been taken, many cases of CDI could have been prevented.

10.11 Recommendations

Recommendation 9: Health Boards should ensure that infection prevention and control is explicitly considered at all clinical governance committee meetings from local level to Board level.

219 [GGC32220316](#)

Chapter 11

The experiences of patients
and relatives

Introduction

This Chapter examines the evidence provided to the Inquiry by patients, relatives and friends of patients at the VOLH (the patient and relative group). It concentrates mainly on the focus period of 1 December 2007 to 1 June 2008. The intention is to look at the evidence through the eyes of the patient and relative group and narrate some of their experiences. The Chapter will then identify issues that have emerged from an analysis of the documentation and of the evidence.

11.1 Sources of evidence

Written and oral evidence

In total 71 people in the patient and relative group provided written statements to the Inquiry. Thereafter the Inquiry selected a number of those who had given statements to provide additional assistance to the Inquiry in the form of oral evidence at the Inquiry's public hearings at Maryhill.

Unfortunately it was only possible to obtain statements from eight patients. Many of the patients who suffered from *C. difficile* infection (CDI) were elderly and, as discussed in Chapter 4, had chronic co-morbidities. Many patients had died, while others were unable to provide statements or give oral evidence due to age or illness. Sixty one further written statements were obtained from relatives and friends of the 63 focus patients.

The Inquiry has considered all of the written witness statements provided by the patient and relative group. It also heard oral evidence from 25 of the witnesses who had provided a written statement. Three of them were patients and 22 were relatives or friends of patients.

Although primarily concerned with the 63 patients who contracted CDI between 1 December 2007 and 1 June 2008, the Inquiry also looked at the treatment of CDI patients from 1 January 2007 to 30 November 2007. The patient records that were available for these patients were examined to assess their nursing management. Two statements were obtained from relatives for that early period before December 2007, and one of those relatives also gave oral evidence to the Inquiry.

Of the 63 focus patients, 24 patients had no involvement with the Inquiry either personally or through their families. Some were unable to participate because they had died or were too unwell. Some patients and relatives declined to participate in the Inquiry. Others simply did not respond to the Inquiry's request for assistance. Having approached them, the Inquiry took the decision not to pursue those patients or relatives who expressed a wish not to become involved or did not respond.

The Inquiry also had access to police statements taken as part of the police investigation prior to the establishment of the Inquiry. There were 86 police statements from the patient and relative group available.

The evidence of patients and families was based on recollections of conversations and experiences that occurred several years before they gave evidence to the Inquiry. Individual recollection of detail will vary, and memories are naturally selective. A few witnesses were able to refer to notes to assist their recollection. Some of the events were clearly so distressing that relatives were able to be clear in their recollections despite the passage of time.

Acceptance of the evidence of the patient and relative group

Without exception, the Inquiry was impressed by the care and candour displayed in the oral evidence provided by the patient and relative group of witnesses. In giving their evidence they were asked to recall events that were highly distressing. In many cases the patient involved had died. There was no exaggeration in their evidence, which was presented with dignity. Those witnesses who provided written statements but did not give oral evidence co-operated fully with the Inquiry and endeavoured to provide as accurate accounts as possible of their experiences.

Many witnesses clearly wanted to support their local hospital. In their evidence many witnesses did not criticise directly the care given by nursing staff, believing that any deficiencies in care could be explained by the nursing staff being overworked and understaffed. Some of the incidents described

by relatives were of concern to the Inquiry and raised issues of the nurses' ability to provide fundamental and basic nursing care.

The context of the patient and relative group evidence

The evidence of the patient and relative group was given prior to the evidence of the nursing and medical experts. This group had not had the benefit of reading the reports or the conclusions of experts commissioned by the Inquiry, which covered the nursing and medical care provided to patients, or of hearing them give evidence. The patient and relative group was also unaware of the scale of the problem with CDI at the VOLH.

11.2 The patients' and relatives' expectations

C.diff Justice Group

The relatives of a number of patients who died were instrumental in bringing about this Inquiry. There were 15 families involved in setting up the C.diff Justice Group. The creation of this Group is considered in Chapter 1.

The search for answers

The patient and relative group wished to obtain answers, in particular, to two questions:

- Why were there so many deaths in which CDI was implicated?
- Why was the extent of the problem with CDI not addressed by NHSGGC prior to June 2008?

Some extracts from the evidence which encapsulate that message are set out below.

“We did it because we want answers, because nobody has ever been truthful with us. We don't know why our family (member) died, we have never been told why. What happened at the Vale happened, and we feel that we deserve the answers”.¹ Relative

“As you know, we've campaigned for two years to be able to get here today, and I think what we want most out of this is closure, that's what the families are looking for. And to get that, what we need is the answers to what actually went wrong at the Vale. One of the big questions that we have got from what happened at the Vale is why a bug or an infection like this was allowed to run rampant throughout the hospital for six months undetected. In fact, when it did actually come out, we were told that they knew about all 55 cases but couldn't link them. That shows to us that there's been a massive systems failure, not only at the Vale of Leven Hospital but throughout the systems in the NHS, and we feel that that's the lessons that need to be learned here to make a difference and hopefully save lives in Scotland”.² Relative

“...when you have to go into hospital, you should feel that you are going into a safe and clean environment, and if you are just going in for tests – my mum went in for tests. She might have had cancer, she would have died eventually, but she wouldn't have died that horrendous death through the *C. diff* if there'd been procedures set in place. Nobody goes into hospital and expects not to come out because they catch some fatal disease, and I feel very strongly about that”.³ Relative

“We are saddened by the fact that in his 90 years, the one and only time dad required hospital care he was badly let down by the NHS and as a result lost his life. We as a family would expect that recommendations already made and any further recommendations resulting from this Inquiry are carried out in full, regularly monitored and regular reviews carried out. This tragedy cannot be allowed to happen again”.⁴ Relative

1 [TRA00020042](#)

2 [TRA00020082](#)

3 [TRA00030131](#)

4 [TRA00020115](#)

“I certainly personally would not like another family to go through the final hours of someone dying with this (*C. difficile*) as a contributory factor or the main factor of a death, because it’s certainly not very pleasant, and if it can stop that happening by being stricter with the controls, keeping people isolated, then that’s really what I would like from the outcome of this...There is every possibility probably he would have died anyway, but this certainly assisted him going a bit quicker, and I certainly wouldn’t want that to happen to anybody else...”⁵ Relative

The other sentiment expressed by the patient and relative group was that others should not be made to suffer in a similar way. This commendable attitude demonstrates that it was not simple self-interest that drove the campaign for an Inquiry.

11.3 Patient care

No direct criticism

In general, as already mentioned, many in the patient and relative group did not criticise the nursing staff directly. Yet witnesses described incidents which indicated that the basic care of patients was not being addressed by nursing staff. Deficiencies in personal care were not attributed to deliberate neglect by nursing staff. There was a perception of a shortage of nursing staff on the wards and an impression that nurses were overworked. This convinced relatives that nurses were providing optimum care in difficult circumstances. Nonetheless, there was a notable consistency in descriptions from witnesses about personal care of patients. The same descriptions were made about patients in different wards.

Descriptions of failures in care

Many of the incidents described by the patient and relative group represented examples of failures in basic nursing care, whatever the explanation. One witness described the care given to her mother, who had just suffered a stroke, in the following way:

5 [TRA00040151](#)

“I just felt as if she was just – it’s not very nice to say this, but I just felt as if she was left in a wheelchair, left to get on with whatever. They just left her alone...I don’t think she got the care that she deserved... when we used to go up to the hospital we had to clean her, and we had to comb her hair and fix her hair and tidy her up a little bit...it was quite upsetting because that wasn’t my mum. My mum always kept herself neat and tidy, and to see her in that condition, it wasn’t very nice for us to see her that way”.⁶ Relative

Some patients in different wards were described by relatives as having dirty fingernails. One witness said that his mother’s fingernails were always dirty and that he took wet wipes in to clean her hands. He found “material”⁷ under his mother’s fingernails.

Another witness said that her father’s fingernails were “always filthy”.⁸ She said that previously he had always been meticulous about his hand cleanliness:

“...one of the things I remember is my father was meticulous about keeping his hands and his nails clean, and in hospital his nails were always filthy and I was always having to clean them for him, and my mother used to do that as well”.⁹ Relative

One relative said that when cutting her mother’s fingernails she found faeces under her nails.¹⁰ Another witness described smelling faeces on her mother-in-law’s hands.¹¹

One patient who was in isolation complained to her daughter that she had no means of washing her hands after she used the commode. The daughter described the position in the following way:

6 [TRA00020031](#)

7 [TRA00050115](#)

8 [TRA00040060](#)

9 [TRA00040060](#)

10 [TRA00010066](#)

11 [TRA00020059](#)

“...she wasn’t offered any way of washing her hands after she had used the commode, and I had given her hand wipes and hand gel for her own personal use, but underneath her fingernails you could see excrement, and I used to go frequently with a face cloth and water, soapy water.... and wash her hands and face and try to clean her nails”.¹² Relative

When asked how often she needed to wash her mother’s hands and face and clean her nails, she said she did this on a daily basis for the full month her mother was in the VOLH.¹³ She did accept that she did not mention to the nursing staff that she had found excrement under her mother’s fingernails, but in any event the nursing staff should have identified that failure in hygiene for themselves and addressed it.

The following description was provided by another witness:

“Well, near enough on every visit we’d go up and see my mum and we had to use baby wipes on her to clean her up because she had dinner on her, either on her face or on her chin or down her front. So we had to clean her up... that was on several occasions that happened”.¹⁴ Relative

Another witness provided the following description of her mother’s appearance:

“..when we went up she would have dried food around her mouth, her lips would be quite dry and chapped, she would just be not clean looking, she just didn’t look clean. So we would go up and we would, like, wash her face with wipes, we would put moisturiser on her hands and on her face, we’d put lip salve on her lips just to kind of freshen her up”.¹⁵ Relative

That same witness also gave the following evidence:

“I think in the whole time she was in the hospital, so we’re talking about maybe eight, nine weeks, they washed her hair twice. She had never–she hadn’t had a bath. As you’ve seen, they’re saying they’re bed bathing her, but that’s not the same”.¹⁶ Relative

The descriptions provided by relatives were not restricted to issues of personal hygiene. Witnesses described taking wipes to the VOLH to wipe down tables and trays because they felt they were not clean.¹⁷ One family group noted that their mother’s catheter bag was usually full at visiting times. They brought this to the attention of nursing staff on more than one occasion. They also saw what were described as puddles at the side of the bed on the floor in the vicinity of the catheter bag. Nurses eventually strapped the bag to the patient’s leg, and the patient subsequently developed sores on her leg where the bag was located.¹⁸

The family of this patient also discovered that she had egg in her mouth from a previous mealtime, and described that discovery in the following way:

“We went in to see my mum and she was sleeping, so I went over ... and then the next minute she just opened her eyes and coughed, which at the time I didn’t know what it was, it appeared to be egg. She had been sleeping with egg in her mouth”.¹⁹ Relative

One witness said that when she visited her mother in ward 6 she saw that her mother had no water beside her bed. That prompted her to take bottles of water to the ward for her mother to drink.²⁰ This was a course of action also adopted by other witnesses.²¹ Another witness described how she went to the nurses’ station to ask for a jug of water for her mother as she knew she could

12 [TRA00030108-109](#)

13 [TRA00030109](#)

14 [TRA00020023](#)

15 [TRA00020051](#)

16 [TRA00020057](#)

17 [TRA00010146](#)

18 [TRA00020051-52](#)

19 [TRA00020013](#)

20 [TRA00010109](#)

21 [TRA00320116](#); [TRA00370046](#)

become dehydrated. This request was refused by the nurses, who said she already had a glass of water.²² Thereafter this witness took water into the VOLH for her mother. One relative was told by another patient that her mother had shouted for an hour and a half for a drink one night but no one had come to attend to her.²³ Another witness described patients shouting to be taken to the toilet and nurses not being able to assist as they were dealing with other patients.²⁴

One patient on ward F rang her bell to catch the attention of nurses because she was concerned about other patients in her bay who were incapable of calling for assistance themselves. She was told by staff to stop doing so.²⁵ This particular patient had been accustomed to having a wash before breakfast at home. Nursing staff were asked to attend to this, but apparently it was never done.²⁶

Some relatives did not witness a real difference in care when patients were diagnosed with CDI.²⁷

“And nobody came to us after she was diagnosed with *C. difficile* and said “She’s got this, we need to make changes in the way that we handle her.” Nothing. There was absolutely no difference in the care and no difference in what was expected from us”.²⁸ Relative

Unacceptable failures in care

Patients should be clean and well cared for by nursing staff. Relatives should not find patients with dirty fingernails. There is no excuse for this poor level of care. Cleanliness can be described as “fundamental care”: a basic level of care that is essential to patient physical and psychological wellbeing. The evidence of a lack of basic personal care raises issues regarding the overall quality of nursing care. The nursing care is considered in more detail in Chapter 12.

11.4 The patients’ and relatives’ view on staffing

Staffing numbers

Many relatives assumed that the nurses’ failures to render basic care was due to a shortage of nursing staff on the wards and because nurses were overworked. There was a belief that nursing staff were doing the best they could in difficult circumstances.

The position was described by one witness in the following way:

“I thought the staff were severely understaffed. If you look at ward F, it is quite a big ward. It was constantly filled at the time we were in, and most times we would see two staff nurses and two auxiliaries that were dealing with that full ward, which is why we think they only had kind of the time to be able to go round each of these patients and give them the medical care they needed, they did not have the time to do the personal care. I don’t think it’s that they neglected the patients or they didn’t want to do it, they physically were unable to give the patients the personal care they needed”.²⁹ Relative

Staff on ward 6 were described as “always on the move”³⁰ or “run off their feet”.³¹ One witness described nurses as “firefighting”.³²

One relative expressed the view that the nursing staff on ward 6 appeared to be young, inexperienced and not properly supervised. She said her mother had to remind them when she needed medication, inhalers or oxygen as they would forget that those tasks needed to be done. Instead of doing one thing at a time, it seemed that they were trying to do half a dozen things at once. This was how she described the position in evidence:

22 [TRA00070148](#)

23 [TRA00030041](#)

24 [TRA00030057](#)

25 [TRA00070048](#)

26 [TRA00070073-74](#)

27 [TRA00050110](#)

28 [TRA00020067](#)

29 [TRA00020073-74](#)

30 [TRA00010049](#)

31 [TRA00010029](#); [TRA00010109](#); [TRA00010147](#);

[TRA00030070](#); [TRA00040097](#)

32 [TRA00050109](#)

“She had to, [her mother] actually, on one occasion, remind the staff that she needed a blood test before she could be released, and they had to be reminded. One thought the other had done it, and the other thought that the other nurse had done it, and nobody had done it at all...”³³ Relative

Another relative spent time with her mother outwith normal visiting times. Nursing staff told her they were grateful that she could come in and sit with her mother because they were so short staffed.

More than one witness described an elderly relative as not wishing to bother nursing staff because the nursing staff were too busy.

Being busy is not a legitimate excuse for the failures in basic care described by relatives. Staffing is also considered in Chapter 12.

Staff morale

Some witnesses formed some impression of staff morale, and thought staff morale was very low.³⁴ One witness said that the general opinion from the staff was that the VOLH was being run down and due to close.

One patient described staff morale in the following way:

“At times morale—I would say that morale was very low as well in the ward, or generally in the hospital, because of the uncertainty surrounding jobs and their future”.³⁵ Patient

11.5 Communication

General communication

There was a real concern expressed by the patient and relative group about a general lack of communication from nursing and medical staff.

Deficiencies in communication did not appear to be confined to any particular ward. Information was not readily provided

by nurses and doctors, and witnesses who were able to obtain information only did so due to persistence. One witness said that information was never volunteered, and that if information was required it was necessary to go and ask.³⁶

The following two witness accounts in particular illustrate the general theme of a lack of communication:

“We were never ever told anything that was going on with my mum. We always had to go and ask things, like did my mum have a good night’s sleep? Did she eat her dinner? We never found out”.³⁷ Relative

“We felt that we were a pest to the staff, because every visit we would ask questions like “How’s she doing? Has she been to the toilet?” We would just ask questions, and although to the staff they were probably trivial questions that didn’t mean much, to us they were really important to know how she was doing, just in even everyday things. But we never felt as though the staff could actually sit down with us and say, “This is what’s happening, this is where we are with your mum. You actually felt as though you were intruding in kind of the system they’d set up when you actually went forward to ask about anything...”³⁸ Relative

One witness thought that the nurses had no time to speak to the relatives. Another witness said it was “rare”³⁹ to be able to pin a nurse down.

One relative resorted to reading her father’s records kept at the bottom of his bed in an attempt to obtain information about his condition, but the notes were taken away when the nurses became aware of this. Thereafter this relative had to go to the nurses’ staff room in order to attract the attention of nursing staff. Usually all she managed to obtain was a brief update. On one occasion the emergency team had been called overnight to attend her father, but the

33 [TRA00070008-09](#)

34 [TRA00010070](#); [TRA00040100](#); [TRA00050109](#); [TRA00010081](#)

35 [TRA00040100](#)

36 [TRA00050061](#)

37 [TRA00020031-32](#)

38 [TRA00020074-75](#)

39 [TRA00040061](#)

family were not contacted by the hospital and advised of this development at that time.⁴⁰

There were also difficulties in obtaining information from medical staff. One witness said that on several occasions the family had asked to speak to a doctor. During the period of 18 months that the patient was in the VOLH they were unable to do so.⁴¹

One witness, whose mother was critically ill, made an appointment to see Dr Javed Akhter, a Locum Consultant Physician. He arrived for the meeting and waited for an hour, but Dr Akhter did not attend the appointment.⁴² Despite the best efforts of nursing staff and his secretary, Dr Akhter could not be found. Dr Akhter later told the witness that he had been on a ward round, although the witness had been told by the nurses that Dr Akhter had not been on that ward. Dr Akhter did later have a meeting with him.

From the evidence of relatives, it was apparent that there was a lack of proper discussion with them about decisions not to resuscitate and DNAR orders.

Importance of communication

Communication is an integral and important element of patient care. Poor communication reflects an attitude that presents a barrier to the provision of good and consistent care. Patients, and where appropriate relatives, have a right to be involved in decisions about care. This is enshrined in the guidance issued both by the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC).⁴³

There was difficulty obtaining information from nursing staff at evening visiting time because this coincided with shift changes when nurses were engaged in handover. There has to be communication between nursing staff during a shift change. Nonetheless, for many relatives visiting time will be the only time they are present with the opportunity of obtaining an update on a

patient's care and likely to seek information. It is important that arrangements are made for a member of staff to be available for family members seeking information.

Communication regarding CDI

There was a lack of communication about CDI. The tenor of the evidence was that CDI did not appear to be considered by nursing staff to be a significant risk. Some witnesses described being told that it was a "wee bug".⁴⁴

The following extract from the evidence of one witness is a typical example of the evidence on this subject:

"She never gave us any inclination of the dangers of *C. diff* or what to do or that it was life-threatening. *C. diff* didn't appeal to me at that time. I thought it was just a bug because she never explained to me what it was".⁴⁵ Relative

One witness asked a member of the nursing staff if CDI could be life-threatening, and was told that it could be, but that her father would be fine because he was on antibiotics.⁴⁶ He subsequently died. *Clostridium difficile* Enteritis is listed on his death certificate as the cause of death⁴⁷ and Professor George Griffin, an infectious diseases expert commissioned by the Inquiry, agreed with this conclusion.⁴⁸

Obtaining information from medical staff was difficult. One witness said that she was unable to speak to a doctor after her mother was diagnosed with CDI. She was given no indication of what the outcome could be or how the infection was being treated. She went on the internet to obtain information and was "horrified"⁴⁹ when she learned what the infection could involve. When her mother's condition deteriorated she asked again to speak to a doctor. She was told that the consultant was too busy to speak to her and that there were no other doctors

40 [TRA00030162-163](#)

41 [TRA00040061](#)

42 [TRA00050088-89](#)

43 [INQ00270018-22](#); [INQ01970004-05](#)

44 [TRA00010122](#); [TRA00010123](#); [TRA00010152](#); [TRA00030025](#); [TRA00030141](#); [TRA00040027](#); [TRA00040038](#)

45 [TRA00020019](#)

46 [TRA00020097-98](#)

47 SPF00020001

48 EXP02590006

49 [TRA00010130](#)

available. Eventually she spoke to a junior doctor, who asked her if she realised that her mother was dying because of the CDI.⁵⁰ She had not realised her mother was dying and described the doctor as being “brutal” in telling her that her mother would not be resuscitated.⁵¹

Another witness asked to see a doctor after her father had been diagnosed with CDI, and was told that she would have to make an appointment. Even then she was told there was no guarantee that she would be able to see a doctor, as doctors were very busy and were not always available at visiting times.⁵²

A similar experience was described in the following way by another relative:

“they all just said he had an infection. Nobody told us what infection he had, and he was always just going for a scan or just going for this. On several occasions I asked to speak to a doctor, and on not one occasion in the whole time, in the whole period he’d been in and out of the Vale, did I ever get to speak to a doctor...There was never anybody available. And the nurses were so busy that it was very rare you could pin a nurse down to speak to a nurse either”.⁵³ Relative

This particular patient had been an inpatient on a number of occasions over a period of about 18 months.

Other witnesses described not being aware that their relatives had CDI until their relative had died. One witness said he was unaware that his mother had been diagnosed with CDI until he saw *C. difficile* on the death certificate. Another witness only found out that her father had been diagnosed with CDI when the police contacted her six months after her father’s death.⁵⁴ Another witness had a similar experience, only becoming aware that his mother had suffered from CDI at the time of the police investigation in

2009.⁵⁵ His mother had tested positive for CDI on two occasions on ward F⁵⁶ in January and February 2008. One witness was not told at VOLH that her father had CDI and it was only when he was transferred to the Royal Alexandra Hospital (RAH) that she discovered that he had the infection.⁵⁷

The lack of information provided on CDI by nursing staff was unacceptable. It is important that, where appropriate, relatives are aware of the diagnosis of CDI and also the implications of the diagnosis. This enables relatives to co-operate with staff in implementing infection control measures.

Information leaflets about CDI

Many family members were not given information leaflets about CDI after a relative was diagnosed with the infection.⁵⁸ In instances where a leaflet was provided no additional explanation was given,⁵⁹ although in ward 14 a witness did receive a leaflet and also a full explanation from the nurse.⁶⁰

One witness explained that she was not given an information leaflet when her mother was in ward F. Her sister asked for a leaflet and was told there was no leaflet available,⁶¹ although later that day she was given one. Her point was that she had to ask for it rather than it being handed to her as a matter of course.

Relatives of patients suffering from CDI should be provided with an understanding of the nature of CDI, particularly if they need to manage a patient’s laundry. A proper understanding can be helpful in the enforcement of infection prevention and control precautions. Leaflets can be useful in reinforcing information but should not be used as a substitute for discussion.

50 [TRA00010132](#)

51 [TRA00010137](#)

52 [TRA00040038-39](#)

53 [TRA00040061-62](#)

54 [TRA00040052](#)

55 [WTS00410004](#)

56 [GGC00260020](#); [GGC27230014](#)

57 [TRA00050040-42](#)

58 [TRA00010037](#); [TRA00020033](#); [TRA00030123](#); [TRA00040044](#); [TRA00050054-55](#); [TRA00050144](#); [TRA00070003](#)

59 [TRA00050112](#); [TRA00030022-23](#)

60 [TRA00050085-86](#)

61 [TRA00070138](#)

11.6 Ward fabric and cleanliness

A poor hospital environment

The patient and relative group painted a picture of a hospital that was run down. As discussed below, there was also evidence that the hospital environment was not particularly clean. Many witnesses were local people who had experience of the hospital over many years and who noted a significant change in its state. Witnesses who had been familiar with the hospital from years previously were shocked at its state.⁶²

One witness who had personal experience of working in hospitals expressed the following opinion:

“Well, I just feel from my own experience of working in hospitals, you know, I’m going back 25, 30 years ago, when we used to have matrons and hospitals smelt of hospitals, everything sort of smelt of disinfectant and everything was always being cleaned and we were meticulous about hygiene, and in the Vale I didn’t ever really see any evidence of that. Even there was plaster falling off the walls, the buildings weren’t maintained properly. ...there was always a stench of urine and/or faeces and nothing ever looked particularly clean. There was never any time where every holder for hand gel had actually hand gel in it”.⁶³ Relative

Another witness presented the following picture:

“I don’t personally believe that the hospital was filthy or dirty. I believe that it was run-down, and the fabric of the building was quite shabby, which obviously gave it a generally unkempt look, but for something to be aged and dated doesn’t necessarily mean it’s dirty. So my personal feelings were that there was nothing I thought in the hospital that looked really, really dirty”.⁶⁴ Relative

It must be borne in mind that the evidence on this issue was provided by witnesses who were only on the premises at visiting times, although some witnesses were present for

lengthy periods, usually when a patient was nearing death.

One relative who was retired and did spend more time at the hospital provided this description:

“During the day when I was there, cleaners would be about. To me, it seemed very hit and miss. They’d come along and do a bit of mopping. They never seemed to move anything. They just basically cleaned what they saw. There was never any effort to clean above head height. The curtains didn’t look very clean, the windows were not very clean”.⁶⁵ Relative

The outward appearance of the hospital was described as poor, tired looking and in need of repair and decoration. There was a general feeling that the hospital was being “run down”.⁶⁶

The fixtures and fittings in ward 6 were described as old. There were chipped tiles, odd tiles missing, and sections of missing plasterboard. The window blinds in one patient’s room in ward 6 had slats missing. The effect of this was that people in the corridor could see directly into the patient’s room. The family did ask if they could be replaced, but they were told that money would not be available for that to be done. The nursing staff cut up a laundry bag and placed that over the slats to give the patient some privacy when getting dressed. The laundry bag remained there even after there had been a deep clean of the ward.⁶⁷

One patient summarised his view of the facilities in the following manner:

“The cabinets were probably the original cabinets since the place was built; the seating, I would say, was the original seating since the place was built; it was very old furniture; the commodes, as I say, were ancient; the windows were held open by a book because the mechanism wasn’t working properly in most of the windows”.⁶⁸ Patient

62 [TRA00010105](#); [TRA00010144](#);

63 [TRA00040059-60](#)

64 [TRA00020077](#)

65 [TRA00050147](#)

66 [TRA00010144](#); [TRA00010153](#); [TRA00020077](#);
[TRA00040141](#); [TRA00050106](#); [TRA00050147](#)

67 [TRA00010063-64](#)

68 [TRA00080025](#)

Another witness had a professional career working in building maintenance. He formed the impression that there had been a lack of funds spent on the fabric of the building, and described it as “really tired looking”.⁶⁹ He indicated that he could put his finger through the window frame in the isolation room.⁷⁰ He was shocked at the state of cleanliness, and described the cleaner washing a path down the middle of the corridor with no tables or chairs moved to enable the edges of the areas to be cleaned properly.

The television remote control in an isolation room in ward 3, where a patient suffering with CDI was being accommodated, was observed to be “really dirty round the buttons”⁷¹ with “particles of whatever people had on their fingers from all the times it had been used in previous months and years”.⁷²

There was one incident where a visiting relative lost a false nail in the ward. Two days later, when visiting her mother, she found the false nail on the floor beside the bed where she had previously been sitting.⁷³ Another witness described a sweet wrapper lying under her mother’s bed for a couple of days.⁷⁴

One witness described putting items back in her mother’s bedside cabinet and finding a yogurt tub and a small tub that contained mould.⁷⁵

One witness described seeing urine on the floor of ward 14. She said that the floor had been wiped but not cleaned and she could smell urine. She brought this to the attention of nursing staff, indicating that it still had not been cleaned. She described the “stench”⁷⁶ on the ward as “disgusting”.⁷⁷

Storage

Various items were stored within patient bays. One witness described boxes stored

opposite her mother’s bed in ward 6, piled up beside a fire escape. She said that when her mother was in isolation in ward 3 the room had boxes stacked up on either side.⁷⁸ The casing on the overhead light was also broken.⁷⁹

Another witness described an old Christmas tree and other items stored in the same area in ward 6. Her mother told her that she had difficulty getting to sleep due to the constant traffic of people obtaining supplies stored in the bay where she was being accommodated.⁸⁰ Jackets and bags belonging to staff were seen to be left in the TV room of ward 6.

Personal hygiene

Some witnesses provided descriptions of faeces on clothing. One witness described her father’s slippers as being badly soiled.⁸¹ They were washed under the shower and then placed on the radiator to dry. Her father also tried to get up at 06:00 every morning to have a shower when the shower was clean, because as the day went on he had a concern about the condition of the shower.⁸²

Another witness complained of dirty commodes.⁸³ This witness also recalled going into her mother’s room and finding her mother’s slippers covered in faeces. There were also faeces on the cord of her mother’s dressing gown. The slippers were on the floor and the dressing gown was lying across the bottom of the bed.

One patient provided a rather graphic picture of the shower area in one of the wards:

“...the shower cubicle, it was black. The mould on the floor, it was coming away from the walls. The shower tray, it was like lino type of material, and that was all loose around the edge. The walls were dirty. As I say, the toilet—I cleaned it every time before I used it and after I used it”.⁸⁴

Patient

69 [TRA00050106](#)

70 [TRA00050106](#)

71 [TRA00030175](#)

72 [TRA00030175](#)

73 [TRA00030066](#)

74 [TRA00070111](#)

75 [TRA00020023](#)

76 [TRA00040031](#)

77 [TRA00040031](#)

78 [TRA00010143](#)

79 [TRA00010143](#)

80 [TRA00010024-25](#)

81 [TRA00030165](#)

82 [TRA00030170-171](#)

83 [TRA00010028](#)

84 [TRA00040092](#)

The importance of the environment

The fabric and cleanliness of a hospital are important to patients and visitors. If a hospital is clean and well maintained⁸⁵ it will be seen as a safe environment. Visible cleanliness is also important from a psychological point of view for both patients and visitors. The fact that a patient thought it necessary to get up early to experience the benefit of a clean shower environment is a feature of unacceptable care.

11.7 Infection prevention and control issues

Hand hygiene

There was some variation in the evidence on hand washing, but it was clear that inadequate information was generally given on hand washing. This was a trend in a number of the wards.

Most witnesses were aware of the need to use hand gels when entering a ward. Some spoke of the presence of notices at entrances to wards advising on the use of hand gels. Some witnesses also spoke of visitors choosing to ignore the instruction to use hand gels when visiting the wards.⁸⁶

There was some evidence that the hand gel dispensers were left empty even when this was brought to the attention of nursing staff. Gel dispensers on each side of the door to ward F, just inside the ward, remained empty for three consecutive days despite relatives making several reports to nursing staff during that period.⁸⁷ There was no evidence that this was a widespread problem that existed in other wards.

There was a lack of information from staff to visitors that hand gels were not always effective. Many were not advised of the importance of the use of soap and water when a patient was diagnosed with CDI,⁸⁸ and

some witnesses did not realise that gels were ineffective against *C. difficile*.⁸⁹ One relative was specifically told to use hand gels when her father was diagnosed with CDI.⁹⁰

It can be difficult to ensure that all visitors will use the hand gels on entering a ward. It is, however, important to take steps to encourage their use, and to ensure that the dispensers are regularly filled.

Laundry

Heavily soiled laundry was being taken home by relatives of patients suffering from CDI. Few witnesses appeared to have been given clear instructions on how to deal with such laundry.⁹¹ Different and conflicting instructions were given in different wards.⁹² A number of relatives believed that in taking soiled laundry home they had exposed themselves and other members of their family to an unacceptable risk of infection.⁹³

There was a lack of consistency about the bags to be used to give relatives soiled laundry. Some witnesses were given soiled laundry in a black bin bag.⁹⁴ One relative said that her mother's laundry was always in a white bag with red writing on it saying "Patient's Clothing" even when the laundry was soiled with diarrhoea.⁹⁵ One witness described her father's laundry being left in his locker in a white plastic bag.⁹⁶ Another described a patient's clothing bag and a carrier bag being used.⁹⁷

One witness said that he could smell the soiled laundry when he went into his mother's room and that the bag would either be at the side of the bed or on the floor beside the radiator, which worsened the

85 [WTS00200002](#); [WTS00510015](#)
86 [TRA00010142](#); [TRA00030105](#); [TRA00050076](#)
87 [TRA00070026](#)
88 [TRA00020019](#); [TRA00020067](#); [TRA00020099](#);
[TRA00020150](#); [TRA00030027](#); [TRA00030033](#);
[TRA00030146](#); [TRA00040012](#); [TRA00040024](#);
[TRA00050052](#); [TRA00050086](#); [TRA00060120](#);
[TRA00070106](#); [TRA00070139-140](#); [TRA00070179](#)

89 [TRA00010052](#); [TRA00070144](#)
90 [TRA00040024](#)
91 [WTS00020007](#); [WTS00030006](#); [WTS00050006-08](#);
[WTS00230011](#); [WTS00290009](#); [WTS00390012](#);
[WTS00590007](#); [WTS00600005](#); [WTS00630013](#);
[WTS00500010](#)
92 [TRA00010061](#); [TRA00020029](#); [TRA00020055-56](#);
[TRA00020102](#); [TRA00020145-146](#); [TRA00030034-35](#);
[TRA00030164-166](#); [TRA00040033-34](#);
[TRA00050103-105](#); [TRA00070008](#); [TRA00070183-184](#)
93 [TRA00070105](#); [TRA00030129-130](#); [TRA00030111-115](#)
94 [TRA00020102](#)
95 [TRA00020034-35](#)
96 [TRA00030166](#)
97 [TRA00070184](#)

smell.⁹⁸ He was given white bags and also red bags. He was told to put the red bag into the washing machine and that it would dissolve. Another witness described putting the soiled laundry bag into the boot of the car and driving home with the car windows open because of the stench from the soiled laundry.⁹⁹

A number of witnesses steeped the soiled laundry.¹⁰⁰ Others washed it separately from the family wash and some put it through a boil wash.¹⁰¹ One witness described putting the dirty laundry in the bath to “dissolve the diarrhoea”¹⁰² before she put it into her washing machine.

The following description was provided by one witness:

“...on one particular day I picked up my mum’s laundry to take it home and I could smell something from the bag, it was quite strong and it was diarrhoea, it was all over her clothes. I got it home and I was actually going to throw the clothes in the bin because they were that bad, but I decided to rinse off the diarrhoea and put them into the washing machine...”¹⁰³

Relative

Another relative who was given no instructions on how to deal with contaminated laundry provided the following description:

“...the laundry by this time was getting steadily worse. I mean, beyond belief. I wouldn’t like to wish this on anyone. It was like going back to having a baby. I had to purchase a separate bucket. I had to scrape it off, rinse it out, and nothing removed these stains. I purchased Napisan, which is what I used to do when I had my children years ago, which is a nappy steriliser, mixed it up in the bucket, put the laundry in there, left it overnight, and then had to boil wash it. And sometimes even that was not enough to

remove these stains, it was such a disgusting mess. And on occasions I eventually had to throw the laundry out”.¹⁰⁴

Relative

On one occasion one of the nurses said to this witness as she was leaving the ward that she should put red laundry bags straight into her washing machine as there was a special bacterial agent in it.¹⁰⁵ The witness was referring to the red alginate bags which should not have been given to relatives to take home as they were designed to dissolve at high temperatures in industrial machines. The witness was unaware of that, and when she opened the machine at the end of the wash she could not find the bag and was concerned that it was stuck in the filter of the machine. When she discussed the incident with nurses she was surprised that the nursing staff did not seem to be aware of how to treat contaminated laundry.¹⁰⁶

Letter of complaint on laundry

A letter of complaint dated 24 January 2008 to the VOLH Divisional Services Manager reflects a number of the issues raised in evidence by witnesses about laundry. The patient concerned tested positive for CDI in January 2008. The letter set out how different family members were given differing advice on laundry while the patient was in ward F and expressed concern over “the lack of information and guidance offered by the staff”.¹⁰⁷ It concluded by asking the hospital to be “transparent about situations such as this in the future.”¹⁰⁸

The response by Ms Anne Harkness, Director of Rehabilitation and Assessment, asserted that:

“staff have been reminded of the importance of providing clear and accurate guidance to relatives with respect to the laundering of clothing”.¹⁰⁹

98 [TRA00050103](#)

99 [TRA00030166](#)

100 [TRA00030034-35](#)

101 [WTS00420005](#)

102 [TRA00020035](#)

103 [TRA00020027-28](#)

104 [TRA00030111-112](#)

105 [TRA00030113](#)

106 [TRA00030114](#)

107 [GGC23530001](#)

108 [GGC23530002](#)

109 [GGC23540001](#)

Despite that assurance, no instructions on how to deal with the laundry were given to the family members of several patients who tested positive for *C. difficile* in ward F between 4 February 2008 and 1 June 2008.¹¹⁰

Dealing with soiled laundry was an unpleasant and distressing experience for relatives.

Wearing of gloves and aprons

There was inconsistent advice given to relatives on whether they should wear gloves and aprons when visiting patients with CDI. Some relatives were asked to do so,¹¹¹ but most were not.¹¹² Initially members of one family were told to wear gloves and aprons when their father was isolated. Later they were told they did not need to do so. Later still they were told to wear gloves but not aprons.¹¹³

Most witnesses said that the nursing staff did wear aprons and gloves when dealing with patients, although many did not witness the patient being cleaned or changed. One witness was able to contrast the staff at the VOLH with the staff at the RAH, having noted that some of the nurses in the VOLH did not wear plastic aprons or gloves as the nurses at RAH did.¹¹⁴

One witness was aware that nursing staff did not wear gloves and aprons at a time when her mother was being barrier nursed,¹¹⁵ although generally the evidence suggested that nursing staff did wear aprons and gloves when dealing with patients suffering from CDI. The evidence of relatives is limited by the fact that they were not often present when patients were being changed or washed.

Isolation of patients/notices

There was evidence from relatives that patients with CDI were not moved into single rooms as soon as they suffered from diarrhoea. Patients were only moved after the diagnosis was confirmed. This evidence is fully supported by analysis of the patient records, and was a practice accepted by the nursing staff who gave oral evidence. Isolation practices are discussed further in Chapter 15.

A number of witnesses did not recall seeing a notice outside their relative's isolation room advising visitors to speak to nursing staff prior to entering the room.¹¹⁶ One witness, who was a qualified nurse, recalled his mother being in an isolation room prior to her death. He assumed it was for terminal care¹¹⁷ but subsequently learned she had CDI. He was not aware of any sign outside the room.

Even when patients were in isolation, strict isolation procedures were not always followed.¹¹⁸ Doors of isolation rooms were left open,¹¹⁹ and at least one area used for isolation did not have a door.¹²⁰

One witness recalled a cleaner coming into her father's isolation room when family members were present. The cleaner mopped the floor and then moved to clean outside on the general ward. She did not see the cleaner change the water.¹²¹

Another witness described the tea lady coming in and out of the isolation room at a time when her relative was diagnosed with CDI.¹²²

Movement of patients

Patients were moved frequently within wards¹²³ and also between wards.¹²⁴ Some relatives were not given information as to

110 [TRA00030035](#); [WTS01460008](#); [WTS00410005](#); [WTS00610006](#)

111 [TRA00020133-134](#); [TRA00020145](#); [TRA00030095](#); [TRA00010020-21](#); [TRA00010042-43](#); [TRA00020099](#)

112 [TRA00040062](#); [TRA00040141](#); [TRA00030026](#); [TRA00030144](#)

113 [WTS00050006](#); [TRA00020098-101](#)

114 [TRA00010141](#)

115 [TRA00020017](#); [TRA00020022](#); [TRA00020036](#); [TRA00020076](#)

116 [TRA00010041](#); [TRA00030104-105](#); [TRA00030175-176](#); [TRA00040041](#); [TRA00040148](#); [TRA00050064](#); [TRA00070178](#); [TRA00080023](#) [TRA00050095](#)

117 [TRA00070178](#)

118 [TRA00030103-105](#); [TRA00010143](#)

119 [TRA00070178](#); [TRA00080034](#)

120 [TRA00010086](#); [TRA000290033](#)

121 [TRA00040028-29](#)

122 [TRA00020109](#)

123 [TRA00010008-13](#); [TRA00010116](#); [TRA00030080-83](#); [TRA00030144-145](#); [TRA00060037-38](#);

[TRA00060128-131](#)

124 [TRA00010116-117](#)

why the patient was moved.¹²⁵ To determine from the medical records when patients were moved between wards has been difficult, as reasons for the move are often not apparent on reading the patient records.

Witnesses recalled patients wandering about freely. More than one witness mentioned a particular patient who was allowed to wander around the ward and who would go in and out of patients' rooms and sit at the nurses' station.¹²⁶ There was another patient who got into bed with other patients and wore their clothes.¹²⁷ One witness did raise with the nurses the fact that this patient was allowed to wander in the ward despite having CDI,¹²⁸ but the nurses' response was that they could not contain her.¹²⁹

Patients were placed in rooms where one or more patients had CDI. One witness recalled her father having diarrhoea and being moved into a room on his own. Later on in the day another patient was moved into the room. The patient had been admitted to the hospital with chest pains. There was no suggestion that he was suffering from CDI, but there was nowhere else to put him.¹³⁰ Two patients were moved into a four-bedded bay where there were other symptomatic patients.¹³¹ The location of patients suffering from CDI is revisited in Chapter 15.

One family did raise the issue of CDI on ward F in February 2008. Their mother had been transferred from another hospital to ward F, and she was placed in what was at the time a four-bedded bay. The family complaint was that she had been transferred into a bay where there were other patients who were suffering from CDI when she herself was not symptomatic.¹³² The placement of an asymptomatic patient into a bay where there was at least one symptomatic patient was a serious failure in care placing the patient at unacceptable risk. This incident is considered more fully in Chapter 12.

The movement of patients within hospital settings may be necessary, and patients may need to be moved between wards, and to different beds within wards, but movement of patients is particularly relevant to issues of infection prevention and control. Where there is infection within a ward, or where a patient is infected and requires to be moved, this must be handled with care and by suitably experienced members of staff.

Bed spacing

There was criticism by some of the witnesses of the lack of space between patients' beds. It is to be noted that these witnesses have approached this from a lay perspective, and the issues they raised related more to access and privacy.

One patient who was admitted to ward 6 said that the beds were so close together patients could touch each other.¹³³ There was no room for a seat between the beds for visitors.

Another witness said that it was not possible to place a plastic bucket type chair between the beds in ward 6. The beds were so close together that her mother could have held hands with the patient in the next bed.¹³⁴ She also described a time when her mother was moved to ward 4 and a patient in the next bed to her mother had died. She said that the bed spacing and the curtain arrangement allowed her to see the covered body of the deceased patient in the next bed. Her mother was also able to see this and found it very distressing.¹³⁵

There was evidence from one witness about the difficulties she encountered in preparing her father for bed in a bay in ward 15 because the beds in that bay were so close together.¹³⁶

There also appeared to be bed space issues in ward 3. One relative explained that in ward 3, where her father was a patient, the spacing between beds was so tight that people moving between the two beds pulled out his oxygen without realising that had

125 [TRA00010110](#); [TRA00010163-164](#); [TRA00010125](#); [TRA00060038](#); [TRA00060130](#)

126 [TRA00040032-33](#); [TRA00050010](#)

127 [TRA00020064-65](#); [TRA00020029-30](#); [TRA00030063](#)

128 [TRA00070072](#)

129 [TRA00410168](#)

130 [TRA00030142](#)

131 [TRA00020072](#); [TRA00070021](#); [TRA00070043-46](#)

132 [TRA00070087-88](#)

133 [TRA00020120](#)

134 [TRA00010014](#)

135 [TRA00010058](#)

136 [TRA00040034-35](#)

happened.¹³⁷ This meant that he could be without oxygen for hours until he started to feel unwell and a nurse checked his oxygen level. This witness also said that she could place a small plastic chair in between the beds, but that her knees would be touching one bed with her back touching the other bed.¹³⁸

It is clear that in some areas of the hospital the beds were so close together that access and privacy were affected. If relatives had difficulty placing chairs between beds, it does raise an issue of how nursing staff would be able to use equipment in the area.

11.8 Conclusion

The patient and relative group wanted to have a public inquiry because they wished a full examination of why there were so many deaths in which CDI was implicated. This group also wished to understand how the CDI problem had gone unnoticed for such a significant period of time. From an analysis of the evidence of relatives the two main areas of concern were personal care of patients and communication from both nursing and medical staff.

Relatives described serious deficiencies in communication on the part of both nursing and medical staff at VOLH. Communication on aspects of CDI was poor.

Relatives did describe incidents which raised significant concerns about the quality of nursing care in a number of wards. The evidence of patients with faeces under fingernails is of particular concern. Patients are entitled to expect to be clean and cared for when they go into hospital. This is a fundamental aspect of care. Some of the events described by relatives confirm the serious deficiencies found on detailed examination of patient notes by the expert witnesses, many of which are considered in Chapter 12. There should be no acceptance of a culture of poor care. It is important that standards are set and that these standards are enforced.

11.9 Recommendations

Recommendation 10: Health Boards should ensure that patients diagnosed with CDI are given information by medical and nursing staff about their condition and prognosis. Patients should be told when there is a suspicion they have CDI, and when there is a definitive diagnosis. Where appropriate, relatives should also be involved.

Recommendation 11: Health Boards should ensure that patients, and relatives where appropriate, are made aware that CDI is a condition that can be life-threatening, particularly in the elderly. The consultant in charge of a patient's care should ensure that the patient and, where appropriate, relatives have reasonable access to fully informed medical staff.

Recommendation 12: Health Boards should ensure that when a patient has CDI patients and relatives are given clear and proper advice on the necessary infection control precautions, particularly hand washing and laundry. Should it be necessary to request relatives to take soiled laundry home, the laundry should be bagged appropriately and clear instructions about washing should be given. Leaflets containing guidance should be provided, and these should be supplemented by discussion with patients and relatives.

137 [TRA00030173](#)

138 [TRA00030173-174](#)

Chapter 12

Nursing care

	Page	
12.1	The Nursing and Midwifery Council Code of Conduct	171
12.2	Use of nursing experts	172
12.3	Overall view of nursing experts	175
12.4	Record keeping	176
12.5	Nursing aspects of infection prevention and control	180
12.6	Isolation issues specific to ward F	189
12.7	Nursing assessments and care planning in the focus period	191
12.8	Nursing notes and charts in the focus period	198
12.9	Pressure damage in the focus period	205
12.10	Nursing care in the early period	210
12.11	Staffing issues and care	210
12.12	Overall conclusions on nursing care	213
12.13	Recommendations	214

Introduction

This Chapter of the Report examines the evidence on the nursing care provided to the patients with *C. difficile* infection (CDI) at the Vale of Leven Hospital (VOLH) during 2007 and 2008. There will be a particular emphasis on the focus period (1 December 2007 to 1 June 2008) but where patient records were available consideration is given to the early period (1 January 2007 to 30 November 2007).

12.1 The Nursing and Midwifery Council Code of Conduct

The Nursing and Midwifery Council

The Nursing and Midwifery Council (NMC) is the national regulator for nurses and midwives in the UK and is independent of Government. Its main statutory objective is to safeguard the health and wellbeing of members of the public using or needing the services of nurses and midwives.¹

The NMC monitors national education and training requirements and maintains a register of nurses, public health nurses and midwives in the UK. It sets standards for nurses and midwives for the provision of safe and appropriate care. It has the power to remove a nurse or midwife from the register and can also restrict the right to practise. It is important to emphasise that this is a UK-wide organisation.

The Nursing and Midwifery Council Code provisions

The Inquiry used the standard requirements set out in the NMC Code of Conduct (the NMC Code) in place from 2007 to May 2008² as a basic guide and benchmark. The NMC Code provides that nurses are personally accountable for their practice.³ The following provisions focus on particular aspects of care:

“1.4 You have a duty of care to your patients and clients, who are entitled to receive safe and competent care”.⁴

“3.1 All patients and clients have a right to receive information about their condition. You must be sensitive to their needs and respect the wishes of those who refuse or are unable to receive information about their condition. Information should be accurate, truthful and presented in such a way as to make it easily understood”.⁵

“4.4 Health care records are a tool of communication within the team. You must ensure that the health care record for the patient or client is an accurate account of treatment, care planning and delivery. It should be consecutive, written with the involvement of the patient or client wherever practicable and completed as soon as possible after an event has occurred. It should provide clear evidence of the care planned, the decisions made, the care delivered and the information shared”.⁶

“6.1 You must keep your knowledge and skills up-to-date throughout your working life. In particular, you should take part regularly in learning activities that develop your competence and performance”.⁷

“6.5 You have a responsibility to deliver care based on current evidence, best practice and, where applicable, validated research when it is available”.⁸

“8.1 You must work with other members of the team to promote health care environments that are conducive to safe, therapeutic and ethical practice”.⁹

1 [EXP00640003](#)

2 [INQ01970001-09](#); [INQ00310001-07](#)

3 [INQ01970003](#)

4 [INQ01970004](#)

5 [INQ01970004](#)

6 [INQ01970006](#)

7 [INQ01970006](#)

8 [INQ01970007](#)

9 [INQ01970007](#)

Additional record keeping advice

In 2007 the NMC issued further advice for nurses on record keeping. The following extract highlights the importance of this:

“Record keeping is an integral part of nursing, midwifery and specialist community public health nursing practice. It is a tool of professional practice and one that should help the care process. It is not separate from this process and it is not an optional extra to be fitted in if circumstances allow.

Good record keeping helps to protect the welfare of patients/clients by promoting:

- high standards of clinical care
- continuity of care
- better communication and dissemination of information between members of the inter-professional health care team
- an accurate account of treatment and care planning and delivery
- the ability to identify risks and detect problems, such as changes in the patient/client’s condition at an early stage
- the concept of confidentiality”.¹⁰

The 2007 advice makes this further point:

“The quality of a registrant’s record keeping is a reflection of the standard of their professional practice. Good record keeping is a mark of a skilled and safe practitioner, while careless or incomplete record keeping often highlights wider problems with that individual’s practice”.¹¹

That advice also stresses the importance of auditing patient records.

Nurses’ view on compliance with the Nursing and Midwifery Council Code

The nurses who gave oral evidence at the Inquiry hearings accepted that they had a professional duty to comply with the NMC Code when providing nursing care to patients at the VOLH. Having reviewed patients’ records, they accepted that there had been

failures to comply with the NMC Code. This is developed in later Sections of this Chapter.

As the guidance provided to nurses emphasises, record keeping is an integral part of nursing practice. If widespread failures can be identified there can be little doubt that care has been compromised.

12.2 Use of nursing experts

Nursing experts

The Inquiry commissioned seven independent nursing experts to provide professional opinions on the quality of nursing care given to patients who suffered from CDI during the focus period. The nursing experts were not given access to the statements obtained from VOLH nursing staff, nor were they present during the evidence of nursing staff. The nursing expert opinion was based solely on their analysis of patient records. Sixty-three cases were distributed so as to ensure as far as possible that the nursing experts reviewed a cross-section of cases from different wards.

Quality of care in nursing is not simply a Scottish question, and the Inquiry was therefore anxious to have views from a number of different geographical perspectives. Of the experts who were commissioned, one is based in Scotland, two are based in Northern Ireland and the remaining experts are based in England. It was clear on meeting with the nursing experts that acceptable standards of nursing care did not differ in the different countries, which is not surprising because, as already mentioned, the NMC Code, which provides guidance on professional standards, applies UK-wide.¹²

Instructions given to nursing experts

The nursing experts were instructed to review the full patient records and Infection Control Cards of the patients allocated to them. To ensure consistency of approach and compliance with the Inquiry’s Terms of Reference they were provided with a template¹³ setting out areas to focus upon when reviewing the patient records. They

¹⁰ [INQ02090001](#)

¹¹ [INQ02090001](#)

¹² [INQ01970001](#)

¹³ [INQ05420001](#)

were asked to use the professional standards issued to each registrant by the NMC, and in particular the NMC Code, as a benchmark for the standard of care expected from nursing staff.

The nursing experts were instructed not to discuss their conclusions with each other during the preparation of their reports, so that they formed their own independent views of the nursing care. There was nevertheless a consistency in the views of the nursing experts on the nursing deficiencies identified. The nursing expert opinions are discussed in detail in the following specific Sections.

Use of patient records to audit patient care

Retrospective audit of patient records against pre-determined criteria is a recognised and accepted approach in the analysis of adverse events,¹⁴ and can help ensure quality of care.¹⁵ This was the approach adopted in the Northern Ireland *C. difficile* Public Inquiry.¹⁶

This kind of audit, particularly if it covers a number of weeks or months, allows the reviewer to form a view on the adequacy of the record keeping and the plan of care individualised to that patient. Valid inferences about the consistency and

quality of that patient's care can be drawn. Where a number of patient records are being reviewed, it may also be possible to make valid inferences about quality of care generally in a hospital.

The early CDI cases

To fulfil the Inquiry remit it was necessary to ascertain whether some of the themes identified by the nursing experts in the focus period were evident in the early period of 1 January to 30 November 2007.

As discussed in Chapter 4, 68 patients contracted CDI in the early period. Records for 37 patients were recovered from NHSGGC. The remaining patient records had been destroyed in accordance with NHSGGC's Records Management Policy. Nursing records were missing from four sets of patient records and they were therefore not considered. In addition to considering patient records in the focus period, one of the nursing experts, Mrs Lynne Phair, was instructed to review the remaining 33 sets of patient records.

The wards in which patients were accommodated during this early period are set out in Table 12.1:

Table 12.1 Early period CDI patients and wards

	Ward 3	Ward 4	Ward 5	Ward 6	Ward F	Ward 14	Ward 15	Total
Number of patients	3	1	5	9	5	6	4	33

14 [INQ05150001](#); [INQ05140001](#)

15 [INQ02090003](#)

16 [INQ04460067](#)

The standard applied to analysis of the early cases

The standard applied on review of the patient records in the early period was again that of proper nursing practice as outlined in the NMC Code.¹⁷ Mrs Phair was asked to focus on the management of CDI and prepared a report¹⁸ summarising her views.

The patient records of these early cases were also reviewed to establish whether key nursing documentation was in place and completed correctly. A judgement was made on the completeness of the nursing records using five descriptor codes designed to reflect the required standard of record keeping described in NMC guidelines.¹⁹

The infection control nursing expert

The Inquiry asked the infection control nursing expert, Mrs Christine Perry²⁰ to prepare a report reviewing some aspects of nursing care during the focus period. She advised the Inquiry primarily on infection control issues, but given her nursing experience she was in a position to provide valuable assistance in areas of general nursing practice.

Mrs Perry attended a number of meetings with the Inquiry Team and visited the VOLH. She had access to witness statements, evidence transcripts, patient records, documents and policies. She did not have access to the nursing expert reports on individual patients and was not asked to consider individual patient records or comment on individual patient care.

She addressed the following issues for the focus period:

- Staffing and management structures
- Infection control
- Hygiene/cleanliness
- Communication

This Chapter will consider the issues in her report relevant to the ward nurses.

Patient records used by experts – general comments

The difficulties in the recovery of documents have already been described in Chapter 2, and the nursing experts encountered significant problems working with the copy patient records provided by NHSGCC. In a number of cases the photocopying was poor. In some cases entries were illegible and information was cut off when photocopied. In a significant number of cases records were found to be missing. Some patient records were provided out of sequence. Some missing records were found. In some cases, however, it was clear that notes had been made but were missing from the patient records.

These factors, combined with poor recording of the care given, lack of signatures and poor documentation of transfer between wards, made the task of identifying a clear timeline of patient care and movement difficult. On occasions it was not possible to identify which member of the nursing team had completed documentation or cared for the patient because some entries were unsigned. The Inquiry Team spent a great deal of time cross-checking medical records with other documentation in attempting to establish a patient's history in the VOLH.

In addition, although the Inquiry focused on one relatively small hospital, the nursing documentation varied from ward to ward. There appeared to be material differences in the documentation used by the wards in the Acute Directorate, the wards in the Rehabilitation and Assessment Directorate (RAD), and Fruin ward. Staff used different pre-prepared charts and, where care planning was evident, different methods of care planning. Entries within the progress sheets also differed.

Many patients' records were voluminous. This, together with the lack of standardisation and structure and missing documentation, made the task of analysing the patient records particularly difficult.

17 [INQ01970001](#)

18 [EXP02790001](#)

19 [EXP02790003](#)

20 [INQ03880001](#)

12.3 Overall view of nursing experts

Expert overview of the standard of nursing care in the focus period

This Section considers the view expressed by nursing experts generally on the nursing care given at VOLH. Specific aspects of care are addressed later in this Chapter. The view of the nursing experts, from their analysis of the patient records at the VOLH during the focus period (1 December 2007 to 1 June 2008), was that overall the standard of nursing care was poor.

General comments from nursing experts for the focus period

It is worthwhile highlighting some general comments made by the nursing experts following review of all their cases.

“My general impression when considering all ten reports that I have completed is that there was a lack of attention to detail. There clearly appears to be a lack of supervision and routine checking by both the registered nurses and ultimately the nurse in charge to ensure that the required standards were being met”.²¹

“Having reviewed ten individual cases as part of the Vale of Leven Hospital Inquiry, it is my expert opinion that the nursing care of these ten patients was poor overall and lamentable at worst... In conclusion, it is my expert opinion that these patients’ significant nursing needs were consistently not met by the nursing staff. Moreover, it is my expert opinion that patients were placed at considerable risk due to the poor standards of care given. Consequently it is my expert opinion that, on the basis of the evidence I have seen thus far, the evidence would appear to suggest that the Vale of Leven Hospital failed to ensure that care to these vulnerable people was delivered to an acceptable standard”.²²

“Overall, nurses failed to demonstrate by their recording that they had provided adequate nursing care. The outcomes of some nursing care were poor and in some areas there was evidence of neglect. Nurses did not adequately assess, plan, evaluate or monitor patients’ care to ensure that their care needs were fully met”.²³

“The nursing staff regularly failed to carry out care that it is reasonable to have expected them to do, and failed to take action to prevent adverse consequences occurring ... In conclusion it is the expert’s opinion that these patients’ nursing needs were neglected by the nursing staff; and the nurse in charge of the wards neglected his/her duty of care to ensure that care was delivered to an acceptable standard”.²⁴

Expert overview of the standard of nursing care in the early period

As mentioned earlier in this Chapter, Mrs Phair was asked to comment on the standard of nursing care at the VOLH of the 33 patients in the early period (1 January 2007 to 30 November 2007) for whom nursing records were available.

Mrs Phair concluded that the patient records reflected a pattern similar to that of the 12 cases she had reviewed from the focus period. The following extracts from her report summarise her conclusions:

“There was no set pattern or clear rationale why some patients had records and assessment undertaken and why others did not. It was not always possible to establish from the medical and nursing notes the progression of a condition. Sometimes the diagnosis of *C. difficile* was not mentioned at all... Care plans did not always reflect the complex needs of the patient and the impact the *C. difficile* would have on the person..... The complex nature of patients’ conditions and the impact of the *C. difficile* on their overall ability, and wellbeing or deterioration and distress, did not appear to be considered in a consistent or methodical manner”.²⁵

21 [EXP01030002](#)

22 [EXP01050004-05; TRA00220087-88](#)

23 [EXP00720006; TRA00280085](#)

24 [EXP00660003; TRA00480057](#)

25 [EXP02790006](#)

“At no time did the records indicate that the nurses were assessing, monitoring or caring for the complications of *C. difficile* and review the risks such as the possibility of confusion, immobility, increased risk of pressure ulcers, possible abdominal pain and the general debilitating effects of *C. difficile*”.²⁶

“It is my professional opinion that the standard of nursing care and record keeping, for 79% of the patients in this audit fell below an acceptable standard”.²⁷

General response of the Senior Charge Nurses to expert evidence

In oral evidence the Senior Charge Nurses (SCNs) were asked to comment on the care given based on their review of the patient records and their own recollection of the patients. The SCNs had read the nursing expert comments on the patient care for their patients and they were aware of the individual criticisms. They did accept that there were deficiencies in note taking and in the preparation of care plans, but they insisted that proper patient care was given.

Overall view

It is clear from the analysis of the patient records that there were serious deficiencies evident not just in the focus period but also in the early period. Moreover, the deficiencies identified were not restricted to one particular ward or individual but were widespread. Some of the deficiencies identified were significant and were likely to affect patient care. The SCNs must accept some of the responsibility for the culture that prevailed at the time. Equally Nursing Management must bear responsibility. By “Nursing Management” the Inquiry means those managers with a professional accountability for nursing. Ultimately the NHSGCC Board also has a responsibility to ensure compliance with standards.

During oral evidence nurses did appear to change their position from that set out in their written statements. Prior to giving oral evidence no member of nursing staff

raised the issue of an inability to keep patient records. Yet in their oral evidence the position appeared to be that where there were deficiencies in record keeping this was due to pressure of work,²⁸ and that despite such deficiencies the care was given. The Inquiry does not accept that all the deficiencies in record keeping could be explained by pressure of work, and this is dealt with later in this Chapter.

It should also be noted that the deficiencies identified were not found in Fruin Ward, which was governed by a different directorate, although only two sets of records of patients nursed in that ward were examined.

12.4 Record keeping

The Nursing and Midwifery Council Code – the standard of record keeping

This Section considers record keeping by nurses against the backdrop of the requirements found in the NMC Code and NMC advice. As set out earlier in this Chapter, the NMC Code and associated advice provide a clear message on the importance of a high standard of record keeping in patient care.²⁹

Principles behind record keeping

The record of a patient’s stay in hospital is an essential clinical tool. Collectively, the patient record forms a permanent record of the patient’s condition and the treatment given. It should contain reasons for decisions made. Properly maintained patient records enable the nurse, or any member of the healthcare team, to reconstruct the essential parts of patient contact without reference to memory. Nursing is not a memory game.³⁰ The records should be sufficiently comprehensive to permit any member of the team caring for a patient to continue the care. Good record keeping assists with communication between members of the healthcare team. As the NMC Guidance stipulates, record keeping is an integral part of good patient care. Good record keeping protects patients and it is not

26 [EXP02790006](#)

27 [EXP02790006](#)

28 [TRA00370021](#); [TRA00390043-44](#); [TRA00410068-69](#); [TRA00450023-24](#); [TRA00460081-82](#)

29 [INQ02090001](#)

30 [TRA00250012](#)

an optional extra. Mrs Catherine MacGillivray, Head of Nursing for the Clyde Acute Directorate in 2007 and 2008, provided this explanation in evidence:

“Well, I see that nursing documentation is very much part of nursing care. Nursing documentation is not an add-on to nursing care; it is part of it”.³¹

She went on to emphasise that nursing documentation was an aid to “good nursing care and it aids continuity of care”.³²

The format of patient records

The NMC does recognise that in the absence of national agreement on the format of nursing records there will be variations in style and format. It does, however, emphasise that whatever the format used, records must follow a logical and methodical sequence with clear milestones and goals. Nursing records should be kept in such a manner that any member of the healthcare team can be informed of a patient’s care and needs so as to be in a position to care for the patient.³³

Expert views – the focus period

All the nursing experts were critical of the standard of record keeping in the focus period. Professor Anthony Palmer concluded that in all ten cases he reviewed the nursing records were of poor professional quality and several patient records were wholly inadequate.³⁴ Of the 12 cases reviewed by Mrs Phair in the focus period, she considered two sets of patient records to represent satisfactory record keeping. The remaining ten sets of patient records were poor and inadequate.³⁵

Most of the patient records reviewed had nursing entries in the progress sheets, but often these did not relate to the care plan. There were cases where there were gaps in the daily progress notes. One nursing expert identified a case in which there was a gap of four days, and where the patient could not have been described as “stable with no ongoing issues or problems”.³⁶

31 [TRA00900157-158](#)

32 [TRA00900158](#)

33 [INQ02090001-02](#)

34 [EXP01050002](#)

35 [EXP00660001](#); [TRA00480053](#)

36 [EXP01030002](#); [TRA00350121](#)

The view of the ward nurses

The nurses who gave oral evidence to the Inquiry accepted that they did have a professional responsibility to maintain accurate patient records. One SCN explained the nurse’s responsibility in the following way:

“Every nurse has a responsibility to ensure that they maintain records of that standard, and it was my responsibility, as a supervisor and leader of the area, to ensure that was maintained”.³⁷

Nurses did not disagree with the view of the nursing experts that the record keeping was not of the standard required by the NMC Code and Guidance. The SCNs who gave evidence said that they had been surprised at the omissions in record keeping found when they reviewed the patient records.³⁸

One SCN accepted that it was her responsibility to look at documentation to confirm that it complied with the Guidance issued by the NMC.³⁹ She said that often she would look at patient records and talk to nurses if charts were not completed properly. She was disappointed to see that there were nursing documents that were not accurately completed.⁴⁰

This SCN did not accept that the record keeping on her ward was careless. She described it as “incomplete”.⁴¹ She maintained that it was necessary to look at the wider picture, by which she meant the activity levels on the ward, staffing levels and the type of patients on the ward.⁴² Other nurses also suggested activity levels as a reason why there were deficiencies in record keeping.⁴³

Another SCN provided the following evidence:

“I don’t think it (record keeping) became separate, but it was never seen by my staff as being as important as the care

37 [TRA00410050](#)

38 [TRA00400041](#)

39 [TRA00450005](#)

40 [TRA00450005-06](#)

41 [TRA00450024](#)

42 [TRA00450024](#)

43 [TRA00370021](#); [TRA00390043-44](#); [TRA00410068-69](#);

[TRA00450023-24](#); [TRA00460081-82](#)

giving, being at the bedside. Despite many conversations—really, many conversations—about the real need to ensure that we did record problems, that we reviewed our interventions, I have to accept that there was an – an absence of record keeping. I just have to accept that and take responsibility for that”.⁴⁴

Although nurses generally appeared to accept that the standard of record keeping was poor, as already mentioned they did not accept that the appropriate patient care was not given. The mantra was that the care was given but was not recorded. This view expressed by one SCN was a typical response:

“Our record keeping was deficient in some instances...but I firmly believe that my nursing staff gave the very best of care within the Code of Conduct”.⁴⁵

This evidence was echoed by other SCNs.⁴⁶

Auditing

The NMC Guidance provides the following advice on auditing:

“Audit is one component of the risk-management process, the aim of which is the promotion of quality ... Audit can play a vital part in ensuring the quality of care being delivered to patients/clients”.⁴⁷

The Guidance adds that auditing of records can identify areas for staff training and development.

Mrs MacGillivray provided some evidence about how it was expected that patient records would be audited. She explained that there was a programme through which nurses from other sites, either the Royal Alexandra Hospital (RAH) or the Inverclyde Royal Hospital (IRH) went to the VOLH to conduct external audits.⁴⁸ She also said that audits were carried out by nurses within the VOLH,⁴⁹ but in fact there was no auditing carried out by the SCNs at the VOLH prior to April or May 2008.

44 [TRA00290024](#)

45 [TRA00310090](#)

46 [TRA00380029](#)

47 [INQ02090003](#)

48 [TRA00900073](#); [TRA00900156](#)

49 [TRA00900155-156](#)

Auditing at the VOLH

Ms Judy Taylor, Senior Nurse, Professional Practice,⁵⁰ was based at the VOLH for a number of years prior to June 2008.⁵¹ She explained that there had been a system of peer audits of patient records in place that involved nurses from a different ward looking at the patient records of another ward and testing the notes by reference to the NMC Guidelines.⁵² These audits did not look in any depth at the actual care given or whether care plans and other assessments were in place. No peer audits had been carried out since 2003⁵³ and Ms Taylor said that, although there was a reference in her statement to “periodically” carrying out “care planning sessions and audits of nursing documentation”,⁵⁴ she did not in fact think that any audits were done from 1 January 2007 to April or May 2008.⁵⁵ For most of 2006 she was not present at the VOLH as she was recovering from an accident, but on her return she did not see any audits for that period.⁵⁶ There was no cover for some aspects of her work when she was off work.

Audits in April or May 2008

There was an audit carried out in the VOLH in April or May 2008.⁵⁷ Ms Taylor took part in that audit, which was carried out over a period of about two weeks.⁵⁸ The patient records of 43 patients from a number of wards were examined and a number of issues raised in this Chapter were identified in that audit. An admission assessment on the risk of pressure damage (Waterlow Score) was only recorded in 33% of cases.⁵⁹ An Activities of Daily Living Assessment was completed for 70% of cases.⁶⁰ Deficiencies were evident in care planning.⁶¹ An admission nutritional score was recorded in only 33% of cases.⁶²

50 [TRA00910045](#)

51 [TRA00910046-48](#)

52 [TRA00910055-56](#)

53 [TRA00910056](#)

54 [WTS02130003](#)

55 [TRA00910058](#)

56 [TRA00910058-59](#)

57 [INQ03530001](#); [TRA00910087](#)

58 [TRA00910088](#)

59 [INQ03530002](#)

60 [INQ03530002](#)

61 [INQ03530002-03](#)

62 [INQ03530003](#);

Ms Taylor said that she would have produced an “Action Plan” following the audit.⁶³ The Inquiry has not seen this, and the handwritten Action Plan produced by her on the day she gave evidence on 29 February 2012, which included the instruction that “care planning sessions”⁶⁴ were to be provided, had only been written by Ms Taylor within the previous two months in an attempt to recall what had been done.⁶⁵ She thought that that would have formed part of the feedback she would have given at the time⁶⁶ but was unsure as to what did in fact happen.⁶⁷ Another audit was to be carried out in December 2008 but Ms Taylor had not seen any evidence of such an audit being carried out.⁶⁸ Ms Taylor would have expected the senior nursing staff to carry out spot checks from time to time to see how the nurses were performing in relation to record keeping.⁶⁹

It is to be noted that the notes of the Professional Nursing Forum Meeting held on 20 May 2008 record that an “external” audit of nursing notes had been completed at the VOLH.⁷⁰ There was no evidence of such an audit taking place and Ms Taylor was surprised at the suggestion in Mrs MacGillivray’s evidence⁷¹ that such an audit had taken place.⁷² Mrs MacGillivray was relying on the record of the meeting of 20 May 2008, but having regard to the timing of that entry it seems more likely that it was referring to the internal audit described by Ms Taylor.⁷³

Although auditing of patient records was part of the job descriptions of SCNs in charge of wards,⁷⁴ there was no evidence that such auditing occurred. Sister Lesley Fox, ward sister in ward F, explained her position in this way:

“I did no individual audit (of records) on the ward. I was never asked to do so, and it had never been requested of us, and we didn’t do audit. There was, from time to time, peer audit done, but there was very little audit at all at the time”.⁷⁵

Sister Fox went on to explain that by “very little” she really meant “none at all”.⁷⁶

Some SCNs did, however, complete patient records themselves and were involved in the preparation of inadequate assessments and care plans. Given these factors, and the extent of the problem, it does seem surprising that the SCNs had not identified the inadequacies in record keeping.

The Inquiry had no evidence on the position on auditing in Fruin ward.

Examination of records in the early period

Of the 33 sets of patient records Mrs Phair reviewed in the early period, she only considered record keeping to be of a good standard in two cases. In 13 cases it was adequate. In 18 cases the standard of record keeping was considered to be poor or inadequate.⁷⁷

Conclusion on record keeping

The examination of the patient records in the VOLH disclosed poor record keeping in a number of wards over a lengthy period of time. A culture had developed in which record keeping was not considered to be a priority. This becomes even more evident later in this Chapter when certain aspects of care, for example care planning and patient assessments, are examined. One approach taken by nursing staff in oral evidence was that record keeping was not an integral component of patient care. They argued that with small wards they were fully aware of the needs of their individual patients without having detailed and complete patient records. This was a seriously flawed approach. As Mrs MacGillivray correctly observed, nursing documentation is very much part of nursing care. Isolated omissions would be perfectly

63 [TRA00910094](#); [TRA00910101](#)

64 [INQ03530004](#); [TRA00910097](#)

65 [TRA00910097-98](#); [TRA00910001](#)

66 [TRA00910098-99](#)

67 [TRA00910100](#)

68 [TRA00910101](#)

69 [TRA00910110](#)

70 [GGC08600014](#)

71 [TRA00900157](#)

72 [TRA00910060](#); [TRA00910060-61](#)

73 [TRA00930052-55](#)

74 [INQ01160001](#)

75 [TRA00290028](#)

76 [TRA00290028](#)

77 [EXP02790004](#); [EXP02790009](#)

understandable in busy wards, but that was not the position in the VOLH. The failures in record keeping discussed in this Section and later in this Chapter were widespread across wards. They were significant and must have contributed to failures in patient care.

SCNs in the VOLH failed to identify poor record keeping on their wards. The absence of a functioning system of audit is not an excuse for this failure, although a functioning system of audit would have assisted in the identification of the deficiencies apparent and such a system should have been in place. Nonetheless, given the extent of the deficiencies identified, the SCNs should have identified these deficiencies and responded to them.

A lack of a proactive approach by Nursing Management contributed to the culture of poor record keeping. The NHSGGC Board has to accept ultimate responsibility for the failures identified in this Section, given its duty to ensure compliance with standards.

12.5 Nursing aspects of infection prevention and control

Nurses' frontline role

It is nurses who plan and deliver the most direct and personal care. To deliver care to an acceptable standard for patients with CDI, nurses must have the relevant knowledge and skills. They have a crucial role in recording information that can assist in the diagnosis, treatment and management of CDI patients. This Section examines nursing involvement in certain aspects of infection prevention and control relevant to patients who contracted CDI.

Information ward nurses should have known about CDI

Nurses on the wards would normally have a different level of knowledge and training from that of the Infection Control Nurses (ICNs). One of the nursing experts commissioned by the Inquiry, Ms Annette Jeanes,⁷⁸ said that she would expect the nurses on the ward to know the following facts:

- *C. difficile* has been the cause of death in a number of outbreaks of infection
- Elderly patients and patients on antibiotics are more at risk than others of developing *C. difficile*
- The principal characteristics of *C. difficile* are persistent foul smelling diarrhoea, possibly a raised temperature, abdominal pain or discomfort
- Symptoms of deterioration include severe abdominal pain, rectal bleeding, dehydration and weight loss
- Rapid identification and treatment are important and early isolation into a single room can prevent the transmission of the infection to other patients
- Hand hygiene is important in the control and prevention of spread of infection
- Cleanliness including careful and regular cleaning are important in the control and spread of infection, particularly the cleaning of toilets and commodes which may become heavily contaminated

Role of the ward nurse in management of the patient with CDI

Mrs Jeanes set out a number of aspects of patient management for the ward nurse in the management of a patient with the diagnosis of CDI:

- Careful documentation of diarrhoea/bowel movements to monitor for improvement or deterioration
- Careful monitoring of liquid and food intake to ensure that the patient is nourished and hydrated
- Careful monitoring of pain and discomfort to ensure that *C. difficile* infection is not progressing to a serious complication
- Attention to the hygiene needs of the patient and in particular to ensure that diarrhoea is cleaned away rapidly and the sacral skin is protected
- Isolation of the patient and the adoption of infection control precautions to protect others in the ward from infection

78 [EXP00680014](#); [TRA00100075-76](#)

- Careful discussion with relatives to inform them of the patient's condition and to protect them from acquisition of the infection
- Careful liaison with medical and other staff to ensure that nothing is done to exacerbate the condition, e.g. the prescription of antibiotics or laxatives
- Regular liaison with infection control to ensure that all that can be done is in place, particularly to prevent further transmission of the infection⁷⁹

Policy provisions

The *C. difficile* Policy in the Infection Control Manual⁸⁰ was available for use by the nurses on the ward. It provides a detailed summary of the symptoms of CDI and identifies those persons most at risk,⁸¹ although it does not make clear what signs and symptoms would indicate deterioration in the patient's clinical condition and when concerns should be raised.⁸² It explains what precautions are to be taken but does not offer any guidance on specific nursing care.⁸³ It does identify the need to inform the patient and next-of-kin of the condition.⁸⁴

Evidence of nurses on knowledge of CDI

In evidence some of the nurses said that they considered CDI to be a serious illness. One Deputy SCN provided this explanation in her extended witness statement:

"It was always taken seriously but I would say we have learnt a lot since then – I think we have learnt how serious the consequences can be. We were always aware that, I mean it wouldn't change our practice, we have changed the ways we speak to the families about it and I would say maybe the info we give out would be different as well".⁸⁵

Two nurses did accept, however, that they were not aware of the significance of the infection. A Staff Nurse told the Inquiry:

"I wasn't aware it was as serious as it was. I am now, but wasn't at that time. I didn't know surgical intervention was part of the management".⁸⁶

Another Deputy SCN said in her witness statement:

"I would tell patients or families that the patient had an infection in his or her stomach, possibly related to antibiotic usage. At the time I was not aware of how serious *C. diff* can be".⁸⁷

These statements are consistent with the evidence of relatives, who gained the impression that nursing staff did not appear to consider that CDI was a major illness. It was described to some relatives by nursing staff as "a wee bug".⁸⁸

Training of staff

Prior to June 2008 the majority of nursing staff at the VOLH had no formal training on CDI. Even if such training might not have enhanced a nurse's state of knowledge, it would have reinforced awareness of the seriousness of CDI. Some attempt to raise awareness had been made, for example in April 2007 there was a "Bug of the Month" newsletter circulated by the Infection Control Service in Clyde giving information to staff on CDI. This explained that the condition could be fatal,⁸⁹ and under the heading "PREVENTION" it emphasised the importance of isolating patients with *C. difficile* diarrhoea and good infection control practices.

Some VOLH staff had completed the Cleanliness Champion Programme, which is described in greater detail in Chapter 15, but the uptake was poor. Across the wards of interest to the Inquiry, there were 96 nursing staff. Of those, 12 nurses, including four SCNs and five Deputy SCNs, had completed the Cleanliness Champions Programme prior to 1 June 2008.

79 [EXP00680014-15](#)

80 [GGC00780252](#)

81 [GGC00780253](#)

82 [GGC00780252-257](#)

83 [EXP00680015](#)

84 [GGC00780255](#)

85 [WTS02250037](#)

86 [WTS02190007](#)

87 [WTS01080012](#)

88 [TRA00010122](#); [TRA00010123](#); [TRA00010152](#);

[TRA00030025](#); [TRA00030141](#); [TRA00040027](#);

[TRA00040038](#)

89 [GGC17790003](#)

The view of the nursing experts on nursing care of CDI in the focus period

The nursing experts were critical of the nursing management of patients who had CDI. From review of the nursing records they considered that there was little to suggest that the nurses were aware that CDI was a serious condition to be managed separately, and in addition to, other conditions.

In the case of one patient Mrs Phair concluded that the diagnosis and management of the CDI “appeared to be a side (almost irrelevant) issue for the nursing staff”.⁹⁰ In the case of another patient she said that the nursing care for CDI was non-existent and fell far below an acceptable standard.⁹¹

Nine patients suffering from CDI were said by Mrs Phair to have received poor or inadequate nursing care. Two patients did not appear to have received any nursing care for their infection. She concluded that overall the care was extremely poor. In her opinion:

“The distress and debilitating nature of *C. difficile* was not mentioned and did not appear to be considered by the nursing staff. When there were assessments and care plans they were extremely limited and focused on the rudimentary aspects of the medical care of *C. difficile*”.⁹²

Professor Palmer summarised his view in relation to the ten patients he reviewed in the following manner:

“Nine of these patients received poor or inadequate nursing care. One patient received care that I consider was reasonable, although not comprehensive. Invariably there was no clear nursing care plan or evidence of the nursing management plan aimed at managing the broader consequences and possible complications associated with a *C. difficile* infection. Indeed, it is my expert opinion that the care of the *C. difficile* infections appeared to be secondary and almost inconsequential to the ongoing identified

medical needs of each patient. Moreover, the serious nature of the infection does not appear to have been recognised throughout the vast majority of the nursing records”.⁹³

Mrs Jeanes’ conclusion was as follows:

“Overall the prevention and nursing management of the *C. difficile* infection in the cases reviewed was inadequate and did not protect patients from complications associated with the infection nor optimise recovery from the infection”.⁹⁴

Although laxatives are contraindicated for patients with CDI, there were cases where laxatives continued to be prescribed and administered to patients with diarrhoea and CDI. In half of the cases reviewed by Mrs Jeanes laxatives continued to be prescribed and administered when a patient had diarrhoea.⁹⁵ This was unacceptable care.

Mrs Jeanes also noted that the monitoring of pain and discomfort was variable and generally poor.⁹⁶ This could be explained by poor record keeping, but could also suggest a lack of knowledge on the part of the nurses.

Awareness of the number of patients on wards with CDI in the focus period

Nursing staff, with the possible exception of those in ward F, did not appear to have any awareness that there was a significantly higher than average number of patients with CDI in their wards. Some were shocked when the numbers were eventually discovered.⁹⁷

Ward F staff did appear to have some awareness of an increase in numbers of patients with CDI. One SCN explained:

“the figures (of *C. difficile*) that I had at the time were the highest I have ever had in ward F”.⁹⁸

90 EXP00080013; TRA00480057

91 EXP00370010; TRA00190065

92 EXP00660002; TRA00480056

93 EXP01050004; TRA00220086-88

94 EXP00680016; TRA00180060

95 EXP00680016; TRA00180063

96 EXP00680015; TRA00180058-59

97 WTS02190008; WTS02260025; WTS02300034

98 TRA00410127

She said she had a vague recollection of a member of staff suggesting to her that they had a higher incidence of CDI.⁹⁹

The evidence provided by one Staff Nurse was that she did consider at the time that there was a higher than average incidence of patients with CDI in ward F.¹⁰⁰ She thought there were four patients who were positive at the same time and said that the Infection Control Team were helpful in providing advice.¹⁰¹

A Deputy SCN in ward F said that she could vaguely recall talking at the desk with colleagues about how many patients there were with CDI.¹⁰² She explained her position in the following way:

“I would find it hard to believe that no-one in the ward noticed that we had a problem, from the ward sister to the auxiliary”.¹⁰³

One SCN said that she had many conversations with Infection Control and that they did not suggest to her there was an outbreak.¹⁰⁴ She provided this explanation in her oral evidence:

“I wasn’t aware that it was a particular problem. I was concerned. We would- -yes. I was very concerned when- -when I was in discussion with infection control, but did I think that there was a particular problem? I have to say no”.¹⁰⁵

This SCN went on to say:

“Each and every case, each and every patient, was discussed with infection control and the information that we would give, the information they would give to us, my expectation would be that it would be infection control that would declare outbreak”.¹⁰⁶

An SCN on a different ward said:

“So I think it’s my responsibility to speak to infection control and let them know of the numbers, and I think ultimately they declare the outbreak”.¹⁰⁷

The Inquiry gave nurses charts completed for each ward detailing patients who had samples sent for testing for *C. difficile* toxin. The SCNs said they were surprised at the volume of samples sent for testing and the numbers of patients with CDI on their wards.

Outbreak Policy

The two successive versions of the Outbreak Policy in the Infection Control Manual¹⁰⁸ in 2007 and 2008 make specific reference to duties upon healthcare workers, which includes nursing staff, to follow the Policy, follow the advice of the Infection Control Team, and report to the Infection Control Team if they suspect there may be an outbreak.¹⁰⁹ This Policy and its application are considered from the infection control perspective in Chapter 15.

Evidence of an outbreak from ward nurses

Nursing staff generally did not appear to consider that there were outbreaks of CDI during the early and focus periods. The position adopted was that it was the duty of the ICN to declare an outbreak, and if this was not done then that was the end of the matter.

One SCN interpreted the guidance in the Outbreak Policy as stating that if she had two or more cases of CDI then that would fit into the generic description of an outbreak. She indicated that she did not think that she had an outbreak at any time after December 2007 in ward 6.¹¹⁰ She said that she had many discussions with ICNs and that they did not suggest that there was an outbreak on her ward although they were fully aware of the number of patients in the ward with diarrhoea and diagnosed with CDI. In her oral evidence this SCN did accept that there had been an outbreak on her ward in March or April 2008.¹¹¹

99 [TRA00440052](#)

100 [WTS00670005](#)

101 [WTS00670005](#)

102 [WTS02250049](#)

103 [WTS02250049](#)

104 [TRA00300114](#)

105 [TRA00310137](#)

106 [TRA00330006](#)

107 [TRA00440054](#)

108 [GGC00780145](#); [GGC27390001](#)

109 [GGC00780147](#)

110 [TRA00300114](#)

111 [TRA00300121](#)

The nursing perspective

The question of whether in fact there were outbreaks of CDI at the VOLH is considered in Chapter 5. What is clear is that the SCNs considered their role was simply to advise the ICNs of diarrhoea and take samples when there was unexplained diarrhoea. Sadly, they did not feel they had a role to play in questioning any decision made by the ICN on whether they did in fact have an outbreak on a ward.

One SCN did say that when there were four people diagnosed with CDI at one time she had a conversation with Mrs Helen O'Neill, the Infection Control Nurse, who advised that the cases could be explained by antibiotic use. The SCN thought that this conversation had occurred in January 2008.¹¹² She said she raised the possibility of closing the ward. She also recalled her own staff raising the issue of ward closure with her.¹¹³

Ward nurses do have an important role to play when there is a potential outbreak. Nursing records are an essential source of information when an outbreak is suspected and investigated. From the analysis of patient records in the VOLH it is clear that important information would not be available for many patients because of deficiencies in record keeping by nursing staff.

Interaction with Infection Control Team

Effective management of a patient with CDI requires a good working relationship and dialogue between the nursing staff involved in the direct care of the patient and the Infection Control Team. The nursing staff thought that the Infection Control Team consisted only of the ICNs. Of those, they had more contact with Mrs O'Neill than Mrs Jean Murray, particularly after Mrs Murray took up the post of Interim Lead Infection Control Nurse for Clyde.¹¹⁴ They had no contact with Dr Elizabeth Biggs, who was the Infection Control Doctor up to February 2008.

Infection Control Nurses' presence on the ward

The role of the ICNs included providing guidance to the ward nurses on the management of the patients with CDI and ensuring that appropriate plans of care were devised and maintained. Most of the nursing staff said that the ICNs did have a presence on the wards, although in fact there is little evidence in the patient records to support this. With a few exceptions the patient records did not record that an ICN had attended to review the patient and there was no evidence of plans of care in the patient records following review by an ICN. In short, there was no evidence from the patient records that the ICNs were closely involved in the management of patients with CDI.¹¹⁵

The Fruin ward operated a different system. That ward was part of a different corporate structure from the rest of the VOLH wards and was covered by a different Infection Control Team. A VOLH ICN would only be called upon if the Fruin ICN was not available, although the Deputy SCN in Fruin ward recalled Mrs O'Neill being involved in the ward. She said that the ICN normally responsible for Fruin ward did review patients, and there was evidence in the patient records that this ICN did make entries in the patient records and put in place care plans for patients with CDI.¹¹⁶

Access to T-cards

The ICNs recorded information about patients with CDI on yellow T-cards, a system examined in Chapter 15. These cards were not retained on the ward and were not part of the patient records. The nursing staff on the ward did not have access to these cards, and the T-cards were not designed to provide information to ward nurses. This is why it was important that a separate record was made in the patient records to enable those rendering care on the ward to have access to the information provided by the Infection Control Team.

112 [TRA00440049-53](#)

113 [TRA00440050-51](#)

114 [TRA01010012](#)

115 [EXP01050004](#); [EXP00720013](#); [EXP00730013](#); [EXP00590014](#); [EXP01030007](#); [EXP00680016](#); [EXP00660002-03](#); [TRA00350146](#)

116 [WTS02200003](#)

Representation at meetings

The SCNs attended bed management meetings with the ICNs. Mrs O'Neill attended a number of the Sisters' meetings¹¹⁷ prior to June 2008, but it seems Mrs Murray only attended the Sisters' meeting of 26 July 2007 at which she announced that she had been appointed as the Interim Lead Infection Control Nurse for the Clyde Division.¹¹⁸ There was in addition an infection control link nurse system in operation during the early and focus periods, under which the link nurse for each ward was supposed to attend meetings and communicate information on infection prevention and control to ward staff. This can be a perfectly good system if it operates properly, but unfortunately that was not the case. The failures in the system are considered in Chapter 15.

It is clear that there were a number of opportunities for ward nurses and ICNs to discuss patients with diarrhoea and CDI, but this did not result in the problem being identified at an earlier point in time. Nor did these opportunities appear to have had an impact on the ward nurses' knowledge of the condition or of how to manage patients with CDI properly.

Interaction with Infection Control Nurses concerning patients with diarrhoea

As far as the nursing staff were concerned, they considered that they complied with their duty to keep the ICNs fully advised of infection control issues on the wards. In particular they said they told the ICNs about

patients with diarrhoea and those with a confirmed diagnosis of CDI.

One SCN said that the ICNs were made fully aware by telephone and at the bed meeting of the number of patients on her ward suffering from unexplained diarrhoea.¹¹⁹ Her position in evidence was that:

“..all the diarrhoea was discussed with infection control, all patients with diarrhoea”.¹²⁰

The ICNs did not accept that they were advised of all patients who had diarrhoea. Their position was that they were advised when a positive diagnosis was made. The Inquiry does not accept that nurses contacted the ICNs in the case of every patient who had potentially infectious diarrhoea.

Early cases and records of Infection Control Nurses' involvement

There was an Infection Control Card available for 27 of the 33 patients from the early period whose records were available for review.¹²¹ Yet only eight of those cards contained a record that the ICNs had visited the patient in the ward.

The Loose Stools Policy

Table 12.2 sets out the Loose Stools Policy in the Infection Control Manual. It was of particular relevance to the nursing management of patients with CDI.¹²² This Policy provided the following direction to ward nurses on the management of patients with potentially infectious diarrhoea:

Table 12.2 The Loose Stools Policy

Accommodation (Patient placement)	<p>Place a patient who could contaminate the environment with faeces in a single room. If the patient is clinically unsuitable for isolation, a risk assessment must be undertaken, by the clinical team, in conjunction with a member of the Infection Control Team (ICT).</p> <p>Babies and children will be isolated if they have symptoms suggestive of an infectious disease which can spread person-to-person. The ICT will advise if necessary.</p> <p>If a single room is not available, consult a member of the ICT and, if applicable, bed manager.</p>
--	---

117 [GGC04020001](#); [GGC14800001](#); [GGC14810001](#); [GGC03950001](#)

118 [GGC03970001-02](#)

119 [TRA00300115](#)

120 [TRA00300120](#)

121 [EXP02790004](#); [EXP02790008](#)

122 [GGC00780259](#); [GGC27590001](#)

Evidence of the ward nurses on isolation of patients during the focus period

In the signed witness statements provided prior to the oral hearings, and initially in oral evidence, the SCNs said that the practice was to isolate patients when they had potentially infectious diarrhoea. In her witness statement one SCN made the following assertion:

“If a patient was suspected of having *C. diff* they would be moved immediately to a single room, whether or not a positive *C. diff* result had come back from the laboratory”.¹²³

The view of the nursing experts on isolation practices on the ward for the focus period

The nursing experts had difficulty identifying when some patients first had diarrhoea and when some patients were isolated. The date of isolation should have been clear from the patient records. Where it was possible to identify when a patient was isolated, in the majority of cases this did not occur until after there was a diagnosis of CDI. This is considered further in Chapter 15.

The nursing experts were critical of the isolation practices.

“Generally, patients were not proactively isolated when they were symptomatic. That usually occurred after the positive result but this was not always documented. It was often not clear whether someone was isolated or not or when they were moved in or out of isolation. In one case there was a very high suspicion of *C. difficile* infection and this was widely documented. Despite this, even that patient was not proactively isolated”.¹²⁴

“In half the cases reviewed patients were not isolated rapidly to prevent the transmission of *C. difficile* and were potentially transmitting *C. difficile* to other patients in the interim period of time.... In most cases there was no reference in the nursing notes to risks and any extra precautions taken to prevent the transmission of *C. difficile*”.¹²⁵

123 [WTS00960014](#)

124 [EXP01030007](#)

125 [EXP00680015](#)

The use of notices

Nurses said in evidence that when a patient was isolated with CDI notices were always in place asking visitors to contact nursing staff before entering the room. Yet few family members recalled seeing notices outside rooms.¹²⁶

Care planning for patients with loose stools

The Loose Stools Policy envisaged that a care plan would be instituted for patients with loose stools, but it was clear from the evidence of nurses that the necessary care plans were rarely prepared. Care planning for CDI is considered later in this Chapter.

Isolation in the early period

Mrs Phair reviewed the patient records in the early period to ascertain whether patients were appropriately isolated as outlined in the Policy. The trends on isolation practices identified in the focus period were again evident in the early period, with isolation mainly dependent upon a positive diagnosis being made.

Laundry Policy

The Laundry Policy in the Infection Control Manual¹²⁷ provided that relatives who took home used and fouled laundry should be given this in a plastic bag and not an alginate bag.¹²⁸ Relatives were to be told before they took laundry home if it was heavily contaminated.¹²⁹ There was also an instruction that staff should not sluice out clothing in clinical areas.¹³⁰

Evidence of nurses on laundry

The nurses' evidence was that they were aware of, and complied with, the laundry instructions in the Policy. Some nurses said that relatives were given alginate bags and advised that the alginate bag could be put directly into the washing machine. One nurse said:

“If the clothing was soiled with faeces then the nurse who identified it would place it in an alginate bag and then double bag it in a plastic bag”.¹³¹

126 [TRA00010033](#); [TRA00030104-105](#); [TRA00040148](#)

127 [GGC00780136](#)

128 [GGC00780141](#)

129 [GGC00780141](#)

130 [GGC00780141](#)

131 [WTS00780003](#)

Another nurse said:

“If the clothing was soiled it was put into an alginate bag and then another separate patient laundry bag. Relatives were advised that the alginate bag could go straight into the washing machine and to take care when decanting it out of the patient laundry bag”.¹³²

Another nurse provided this evidence:

“I used to sluice patients’ soiled clothing and put it into a patient laundry bag. I had been doing that for years and was never told not to”.¹³³

Nurses also said that relatives were given clear instructions on how to deal with laundry.¹³⁴

Relatives’ evidence on laundry

The evidence of some relatives suggested that nurses on the ward were either unaware of the Laundry Policy or chose to ignore it. Some described receiving alginate bags but said that they were not always given information on how to use the bag.¹³⁵ Some were not clear whether the bag could be placed into the washing machine.¹³⁶ Some relatives described finding fouled laundry left out for them without any prior warning from staff.¹³⁷

Advice leaflets on laundry

There was evidence of a leaflet being available for relatives to inform them on how to deal with soiled laundry.¹³⁸ Many relatives were not given this leaflet and some nursing staff said they did not have the leaflet available on the ward.¹³⁹

The use of Personal Protective Equipment

The evidence of nurses was that Personal Protective Equipment (PPE) was used when

dealing with patients with CDI.¹⁴⁰ This did not seem to be disputed by the patients and relatives, although only two patients gave evidence and relatives tended only to be present at visiting times. If a patient required to be changed when a relative was visiting the relative usually left the room. There was, however, evidence that domestic and support staff did enter isolation rooms without PPE to clean or provide meals.¹⁴¹

One Deputy SCN described a situation where personal protective equipment was used, but was ineffective. The patient had explosive diarrhoea and the nursing staff used sheets to cover themselves to try and keep clean:

“We had to improvise to try and keep ourselves clean. She was in room 16 at the time, bed 3. There was very little space. There were four beds occupied in there at the time... I can remember like it was yesterday”.¹⁴²

This nurse said everything had to be scrubbed down, including the bed frame, locker and radiator. The patient’s bed had to be stripped down. The patient had to remain in the bay as there was nowhere else to put the patient. This episode does highlight the time-consuming nature of the management of patients with CDI and the distress and lack of dignity associated with the infection.

Aspects of hand hygiene

There were three aspects to the issue of hand hygiene at the VOLH during the early and focus periods. The first was the lack of wash-hand basins. The second was whether staff washed their hands appropriately when dealing with patients. The third was the provision of information on appropriate hand washing to visitors of patients who had CDI. This Section reviews hand hygiene as it relates to the nurses on the wards.

Wash-hand basins

It is clear that there were insufficient wash-hand basins in certain wards¹⁴³ even although some members of the nursing staff did not appear to be aware of this deficiency. Sister

132 [WTS00730003](#)

133 [WTS00690005](#)

134 [TRA00370137-138](#); [TRA00410025](#); [WTS01010005](#)

135 [TRA00020102](#); [TRA00070183-184](#); [TRA00010060-61](#)

136 [TRA00030034-35](#); [TRA00070146-147](#)

137 [TRA00020028](#); [TRA00020102](#); [TRA00020056](#);

[TRA00030164-165](#)

138 [TAY0040009-10](#)

139 [TRA00960018](#); [WTS01160012](#)

140 [TRA00300125-127](#); [TRA00400150-151](#)

141 [TRA00020109](#); [TRA00040028-29](#)

142 [WTS02250046-47](#)

143 [GGC11050003-04](#); [GGC07560002](#)

Fox was of the view that ward 6 did have sufficient wash-hand basins, although further sinks were installed following the walk round discussed in Chapter 15.

Advice to relatives on hand hygiene

The evidence of the relatives was that they were not given consistent and accurate information on proper hand washing by nursing staff when there was a diagnosis of CDI. By the time they gave evidence the nursing staff were aware that soap and water required to be used to wash hands where a patient had CDI. The evidence of the relatives, as discussed in Chapter 11, was that nursing staff did not always appear to be aware of this fact. The Inquiry accepts the evidence of the relatives on this issue.

Conclusions on nursing aspects of infection prevention and control

As discussed later in this Chapter, nurses did not recognise the importance of the monitoring of fluid balance, nutrition, pain, bowel movements, and pressure care, or the relevance of falls risk assessments and moving and handling assessments in the management of patients with CDI. Furthermore, as discussed in Chapter 13, the delays identified in the administration of antibiotics prescribed for patients diagnosed with CDI were unacceptable. It is clear to the Inquiry that nurses were not fully aware at the time of the potential seriousness of CDI as an illness, particularly in the elderly and vulnerable. Ultimately this comes down to a lack of proper education, training and supervision. The lack of nursing knowledge compromised patient care.

Any advice given by the ICNs ought to have been detailed in the patient records and in the care plans. The need for continuity of care in the case of a patient with CDI cannot be overemphasised. The absence of direction from the ICNs within the notes would have compromised patient care.

Nurses have an important role to play where there is a potential outbreak of CDI. Good record keeping will assist in the investigation and management of a suspected outbreak. Deficiencies in record keeping meant that important information was not available. These deficiencies should have been

identified by the SCNs. Nursing staff should have been trained to ensure they were fully aware that information specified in the Infection Control Manual required to be recorded for patients with CDI.

It was clear from the expert nurse analysis of the records, and accepted by the SCNs, that patients were not being isolated when they became symptomatic. The SCNs were aware of this practice at the time. They should have complied with the Isolation Policy and ensured that staff on their wards complied with the Policy. If they were unable to comply due to shortage of isolation rooms this should have been brought to the attention of Nursing Management and the Bed Manager, with arrangements made to reduce the risk of cross-infection.

Nursing Management appeared to be unaware that patients were not being isolated appropriately. Had they been more proactively involved in the management of the wards they would have become aware of this practice. Ignorance is not an excuse in a situation where managers could with reasonable diligence have obtained the knowledge.

Care planning for patients with loose stools was inadequate. SCNs should have ensured that there was adequate and appropriate care planning for patients with loose stools. The absence of a functioning system of audit contributed to these failures.

There was evidence from relatives that appropriate notices were not visible outside isolation rooms. Notices were either not placed at all times or were placed in such a way that they were not obvious to those entering isolation rooms.

The Laundry Policy was not complied with. Nursing staff did not know how best to deal with soiled laundry. There were failures in communication of information on laundry to relatives. This would suggest that there was a lack of appropriate training.

Nursing staff failed to ensure that the correct information on hand washing was provided to relatives.

Nursing Management and ultimately the NHSGC Board have to accept responsibility for the failures identified in this Section.

12.6 Isolation issues specific to ward F

The patient Jessie Jones

Mrs Jessie Jones was transferred from the Western Infirmary and admitted to ward F, bay 16 at the VOLH on 8 February 2008.¹⁴⁴ There were three other patients in the bay when Mrs Jones was admitted, two of whom had previously tested positive for CDI, and there was at least one symptomatic patient in the bay at that time.¹⁴⁵ Mrs Jones was not symptomatic for CDI on admission, but later contracted CDI.¹⁴⁶

Bay 16 was normally used as a three-bedded bay but when necessary a fourth contingency bed could be installed, and that was the position when Mrs Jones was admitted.

Evidence of Sister Gargaro

Sister Laura Gargaro's evidence about the admission of Mrs Jones was contradictory and unsatisfactory. In her witness statement her position was as follows:

"On 8th February, the two previously infected patients were 48-hour free of symptoms and were therefore deemed to be low risk... Therefore on the day of Jessie's admission to ward F the four-bedded area had no positive *C. diff* patients. On 8th February at the morning bed meeting I again made our concerns known as one of the patients could become positive again and we had difficulty in managing her barrier procedures due to her wandering and confusion".¹⁴⁷

Initially in evidence Sister Gargaro said that when she was aware of the potential transfer of Mrs Jones she attended the bed management meeting with the intention of having the fourth contingency bed removed.¹⁴⁸ Sister Gargaro made a number of differing comments on her knowledge of CDI patients in bay 16 at the time she attended the bed management meeting, but her final position seemed to be that she was unaware that there was a symptomatic patient in

bay 16 at the time she attended the bed management meeting.¹⁴⁹ She accepted that perusal of the patient records would have confirmed there was a symptomatic patient in the bay. She suggested that she may not have had time to look at the patient records prior to the meeting, or she may have been given erroneous information as she had just returned from leave. She had been aware prior to her leave that there was a symptomatic patient in the bay.

Evidence about the call to ward F requesting information

Mrs Jones' daughter telephoned ward F on 18 February 2008 after her mother had been admitted and specifically asked if there were any infections such as MRSA, Norovirus and CDI in ward F. She was told "categorically" that there were no hospital infections.¹⁵⁰

Sister Gargaro accepted that this call was made and that it was incorrect to suggest there were no hospital infections in ward F.¹⁵¹ Sister Gargaro provided the following explanation:

"...my staff do not feel it's appropriate to discuss any conditions that other patients may have and to only discuss the condition of their particular relative at the time".¹⁵²

It is correct that information about particular patients cannot be disclosed, but if a relative wishes to ascertain whether there is an infection such as CDI present on a ward this information should be given honestly by staff.

When Mrs Jones' daughter found out that there was CDI on the ward, and indeed in the bay where her mother had been placed, she asked Mrs Murray why her mother had been admitted to a potentially life-threatening ward. She was told that the ward was under pressure from the Western Infirmary as they needed beds, and that they had nowhere else to put her mother.¹⁵³

144 EXP01960006; [TRA00430083](#); [WTS02250051](#)

145 [TRA00430122](#)

146 GGC21010087

147 [GGC14500001](#)

148 [TRA00430113](#)

149 [TRA00430125-127](#); [TRA00430153-156](#)

150 [WTS01520005](#); [TRA00070042](#)

151 [TRA00430103](#)

152 [TRA00430099](#); [GGC14500001](#)

153 [WTS01520007](#)

Involvement of the Bed Manager

The Bed Manager at VOLH was Ms Isobel Law, whose responsibilities included managing the admission and transfer of patients and allocation to specific wards.¹⁵⁴ Ms Law said that she was unaware of the infection status of the patients on the ward.¹⁵⁵ She did recall a discussion about the admission of Mrs Jones in which Sister Gargaro wanted the contingency bed removed. She said that the decision to keep the bed and admit Mrs Jones would have been made by one of the Lead Nurses.¹⁵⁶ She thought Mrs Murray was also involved.¹⁵⁷

Sister Gargaro's responsibility

As mentioned previously, Sister Gargaro's position appeared to be that she was unaware there was a symptomatic patient in the bay. When she returned from leave, and prior to going to the bed management meeting, Sister Gargaro should have ascertained the infection control status of patients on her ward. If she did attend the meeting in ignorance of the infection control status of her patients she should not have accepted a transfer into the bay until she had satisfied herself that it was safe to accept a patient. She was well aware that there had been symptomatic patients, particularly in that bay, prior to her leave. In such circumstances asymptomatic patients would be exposed to a contaminated environment which would place them at risk. As the SCN Sister Gargaro should have been aware of this risk and she should have checked before accepting a transfer into the bay.

Meeting with the Lead Nurse

The relatives of Mrs Jones had a meeting with the Lead Nurse, Mrs Elizabeth Rawle, and also made a formal complaint.¹⁵⁸ The essence of the complaint was that Mrs Jones had been placed in a four-bedded bay in ward F in an area where patients were already known to be infected with CDI.

Response to the complaint

Sister Gargaro provided a response¹⁵⁹ to the complaint in September 2008 which was used by the then Chief Operating Officer, Acute Services, Mr Robert Calderwood, in responding to the complaint. Sister Gargaro said in her response that when Mrs Jones was admitted to the four-bedded area there were no positive patients in the bay. She eventually accepted in evidence that this was palpably wrong.¹⁶⁰

Sister Gargaro accepted that when preparing the response she had access to the relevant patient records and initially could not offer an explanation why she misled Mr Calderwood.¹⁶¹ Later in evidence she suggested she must have misinterpreted the nursing notes when she made her response.¹⁶² She said that she did not review the microbiology results.

Conclusion on the admission of Mrs Jones

In her role as the nurse in charge of the ward Sister Gargaro failed to take proper care not to expose Mrs Jones to the risk of CDI. Prior to her leave she was well aware that there had been patients in the ward, and in that particular bay, who had been positive for CDI.

The Jones' family complaint was poorly managed. A complaint of this nature should not have been investigated by the SCN alone, but by a more senior member of the management team such as the Clinical Nurse Manager.

The information given to the relatives in the response was incorrect, and this should not have occurred. Sister Gargaro either failed to answer the complaint honestly or failed properly to peruse the information available to her, and as a result provided inaccurate and misleading information to relatives. Either course of action was unacceptable and was a serious failure by her.

154 [WTS00890005](#)

155 [TRA00890034](#)

156 [TRA00890034](#)

157 [TRA00890034-35](#)

158 [GGC14490001](#)

159 [GGC14500001](#)

160 [TRA00440042-44](#)

161 [TRA00430135-137](#)

162 [TRA00440037-40](#)

Sister Gargaro's evidence on the admission of Mrs Jones and the investigation of the complaint was unsatisfactory. It was necessary to adjourn the Inquiry during her evidence, and the Chairman permitted her to consult with her Solicitor during the adjournment. This was done in the interests of fairness to enable Sister Gargaro to have the benefit of legal advice given the nature of the contradictory evidence she gave. Following a brief adjournment Sister Gargaro indicated that she did not wish to change any of the evidence given.¹⁶³ She did emphasise that she provided a copy of her written response to the complaint voluntarily.¹⁶⁴

When relatives or patients raise issues, these should be addressed fully and honestly. Senior management, and ultimately the Board, have a responsibility to ensure that the complaints process is properly managed. In his oral evidence Mr Calderwood said that he responded to the complaint in good faith at the time and the Inquiry has no reason to doubt that. On learning of the error he apologised to the family for misleading them.¹⁶⁵

12.7 Nursing assessments and care planning in the focus period

The nursing assessment

When a patient is admitted to hospital a nursing assessment should be carried out. This is an important aspect of nursing care and enables the nurse to plan the patient's care in an effective way.

Nursing expert Mrs Sharon Stower described the purpose of the nursing assessment in the following manner:

“Nursing assessment is a systematic, deliberate and interactive process that underpins every aspect of nursing care. It is the process by which the nurse and patient together identify needs and concerns and is seen as the cornerstone to individualised patient care. It is the only way the uniqueness of each patient can be recognised and considered in the care process”.¹⁶⁶

She emphasised that effective patient assessment is integral to the safety, continuity and quality of patient care. The assessment provides baseline information on which to plan the interventions and outcomes of the care to be achieved. She explained that:

“It facilitates evaluation of the care given and it is a dimension of care that influences a patient's outcome and potential survival”.¹⁶⁷

The nursing expert Mr William Evans provided this evidence:

“It is essential that nursing assessments are completed in order that a full and accurate picture of the patient's situation, abilities and problems is obtained. It is difficult to plan care appropriately without accurate baseline assessment”.¹⁶⁸

There were appropriate pro forma assessment forms available to nursing staff. The issue under consideration here is the failure by nursing staff to complete these assessments.

Activity of Daily Living Assessments

An Activity of Daily Living Assessment should be performed when a patient is admitted to hospital. This assessment and the initial nursing assessment underpin the care planning and allow the nurse to gather vital information about the patient which then informs the care planning. The assessments provide a benchmark to gauge progress or deterioration of the patient.

Deficiencies in the initial assessments

The nursing experts noted that many basic details were often not recorded in initial assessments. Sections were not completed. Assessments were not signed or dated and the information that was provided did not always give an accurate picture of the patient.

The most common details omitted were the patient's weight, an assessment of the risk of pressure damage, and baseline observations

163 [TRA00440046-47](#)

164 [TRA00440049](#)

165 [TRA01240100](#)

166 [EXP00590004](#); [TRA00160133-134](#)

167 [EXP00590004](#)

168 [EXP00700029](#)

of temperature, pulse, respiration and blood pressure. The pain score/comments on sleeping patterns Sections were usually blank.

Professor Palmer said that of the ten patients he reviewed not one of them had an adequate or satisfactory assessment.¹⁶⁹ Six of the patients he reviewed had an assessment which was of a significantly poor professional standard.¹⁷⁰

Nutritional assessments

Patients with diarrhoea as a result of CDI, particularly elderly patients, can become nutritionally depleted very quickly. This has an impact on their ability to survive the infection. Loss of appetite and nausea can also be symptoms associated with CDI, and for a variety of reasons many elderly patients will already be nutritionally depleted when they enter hospital.

Nutritional screening

Nutritional screening is a simple procedure conducted by nursing staff when a patient is admitted to hospital. A basic nutritional screening should document a patient's recent unintended weight loss, appetite and ability to eat. Patients should be weighed on admission and thereafter throughout their stay in hospital.¹⁷¹

Nutritional screening can be contrasted with a nutritional assessment, which is a more detailed and specific evaluation of a patient's nutritional status usually conducted by an expert such as a dietician.

Nutritional assessment documentation in the VOLH

In the VOLH during 2007 and 2008 there were standardised nutritional assessment forms available but they had not been distributed to all wards. The Clyde Acute Directorate did not have pre-prepared nutritional assessment forms,¹⁷² although the Rehabilitation and Assessment Directorate did have these.

169 [EXP01050002](#)

170 [EXP01050002](#); [TRA00220087-89](#)

171 [INQ02450148](#)

172 [TRA00290134-135](#)

The expert view on the standard of nutritional assessment

The nursing experts were critical of the standard of nutritional assessment of the patients reviewed. Professor Palmer identified one patient who was malnourished/emaciated on admission and had not been eating and drinking.¹⁷³ There was no evidence in the nursing records of any care plan to improve this patient's nutritional state. Nor was there evidence that the patient was weighed or that a nutritional chart was maintained to monitor dietary intake. He described this failure as significantly below the standard to be expected.¹⁷⁴

Mrs Jeanes noted that one patient was not deemed to be at risk when her nutrition was assessed despite having lost more than six kilograms in a few weeks.¹⁷⁵ Another patient had no nutritional assessment, little documentation of food intake, no food charts and no record of the food she enjoyed or preferred.¹⁷⁶ An elderly patient had a weak left hand and impaired sight, yet there was no documented assessment of this patient's ability to eat unaided, no record of food intake, no food chart, and the patient was not weighed during her stay.¹⁷⁷

In one case the patient's weight was not regularly documented even though there was a specific request and a care plan intervention for that to be done.¹⁷⁸

In the case of one patient who had diarrhoea and who was intermittently nauseous, vomiting, and declining food, there was no nutritional assessment or any record of actions needed to optimise nutritional intake. She was not weighed. She was given medication to control nausea but no plan of care was instituted to ensure that her mouth was clean and comfortable. Towards the end of her life she was either not being given fluids on medical instructions or not taking fluids, and there is no evidence that regular mouth care was given.¹⁷⁹

173 [EXP00020019](#); [TRA00200079](#)

174 [EXP00020024](#); [TRA00200082](#)

175 [EXP00680018](#); [TRA00120142-143](#)

176 [EXP00680019](#); [TRA00120065-66](#)

177 [EXP00220017](#); [TRA00120066](#)

178 [EXP00150011](#); [TRA00350059-60](#)

179 [EXP00280011](#); [TRA00100157-159](#)

In the review of all his cases Professor Palmer concluded:

“The needs of the patients indicated that a nutritional assessment and care plan was required. Only two nutritional assessments or care plans were considered adequate. The remaining eight assessments or care plans were either absent or inadequate”.¹⁸⁰

Mrs Jeanes concluded:

“The systematic planning and documentation of efforts to improve nutritional intake including the maintenance of food charts was generally poor”.¹⁸¹

Deficiencies noted in nutritional assessments

The nursing experts identified a number of failures:

- Assessments were undated, incomplete or inaccurately scored when they were completed
- Completion of assessments was delayed
- Initial assessments when completed were not regularly re-assessed
- There were delays in patients being referred to a dietician
- Food charts were not implemented even when requested by a dietician
- When food charts were commenced they were poorly completed or stopped too soon
- Patients were not being routinely weighed on admission or regularly weighed thereafter¹⁸²

Evidence of nurses on nutritional assessments and weighing patients

The nurses who gave oral evidence accepted that patients were not always weighed on admission and that some patients who should have been weighed after admission were not weighed regularly thereafter. They offered

various explanations for these failures. One explanation was that there was a lack of appropriate equipment to weigh patients. On one ward the SCN explained that frail patients were not weighed as they did not have the appropriate scales. A tombola was organised to collect money to purchase scales.¹⁸³ The Deputy SCN on ward 6 said that they obtained chair scales after June 2008 after a few years with no scales. Scales had been bought from Argos with ward funds but there were no funds for more expensive scales.¹⁸⁴

Moving and handling assessments

It is important to know how to move and handle a patient safely, in order to avoid causing harm to the patient and to prevent back strain and injury to staff. Moving and handling assessments are of particular relevance to the management of elderly patients with CDI. These patients often become rapidly debilitated and need changed and cleaned more frequently. Often their skin is vulnerable to damage associated with poor moving and handling techniques.

Some patients did have a moving and handling care plan although no risk assessment seemed to have been performed.¹⁸⁵ A risk assessment should have been performed to assist and inform the development of the appropriate care plan for the patient.

View of the expert witnesses on moving and handling assessments

The nursing expert witnesses were critical of the attention to moving and handling issues. According to Mrs Jeanes:

“Generally the attention to moving and handling issues was not well documented and it is not clear if this was a lack of documentation and attention or poor practice in the organisation”.¹⁸⁶

Out of 63 focus patients, only 16 had a moving and handling assessment in the patient records. Of the 47 patients who

180 [EXP01050003](#)

181 [EXP00680019](#)

182 [EXP00020024](#); [EXP00050027](#); [EXP00670025](#); [EXP00720009](#); [EXP00200017](#); [TRA00190077](#); [TRA00100014](#); [EXP00100018](#); [EXP00340012](#); [TRA00340008-09](#); [EXP00120022](#); [EXP00090016](#); [TRA00180065-66](#); [TRA00190031](#); [TRA00270079](#); [TRA00270157](#); [TRA00170028](#); [TRA00360046](#); [EXP00040022](#); [EXP00170041](#)

183 [TRA00360048-49](#)

184 [TRA00360047-49](#)

185 [GGC00110158](#)

186 [EXP00680018](#); [TRA00180065](#)

did not have an assessment in the patient records, for 13 there was mention of the need for assessment in the patient records, but there is no record that one was carried out.

Main deficiencies identified in the moving and handling assessments

The main criticisms in the cases reviewed were as follows:

- There was no evidence of a moving and handling assessment for patients with significant moving and handling needs
- For patients assessed as requiring assistance to mobilise it was not clear what actions were taken
- Patients were assessed as requiring assistance to mobilise but this was not included in the patient care plan
- There were delays in assessments being undertaken, sometimes weeks after admission¹⁸⁷

Falls risk assessments

Patients with CDI, particularly if they are elderly, are at risk of falls. The debilitation associated with CDI renders a fall more likely, and when a patient has CDI a fall can occur in the rush to a toilet. A falls risk assessment should be performed to identify which patients are likely to fall and to intervene to prevent falling or reduce the risk of falls. A fall for an elderly patient can be fatal.

View of the nursing experts on falls risk assessment

Some of the criticisms by the nursing experts highlighted serious failures. Mrs Phair noted one patient who had suffered a stroke and required physiotherapy for whom there was no record of a falls risk assessment.¹⁸⁸ Another patient was admitted with dizziness and a stroke. She was at risk of falls yet no falls risk assessment was prepared. She had a number of falls when she was a patient. Mrs Phair said that when this patient contracted CDI her risk of falls increased because of

the debilitating nature of the infection. Yet despite that increased risk no falls risk assessment or care plan was prepared.¹⁸⁹

This was the conclusion arrived at by Mrs Jeanes:

“Generally the recognition of risk of falls and attention to preventing falls was not well documented and it is not clear if this was a lack of documentation and attention or poor practice in the organisation”.¹⁹⁰

Professor Palmer identified one patient who had been assessed wrongly as at “high risk” of falling and who should in fact have been put in the “very high risk” category. Despite having numerous falls, which were documented, he noted that nursing staff failed to introduce a reasonable regime of supervision and observation. His opinion was that the precautions introduced to prevent the patient falling “were wholly inadequate” and “grossly negligent”.¹⁹¹ This patient subsequently had a significant fall resulting in a fractured femur¹⁹² that later contributed to the patient’s death.¹⁹³

Main deficiencies identified with the falls risk assessments

The main deficiencies relating to falls risk assessments identified by the experts were as follows:

- When a falls risk assessment was performed the scoring was inaccurate
- There was no evidence of re-assessment in many instances
- Failure to perform a falls risk assessment when it was required
- Failure to re-assess when a patient had frequent falls
- Identification of a patient and risk of falls but failing to introduce precautions to minimise the risk¹⁹⁴

187 [EXP00590013](#); [EXP00680018](#); [EXP00720012](#); [EXP00730010-11](#); [EXP01030006](#); [EXP01050004](#); [TRA00160143](#); [TRA00180065](#); [TRA00240061-62](#); [TRA00350138](#)

188 [EXP00090016](#) ; [TRA00170085](#)

189 [EXP00030022](#) ; [TRA00170034](#)

190 [EXP00680018](#); [TRA00180065](#)

191 [EXP00750022](#)

192 [TRA00210004-05](#)

193 [EXP00750022](#); [TRA00210032-33](#)

194 [EXP01030006](#); [EXP00240022](#); [EXP00330026](#); [TRA00250118-119](#); [TRA00350114-115](#)

Care planning

Care planning is a term used to describe the process of assessing a patient's needs:

“prescribing care, delivering and documenting the care delivered, evaluating the effectiveness of that care and changing the care plan as needs change”.¹⁹⁵

The care plan is the written record of this process. It is a prescription of care for the patient and is one of the most important aspects of planning nursing care.

The ability to prepare an appropriate care plan is a core skill. If there is no care plan, or where the care plan is poorly prepared or incomplete, it becomes difficult for nurses and other members of the healthcare team (doctors, physiotherapists, occupational therapists) to deliver consistent and co-ordinated care. The provision of appropriate and adequate care plans for a patient is not an optional extra but a mandatory professional responsibility.

On this issue Mrs Jeanes provided this explanation:

“Nursing care plans are important as they offer an opportunity to individualise care, take into account all the problems present and help ensure continuity of the care delivered”.¹⁹⁶

The Standards of Proficiency for pre-registration nursing education from the NMC provide that a nurse should be able to:

“Undertake and document a comprehensive, systematic and accurate nursing assessment of the physical, psychological, social and spiritual needs of patients, clients and communities” and

“Formulate and document a plan of nursing care, where possible in partnership with patients, clients, their carers and family and friends, within a framework of informed consent”.¹⁹⁷

Methods of care planning

In the VOLH different wards used different methods of care planning. There are several acceptable methods of recording patient care, for example core or standardised care plans, individualised care plans and care pathways. Of importance is the information contained within the care plan. Whatever the approach chosen, it must provide a systematic framework that can be used by all those involved in a patient's care to provide a consistent, comprehensive and accurate account of the patient's care.

Expert view on the standard of care planning

Generally the professional expert witnesses were critical of the lack of proper care planning. The following views are typical.

“In general, care plans were poorly completed and did not reflect all of the patients' problems and there was little evidence that they were reviewed appropriately. They were often not numbered and nursing evaluation sheets rarely related to the care plan”.¹⁹⁸

“In my expert opinion none of the care plans (ten cases were reviewed) were considered professionally adequate. Eight patients had care plans in place but were considered of poor quality or inadequate and two patients had care plans which were considered wholly inadequate”.¹⁹⁹

“In all the records I reviewed none of the care plans reflected all the problems and requirements of the patient at the time of assessment. In most of the plans the planned interventions did not give sufficient detail of the planned care to ensure risks were identified and minimised or that subsequent care was consistent..... It is not clear how care could be delivered appropriately and consistently without regular assessment of problems and the planning of care to be delivered. There was little evidence that care plans were used to guide the care given and generally they were not referred to in the regular evaluation”.²⁰⁰

195 [EXP00640009](#)

196 [EXP00680005](#)

197 [INQ05350004](#)

198 [EXP01030003](#); [TRA00350127](#)

199 [EXP01050002](#)

200 [EXP00680006-07](#)

“It is my expert opinion that the absence of specific nursing care plans aimed at addressing the significant problems that were present for (the patient) represents nursing care that falls significantly below the standard expected of a competent nursing team. Indeed it is my expert opinion that the absence of a nursing care plan in this instance represents wholly inadequate nursing care which would expose the organisation and individual practitioners to claims of negligence”.²⁰¹

Mrs Phair concluded that for the 12 patients she reviewed in the focus period the care planning, as disclosed by the patient records, was inadequate.²⁰²

Deficiencies identified in care planning

The deficiencies found by the nursing experts concerning the care planning reviewed can be summarised as follows:

- Care plans were not completed in a timely fashion
- Care plans were not dated
- Goals in care plans were vague
- Care plans consisted of a checklist of tasks done or to be done
- There was a lack of nursing focus
- Ward 6 used a “medical model” of care planning which is not a recognised method
- Care plans were not initiated where appropriate to address significant nursing needs of patients

The nursing evidence on care planning

Ward 6 initially used the well recognised Roper Logan and Tierney (RLT) model for care planning and then moved to a “medical model”.²⁰³

Sister Fox, the SCN for ward 6, explained her position in the following way:

“In the past we did start out with a nursing model. Over time- -and I clearly saw that when I looked into the notes- -over time,

that model changed, and it did become much more of a medical model of care, and I can only accept that and take responsibility for that”.²⁰⁴

The medical model of care planning simply listed the medical instructions on the care plan documentation. From a review of patient records in ward 6 this practice had been followed for some time. This is not an appropriate model of care planning.

Sister Fox maintained that the medical model of care planning did not affect patient care. This was her position:

“What we did not do at all times, was the actual written documentation, but we certainly discussed the patients’ care, we knew what the patients needed and we communicated this to one another within the team”.²⁰⁵

This was her explanation for the care planning failures:

“..every care plan that I looked at, every single one that I looked at, there were absences, and I can only say that it is – it’s as a result of barriers that are put in our way, it is extreme – absolutely extreme activity levels”.²⁰⁶

The Lead Nurse responsible for a number of wards in the VOLH including ward 6 said that she was not aware that ward 6 had moved away from the RLT model of care planning.²⁰⁷

Another SCN said that she was aware of the RLT model of care planning but said the method used in her ward was more of a problem solving approach.²⁰⁸ She provided the following explanation of care planning on her ward:

“When a patient was admitted to the ward, their presenting problem, we would plan for that problem, and use a care plan for that problem, and then we would use sort of progress charts to evaluate”.²⁰⁹

201 EXP00750017

202 EXP00660001; TRA00480053-54

203 TRA00290013-14

204 TRA00290016-17

205 TRA00290067

206 TRA00290016

207 TRA00930076-77

208 TRA00450009-10

209 TRA00450009

Another SCN accepted in evidence that she had found incomplete care plans on her ward when she reviewed the patient records prior to giving evidence. She offered as an explanation the fact the ward was going through a period of transition because they had only recently moved onto a 12-hour shift pattern. Previously they had worked with a named nurse philosophy, with the named nurse taking responsibility for the generation of the care plan.²¹⁰

Care planning for patients with CDI

Nurses accepted that a patient with CDI should have a care plan prepared for that condition. It was also accepted by SCNs that care plans had not been prepared for many of the patients who contracted CDI.²¹¹ There was no pro forma *C. difficile* care plan in use at the VOLH during the early and focus periods for patients diagnosed with CDI²¹² although the *C. difficile* Policy did envisage that a care plan would be available.²¹³

One SCN said in evidence that the only care plans she could find on review of the patient records were for patients whose presenting problem was CDI.²¹⁴ For those who later developed the infection when on the ward she said there was not a formal written care plan.²¹⁵ She provided the following explanation:

“I think a lot of the time it was due to high activity levels in the ward. You know, the ward was very busy and the nurses were always very busy, so it wasn’t that they weren’t consciously thinking of the plan that needs to be put in place, and they were using the progress notes to note things rather than to do a separate care plan”.²¹⁶

She maintained that on her ward the nurses were “giving the care and the care was there in place”.²¹⁷

One Deputy SCN explained that there should have been care plans for patients with CDI on her ward, but accepted that “as you can see from the notes, they are sadly lacking”.²¹⁸ She was asked whether it was the practice on her ward to prepare care plans for patients with CDI and her position was as follows:

“It doesn’t look like it. To be honest we were quite shocked to see in the notes some patients didn’t have a care plan. Generally the staff were very good at doing care plans. It was time-consuming. I can only think that it was pressure at work. I didn’t know at the time that they hadn’t been done”.²¹⁹

One SCN provided this explanation:

“My explanation (for the lack of care plans) would be that all of the staff knew what the patient would require, and they would have felt that what they had written was sufficient and adequate. That is my explanation. We now have - we have now quite specific care plans for both loose stools and *C. difficile*, which we didn’t actually have at that time”.²²⁰

In response to questions about the lack of care plans for patients with CDI in isolation this SCN said:

“I suppose there was an assumption on the nursing - on the part of the nursing staff that it was enough to say that the patient had *C. diff* and was in isolation. Because what was written in the narrative would have indicated what was happening with the patient. The information was there, it just wasn’t in the form of a care plan”.²²¹

Conclusions on nursing assessments and care planning in the focus period

Examination of the patient records disclosed that nursing assessments made on admission to the VOLH were generally poorly completed. These deficiencies should have been discovered by the SCNs. A functioning system of audit would also have identified these failures.

210 [TRA00410055](#)

211 [TRA00440071](#); [TRA00290067](#)

212 [TRA00380133](#); [TRA00300136](#)

213 [GGC00780254](#)

214 [TRA00450010](#)

215 [TRA00450010](#)

216 [TRA00450010-11](#)

217 [TRA00450012](#)

218 [WTS02250042](#)

219 [WTS02250044](#)

220 [TRA00300136](#)

221 [TRA00310028-29](#)

Among the areas of real concern is that of the inadequate care planning practices that developed on a number of wards. This resulted in CDI not being viewed as a condition that required to be addressed separately from other medical issues. Had Nursing Management been more proactive, the inadequacies in care planning would have been identified. The medical model of care planning that became the norm in ward 6 did not form a proper basis for patients to be given appropriate and consistent care. This approach represented a serious failure in nursing care for which Sister Fox has to accept direct responsibility.

The *C. difficile* Policy envisaged that a pro forma care plan for CDI would be available and NHS GGC should have ensured that such a pro forma care plan was available. The absence of a pro forma care plan is not, however, a legitimate excuse for the failures to put care plans in place for patients with CDI.

12.8 Nursing notes and charts in the focus period

Nursing evaluation records

The nursing evaluation records are an important part of the patient records and are the direct responsibility of the nurses caring for the patients.

A patient's condition should be recorded in the nursing evaluation records. These are separate from the care plan and the nursing assessments. In the VOLH (except Fruin) the practice was for nursing information to be contained in nursing evaluation records while the medical input to the patient's records was in a separate part. In Fruin ward the system was different. The records were multi-disciplinary and any person involved with the patient would note his or her observations chronologically. The records were viewed "as a patient journey".²²² Gaps were not identified in the notes examined from Fruin ward.

Evidence of nurses on the nursing evaluation records

Nursing staff generally were of the view that the patient care was well described in the evaluation records.²²³ One SCN said that although there were omissions in care planning on her ward she was of the view that the care was well described in the evaluation records.²²⁴

Another SCN said that there was a point in time when she became aware that there were gaps in the evaluation records. She had discussed this with nursing staff and the explanation she was given for the gaps was pressure of work and the fact they had one trained nurse for 12 patients.²²⁵ She agreed that gaps found of five days, ten days and 20 days in the records of patients in her ward were not acceptable.²²⁶

The expert witnesses on assessment of the evaluation records

The nursing evaluation records were found by the nursing experts to be generally of an inadequate standard. Many evaluation records provided little information of value in determining the condition of the patient.

Mrs Jeanes criticised the nursing evaluations records as echoing the conclusions of medical staff. Rarely did they include any indication of what input the nursing staff had in the clinical decision-making process.²²⁷

Mrs Jeanes expected that the nursing evaluation records would be checked regularly by the person in charge of the ward to ensure that they were an accurate reflection of the care and progress. She said that there was no evidence from the nursing records that this had been done.

Nursing handovers

At the end of each shift the nursing staff handed over information on patients to the shift coming on duty. This was done using a handover sheet.

222 [WTS02200015](#)

223 [TRA00410056-58](#); [TRA00430024](#)

224 [TRA00290014](#)

225 [TRA00390056](#)

226 [TRA00390156-157](#); [TRA00400051](#)

227 [EXP00680008](#)

Information obtained by the nurse during the shift was noted on the handover sheet. On many occasions this information had not been entered into the patient records. The handover sheets were not retained.²²⁸

One deputy SCN explained in her witness statement that at handover on her ward she would write information about her patients on a separate sheet and transfer that information into the nursing notes. She then shredded the sheet of paper. She also explained that:

“There was lots of information to communicate, which is why handovers took so long”.²²⁹

One SCN said that they:

“very much depended on handover being robust and all the communication within the team to make sure we shared the information widely”.²³⁰

Another SCN explained her position at handover in the following way:

“...we had very strong teamwork within ward 6 and handover took so long because every patient was discussed totally individually, important information was given then, it would have just been far better that all of that verbal communication had been documented, but, unfortunately, time just did not allow it”.²³¹

The nursing handover in the evening coincided with the evening visiting period and was a time identified by relatives when it was difficult to contact nursing staff for information.

Patient observations

The recording of a patient's baseline temperature, pulse, respirations, oxygen saturations and blood pressure is an important feature of the treatment of a patient with CDI. It enables the medical and nursing staff to assess the response to treatment and a patient's overall condition.

Such observations are basic and easily obtainable indicators of critical illness. The frequency of assessment is dictated by the patient's clinical condition.

Deficiencies identified in recording of observations

The expert nursing witnesses were critical of the standard of observations. There were a number of issues identified by them:

- There was no clear rationale for the frequency of observations in individual patients
- The frequency of recording did not always reflect the severity of the patient's condition and need for monitoring
- Some patients on wards did not have observations taken for several days at a time
- There was a failure to comply with medical instructions about the frequency of observations
- Where observations were abnormal there was no indication this was appreciated or acted upon

Expert view on recording of observations

Mr Evans said that vital signs were not adequately recorded in the majority of the cases he examined.²³² In one case he noted:

“The patient was *C. difficile* positive and symptomatic and there is no evidence of regular observations, overall, to accurately monitor her condition. There are specific examples of where the patient's condition required regular observations and they were not recorded for three days, in one instance, and nine days in another. Her treatment plan, at one stage, depended on observation of her temperature. The chart showed that it was only recorded once that day. Observations were not recorded then for 17 days, and on that day the temperature was not even recorded. The overall standard of observations of vital signs with this patient was totally inadequate”.²³³

228 [TRA00290129-130](#)

229 [WTS02250015](#)

230 [TRA00420017](#)

231 [TRA00290027](#)

232 [EXP01030003](#); [TRA00350124-125](#)

233 [EXP00240024](#); [TRA00250095](#)

Professor Palmer noted in the cases he reviewed that there were patients where observations were required but not recorded for significant periods of time. One patient had no observations recorded for several days at a time despite the fact he had undergone major surgery. Professor Palmer was “alarmed” that on the occasions observations were completed they were not completed adequately or competently.²³⁴

Recording of pain levels

Pain levels were rarely recorded. Nor were there attempts to measure pain systematically.²³⁵ The nursing staff did not appear to consider that the monitoring and recording of pain was an important aspect of patient care.

The monitoring of pain for CDI patients is an essential element of care. An increase in pain can be an early warning of progression of the infection. Good practice would be to ask the patient to identify the source of pain and use comparators such as a scale of pain.

Mrs Stower was critical of the monitoring of pain in the patient records she reviewed. Patients scored “0” in relation to pain when in the clinical records it was noted the patients were complaining of pain and had been given analgesia for pain relief.²³⁶

Mrs Jeanes noted that one patient was given analgesia including paracetamol, co-codamol, co-dydramol and diamorphine, with no attempt to monitor or measure pain.²³⁷ She said it was unclear if staff understood the effects and potential side-effects of the analgesic drugs used.²³⁸ Drugs which could cause nausea should be accompanied by the administration of drugs to control nausea, but this was not done. She said that the pain of one patient was so poorly monitored and documented that it was unlikely that medical staff could be given a clear and consistent picture of the pain the patient experienced.²³⁹

Overall, Mrs Jeanes arrived at the following conclusion on the pain management of patients:

“The absence of regular assessment and monitoring of pain and the lack of a consistent and coherent strategy for the management of the pain and use of analgesics in some patients was exceedingly poor practice”.²⁴⁰

Recording of bowel movements

CDI can range from mild to very severe, with ulceration and bleeding from the colon (colitis) and at worst perforation of the intestine leading to peritonitis. Recording of bowel movements is recognised as important in monitoring the treatment of the condition.

Documentation for recording bowel movements - the Bristol Stool Chart

Bowel movements can be recorded in a fluid chart, but a detailed stool chart provides a more comprehensive picture of consistency, volume and other characteristics. A widely used method of charting stools is the Bristol Stool Chart,²⁴¹ which is a medical aid designed to classify faeces into seven groups and has been recognised as a useful tool in evaluating the effectiveness of treatment for CDI. Figure 12.1 sets out the form of the Bristol Stool Chart.

234 EXP00400020; [TRA00200051](#)

235 [TRA00350053](#); [TRA00350120](#)

236 [EXP00590008](#); [TRA00160138-140](#)

237 EXP00260022-23

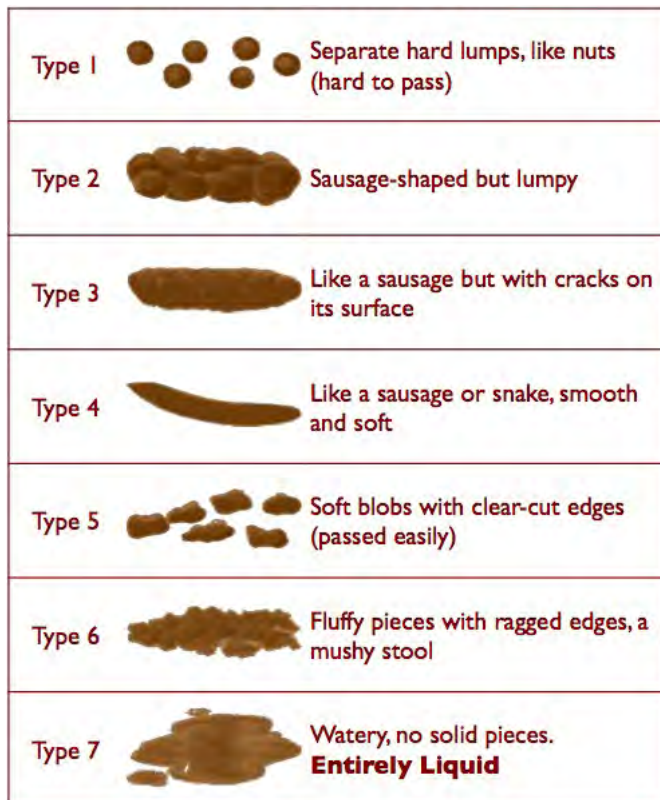
238 [TRA00180059](#)

239 EXP00260021-24

240 [EXP00680013](#); [TRA00180058-59](#)

241 [INQ00020001](#)

Figure 12.1 Bristol Stool Chart



- Type 1 to 2 indicate constipation
- Type 3 to 4 are ideal stools as they are easier to pass, and
- Type 5 to 7 may indicate diarrhoea and urgency

The view of HPS

Professor Jacqui Reilly from HPS explained that the use of the Bristol Stool Chart is not a key recommendation in the guidance on CDI published in September 2009.²⁴² The guidance is as follows:

“Healthcare staff may find it useful to use the Bristol Stool Chart to assess the severity of diarrhoea”.²⁴³

The unanimous view of the nursing experts, however, was that the use of a chart like the Bristol Stool Chart was an important monitoring tool for patients suffering from CDI. NHSGGC’s Loose Stools Policy, effective from December 2007, identifies the Bristol Stool Chart as the appropriate monitoring tool to use.²⁴⁴ The weight of the

evidence supports the value from a nursing perspective of the use of a monitoring tool like the Bristol Stool Chart.

Evidence of nurses on charting of stools

All the nurses who gave oral evidence accepted that they should have been charting the stools of patients with diarrhoea and CDI.

Sister Fox suggested in her witness statement that in ward 6 the Bristol Stool Chart was used.²⁴⁵ Initially she said in her oral evidence that the Bristol Stool Chart was used in ward 6, at least from December 2007.²⁴⁶ She said there was a laminated copy of the Bristol Stool Chart both in the sluice area and in the “Really useful” folder.²⁴⁷ She expected that her nurses would refer to it when describing a patient’s stools. Subsequently she accepted in oral evidence that on review of the patient records this was not the case. Her explanation at that time was that the information would be contained in the narrative in the evaluation sheets.²⁴⁸

Another SCN from another ward accepted that stool charts were poorly completed and provided the following explanation:

“Yes, a lot of the stool charts were poorly completed, yes...I think we were aware of the situation at the time. We have certainly been able to document the stools in detail through the nursing narrative, so we were taking serious consideration at that point, but we just can’t evidence it on a stool chart”.²⁴⁹

Bowel Function Chart

Some wards at the VOLH used a Bowel Function Chart to record episodes of diarrhoea. This is not a stool chart. It allows the nurse to identify a date where there has been a bowel movement but it does not enable the nurse to record the nature of the diarrhoea or the number of episodes. This type of chart was not adequate as a method of recording information on the bowel movements of patients suffering from CDI.

242 [TRA01100123](#)

243 [HPS01860027](#)

244 [GGC27590008](#)

245 [WTS00960013](#)

246 [TRA00310001](#); [TRA00310105-106](#)

247 [TRA00300145](#)

248 [TRA00300147-148](#)

249 [TRA00440064-65](#)

Other charts

On occasions a stool chart was used which did have sections to describe the nature of the stool. The chart did not provide a Bristol Stool type classification but because the nurse was required to document details of the stool this chart would assist in the management of the patient.

The expert view on the recording of stools

The nursing expert witnesses were critical of the practices at the VOLH on the recording of stools in patients with diarrhoea. The following criticisms were typical of the views expressed by the nursing experts:

“Overall, the completion of stool charts was inadequate to determine the extent of diarrhoea in terms of volume and frequency”.²⁵⁰

“The NMC Code states that there is a duty “to act to identify and minimise the risk to patients and clients”. The lack of systematic and clear recording of the frequency, quantity and characteristics of bowel movement did not act to reduce the risks of *C. difficile*, anaemia and dehydration. This was poor practice”.²⁵¹

“All patients required a stool chart. None of the patients I reviewed had stool charts that were considered to be completed to a satisfactory or adequate standard. In two cases the stool charts appear to be missing or were not completed. Eight patients had charts in place, which were considered to be poor or inadequate because the nurses failed to provide sufficient detail or the stool charts were not completed during episodes of infection”.²⁵²

“It was extremely difficult to establish the severity of her diarrhoea during her episode of *C. difficile* and it was impossible to identify when she was asymptomatic. It was also unclear when she actually commenced the symptoms of *C. difficile*”.²⁵³

Fluid balance

Fluid balance is the maintenance of the correct amount of fluid in the body. Fluid balance can be affected where a patient has diarrhoea as a consequence of CDI. Dehydration can contribute to the development of urinary tract infections, constipation, and the increased risk of pressure ulcers and falls.

Fluid balance charts

The fluid intake and output of patients are recorded by nurses on fluid balance charts. The charts are designed to monitor the amount of fluid input and output over a 24-hour period²⁵⁴ and are used to assess patient hydration. Accurate recording is important for patient wellbeing. Medical staff rely upon information contained within fluid balance charts to inform decisions on care.²⁵⁵

Nursing expert, Ms Elaine Connolly provided this important description of the role of fluid balance charts in patient management:

“The role of the nurse in the management of fluid balance in both maintaining an accurate record of the patient’s fluid intake and output and reconciling the totals at the end of each 12-hour period is vital. This information is the key to the patient’s care delivery and is a record which enables other professionals involved in the patient’s care to make appropriate decisions”.²⁵⁶

Nurses therefore have a responsibility to ensure that those at risk of dehydration, or who become dehydrated during their admission to hospital, are identified, monitored and adequately hydrated.²⁵⁷ Dehydration can occur quickly in those with diarrhoea as a result of CDI, particularly the elderly.

Poor documentation on fluid balance charts, poor assessment of hydration and lack of monitoring of fluid intake are factors that can increase the mortality of patients. As explained by Mrs Phair:

250 [EXP00680017](#); [TRA00180063](#)

251 [EXP00340014](#); [TRA00100125](#)

252 [EXP01050003](#)

253 [EXP00040023](#); [TRA00170148-149](#)

254 [EXP00640019-20](#)

255 [EXP00770013](#)

256 [EXP00520028](#)

257 [EXP00720010](#); [EXP00730009](#)

“A reduction in body fluids can have major effects on the body: a reduction of 5% will cause thirst, a reduction of 8% will cause illness; and a 10% reduction in fluid can cause death (Carol 2000)”.²⁵⁸

Expert review of fluid recording

The nursing experts were critical of the monitoring of fluid balance in the cases reviewed. Professor Palmer noted that in one case the fluid balance charts did not demonstrate that a patient had been receiving appropriate amounts of fluids either intravenously or through a nasogastric tube prior to a significant deterioration in his condition.²⁵⁹

If correct, the fluid balance charts in another patient with active CDI suggested that her fluid intake was grossly inadequate in the face of a specific medical direction on the charts to “push fluids”.²⁶⁰

In his overview report Professor Palmer summarised the position as follows:

“The standard of fluid balance recording overall was lamentable and, on several occasions, professionally negligent.... There are several examples where the evidence would suggest that patients did not receive adequate fluids throughout a 24-hour period, or indeed over several days in succession”.²⁶¹

Mrs Jeanes was also highly critical of the fluid balance recording in the cases she examined. In one patient she noted that the fluid charts and nursing evaluation record did not always match. She explained that:

“Urine output was also poorly recorded at times and it is unclear when she had a urinary catheter in place and if this always drained anything. Intravenous fluids were also missed from the fluid charts and on the whole the fluid charts were of very limited value in clinical decision making”.²⁶²

Mrs Phair noted that fluid balance charts were completed erratically in the case of one patient despite the fact the medical staff had prescribed the need for accurate and detailed fluid balance charts.²⁶³ In this case there were many days where there was no chart completed at all and no evidence that the patient was ever offered a drink.²⁶⁴

Mr Evans summarised the position from the cases he reviewed in the following way:

“The overall standard of fluid balance recording was very poor”.²⁶⁵

The nursing experts also observed that the failures in fluid balance recording were not picked up by the SCNs on the wards.

Deficiencies in fluid balance recording

Listed below are examples of specific deficiencies identified by the nursing experts in fluid balance recording.

- Instances where patients were on fluid restriction and recording was poor²⁶⁶
- Input and output were at times blank or incomplete²⁶⁷
- Charts were continued for a frequency inappropriate to a patient’s needs²⁶⁸
- 24-hour totals were not calculated²⁶⁹
- There were no fluid balance charts for patients who should have had fluid balance charts²⁷⁰
- IV fluids were not appropriately added to the input column²⁷¹
- Charts were not properly maintained even when medical staff had asked for charts to be maintained²⁷²

263 EXP00170038; [TRA00480036-37](#)

264 EXP00170038

265 [EXP01030005](#); [TRA00350133](#)

266 EXP00060017; EXP00390011; [EXP00590009](#); [TRA00150044-45](#); [TRA00160140](#)

267 [EXP01030005](#); EXP00570014; [TRA00350133](#); [TRA00260123](#); [TRA00230151](#)

268 [EXP01030005](#); [TRA00350133](#)

269 [EXP01030005](#); [EXP01050003](#); EXP00570014; EXP00710029; [TRA00350133](#)

270 [EXP01030005](#)

271 [EXP01030005](#)

272 EXP00200015

258 [EXP00640019](#)

259 EXP00670017

260 EXP00450016; [TRA00200032](#)

261 [EXP01050003](#); [TRA00220086](#)

262 EXP00260027; [TRA00120006-07](#)

- One patient had 23 fluid balance charts and not one was completed adequately²⁷³
- Patients had two fluid balance charts for the same date²⁷⁴
- One patient who was in renal failure did not have properly completed fluid balance charts²⁷⁵

The nursing evidence on fluid recording

The nurses who gave evidence accepted that there were deficiencies in the monitoring of fluid balance in the records they reviewed.

Having reviewed the fluid balance charts on her ward, one SCN provided this evidence:

“I have read many of the documents with regard to each and every patient that has been looked at within the Inquiry, and there are some charts which are absolutely fine. Unfortunately, the majority of charts are not, and I can only accept that. I must accept that criticism”.²⁷⁶

The nursing staff accepted that it was important to keep accurate fluid balance charts for patients, particularly for patients with CDAD. They did not accept that patients were not given fluids.

The nursing staff also maintained that it is often extremely difficult to keep accurate fluid balance charts. That is undoubtedly correct.

One SCN explained her own approach, and that of her staff in the following way:

“I do not believe that my staff willingly, wantonly – and myself – failed to complete these charts properly. We had many discussions – many discussions – in the ward, where it was highlighted that the fluid balance charts needed to be much more accurately maintained, and this would improve, and then, for whatever reason, it didn’t happen”.²⁷⁷

273 EXP00010016

274 EXP00480023-24; EXP00580035

275 EXP00150011; [TRA00350060](#)

276 [TRA00290010](#)

277 [TRA00290011](#)

A number of possible explanations were given in an attempt to justify the failure to complete accurate fluid balance records. Some of these are as follows:

- Poor levels of staff²⁷⁸
- Dependency of patients²⁷⁹
- Access to charts²⁸⁰
- Distractions with other patients or tasks²⁸¹
- Forgetting the amount taken when distracted²⁸²
- Patient continence²⁸³

Recognition of inadequacy of the fluid recording

From the evidence, there was some recognition around early 2008 that fluid balance charts were not being completed accurately. The issue was raised at the Sisters’ Meetings,²⁸⁴ and at the Sisters’ Meeting of 28 February 2008 concern was expressed that “(fluid balance) charts were not being filled in correctly and in some cases not at all”.²⁸⁵ Somewhat tellingly, this information was not provided from monitoring by SCNs but as feedback from GPs.

Medical staff had also highlighted the inadequacy of fluid balance recording on some wards.²⁸⁶ Nursing staff were reminded by SCNs that it was important to keep accurate fluid balance charts, but after some initial improvement this was not maintained.²⁸⁷

Conclusions on nursing notes and charts in the focus period

There were serious failures in the recording of patient information in the nursing records. There were unacceptable gaps in these records. The extent of the failures in important areas such as the recording of fluid balance and the charting of loose stools was such that there must have been an impact

278 [TRA00450024](#)

279 [TRA00450024](#); [TRA00460082-84](#)

280 [TRA00420084-85](#); [TRA00420096-97](#)

281 [TRA00460082-83](#)

282 [TRA00460082-84](#)

283 [TRA00380028](#)

284 [TRA00450026](#); [TRA00310054-56](#); [TRA00420080-81](#);
[TRA00380156-158](#)

285 [GGC14790003](#)

286 [TRA00340023-26](#); [TRA00370091](#)

287 [TRA00370002-03](#)

on the ability of the nurses on the wards to provide safe and consistent care. The serious failures identified in the recording of observations represent poor nursing care.

The handover practices adopted meant that information handed over did not enter the patient records. The SCNs were aware of this practice and they should not have allowed it to continue.

It is for the SCNs to lead the care given on their wards. They should have ensured that all nurses on the ward were aware of the importance of maintaining proper records on the aspects of basic care identified in this Section.

The extent of the failures discloses a serious lack of understanding of the important role played in patient care by good record keeping.

The lack of proactive involvement of nurse managers in the wards meant that Nursing Management was unaware of the extent of the nursing problems in the VOLH. Had there been a functioning system of audit the failures identified in this Section would have been identified and remedial action taken.

Nursing Management and ultimately the Board must accept responsibility for the failures identified in this Section.

12.9 Pressure damage in the focus period

General principles of pressure and wound management

When patients remain in the same position for periods of time, the points of the body which are in contact with a surface, such as a mattress or chair, may be at risk of pressure damage. This risk is exacerbated by the shearing action of movement across the skin when the patient is moved, particularly when moisture is present from body substances such as sweat, urine or diarrhoea. The risk is also increased with poor hydration, poor diet, peripheral oxygenation, circulation and other conditions such as diabetes.²⁸⁸

Immobile, sick and weak patients are unable to move effectively and are dependent on their carers to assist them. They are at particular risk of sustaining pressure damage. Patients who have CDI with profuse diarrhoea are particularly vulnerable to skin damage.²⁸⁹ Incontinence may also exacerbate existing skin damage. The importance of moving and handling techniques in avoiding skin damage has been considered in Section 12.7.

The development of pressure damage

Pressure damage first becomes evident as a redness of the skin which causes discomfort. Untreated, this early damage can continue to develop and can cause open painful wounds that are difficult to treat and can lead to more serious complications. Nursing care is designed to prevent pressure damage where possible.²⁹⁰ In frail, elderly patients action to prevent pressure damage must be taken rapidly as damage is likely and is difficult to cure.

Assessment of the risk of pressure damage

The cardinal rule is to avoid pressure damage wherever possible. Early assessment of the risk to the patient is imperative so that appropriate measures can be put in place to prevent pressure damage or at least reduce the risk.

The risk of pressure damage must be assessed on admission to hospital and thereafter at regular intervals based on the initial risk assessment. This risk is assessed by using a number of established criteria such as the Waterlow Score. The Waterlow Score provides an estimated risk for the development of a pressure sore in a given patient and is the most frequently used system in the UK. As with all risk assessment scoring systems, it is a tool to assist the nurse and must be used in conjunction with the nurse's professional judgement.

The Waterlow assessment allows the nurse to take steps to prevent pressure damage. In some cases this can be achieved by ensuring

288 [EXP00680010](#)

289 [EXP00680010](#); [EXP00720004](#); [EXP00730007](#)

290 [EXP00680010-11](#)

that regular positional changes occur and by optimising mobility for those at minimal risk. Patients with a high degree of risk of pressure damage require more extensive interventions. These can include pressure-relieving mattresses, regular and documented turning or positional changes, and scrupulous monitoring and documentation of pressure points to identify potential damage at an early stage.

Hydration, oxygenation and nutrition are important in ensuring that skin remains in good condition. Where early skin damage is present (redness) the normal treatment is to relieve the pressure and, in patients at risk of damage, apply a thin protective layer or dressing. All assessments and re-assessments must be documented and the plan of care adjusted accordingly.²⁹¹

The Waterlow Score

A Waterlow Score²⁹² document was available to nurses in the VOLH during the early and focus periods as a guide to assess the risk of pressure damage. Since June 2008 a new pro forma document²⁹³ has been available.

In using the Waterlow Score the following areas are assessed for each patient and assigned a value:

- Build/weight for height
- Skin type/visual risk areas
- Sex and age
- Malnutrition Screening Tool
- Contenance
- Mobility

Additional points are assigned to selected patients in special risk categories for:

- Tissue malnutrition
- Neurological deficit
- Major surgery or trauma

A total Waterlow Score of 10 to 14 indicates that there is a risk of pressure damage. A high risk score is 15 to 19. A very high risk exists at scores of over 20. In relation to frequency of review, the Waterlow document used at the VOLH contained the information in Table 12.3.

Table 12.3 Recommended/documentation of risk status

Recommended/documentation of risk status		
Score on Admission	Category	Frequency of Assessment
Under 10	At Low Risk	ONLY if the patient's general condition changes
10 to 14	At Risk	At least WEEKLY; sooner if the patient's general condition changes
15 to 19	At High Risk	EVERY SECOND DAY; sooner if the patient's general condition changes
Over 20	At Very High Risk	DAILY, or as the patient's general condition changes

291 [EXP00680011](#); [EXP00640012-14](#)

292 [INQ01030001-02](#)

293 [INQ01050001-02](#)

Evidence of nurses on the use of the Waterlow scoring system

It was accepted by nursing staff that the Waterlow scoring system should have been used as part of the patient admission process to assess the likely risk of pressure damage to a patient, and that the patient required to be re-assessed on a regular basis in accordance with the guidance in Table 12.3.

Sister Fox, who was the designated VOLH Tissue Viability Nurse (TVN), maintained that all nurses would be familiar with the Waterlow Score and that it was an integral part of nursing. She said laminated copies of the Waterlow Score Tool were displayed around the nursing stations on her ward.²⁹⁴

The clear message from the nurses' evidence was that assessments were being done, but not recorded. Nursing staff accepted in evidence that review, as suggested in the document in Table 12.3, was not documented and in some cases not performed in compliance with the guidance.²⁹⁵

Evidence of nurses on recording of pressure damage and wounds

Where a patient has pressure damage there should be clear documentation of the damage in the patient records. Sister Fox said in her witness statement that:

“a wound management care plan would be created, as a matter of course, for each patient ...”²⁹⁶

Nursing staff did accept that care plans should have been completed where there was pressure damage. These should clearly document the nature of the damage and the plan of care. Sister Fox said in her witness statement that the nurses would describe or map out the wound in the care plans. She maintained that the kind of information that would be recorded would be the depth, size and colour of the wound and the amount, smell and colour of the exudate.²⁹⁷

As a matter of fact, the Waterlow scoring system documentation was not being used in ward 6 during the early and focus periods. Sister Fox provided an erroneous signed statement to the Inquiry that claimed the Waterlow scoring system was used in ward 6 and that there was regular review. In her oral evidence she accepted that, having reviewed the patients' notes, there was no evidence that this was the case.²⁹⁸ Nevertheless, she maintained that patients were assessed and that the principles of the Waterlow scoring system were in fact applied, linking the failure to use the appropriate documentation to the level of activity on ward 6 at the time.²⁹⁹

Sister Fox said in oral evidence that she took photographs of some patient wounds in her role as TVN but later shredded these photographs.³⁰⁰ She was aware the photographs were part of the patient records but her understanding at the time was that they should be destroyed when no longer required for patient care.

The expert view on pressure and wound management

The nursing expert witnesses identified a lack of pressure wound management charts for patients with pressure damage and also a lack of care planning for pressure damage.

In the opinion of Professor Palmer the care provided for pressure damage was of a poor standard.³⁰¹ For example, he noted that in one case a patient did develop a sacral sore and that nursing staff failed to introduce an appropriate plan of nursing to deal with the healing and management of the sore. The nursing staff also failed to address the measures necessary to prevent the development of further sores. He noted that there were a number of cases where patients were displaying early but significant signs of pressure damage with little evidence that the nursing staff introduced precautionary measures.³⁰²

294 [WTS01870005](#)

295 [TRA00360017](#); [TRA00370128](#); [TRA00410037-38](#)

296 [WTS01870006](#)

297 [WTS01870007](#)

298 [TRA00300002](#); [TRA00300028](#)

299 [TRA00300029](#)

300 [TRA00300048-49](#)

301 [EXP01050003](#)

302 [EXP01050003](#)

Mrs Jeanes identified one patient with leg lesions with no plan of care.³⁰³ Another patient had groin wounds, and while there was a plan of care for her it was not systematically utilised and evaluated.³⁰⁴ Another patient had necrotic pressure points but the documentation was too poor to judge if actions taken to deal with the pressure damage were effective.³⁰⁵ Mrs Jeanes was highly critical:

“The assessment, planning, prevention and management of pressure damage in some patients was lamentable”.³⁰⁶

Mrs Stower was also critical of the care on pressure damage:

“I am highly critical of the standard of assessment, planning, evaluation and review of the nursing care relating to this group of patients skin/pressure management and the lack of involvement of the TV (Tissue Viability) Specialist Nurse (who should be the expert in this field). This was a group of frail elderly patients, whose overall health and wellbeing was further compromised by *C. difficile* diarrhoea, which in most cases was a contributory factor to their deteriorating skin viability. I was saddened that some of these patients' care was so lacking, that they would have suffered from the pain and discomfort of excoriated skin, deep sores, and matted scalp hair...”.³⁰⁷

Mr Evans identified examples in the cases he reviewed of patient wounds being treated with products that were not in the nursing formulary and of formulary products being used inappropriately on wounds.³⁰⁸

In one patient at least 11 products were used for pressure damage, often with no rationale, no plan, and no assessment of progress. Mrs Jeanes provided this opinion in the case of this patient:

303 EXP00220016; [TRA00120062-63](#)

304 EXP00230025; [TRA00180056](#)

305 EXP00680010; [TRA00180056](#)

306 EXP00680012; [TRA00180058](#)

307 EXP00590007-08; [TRA00160138](#)

308 EXP01030004; [TRA00350131](#)

“Whilst it is clear that many nursing staff made efforts to manage the pressure damage, the lack of consistency in approach was poor practice, although the record keeping is so poor that it is difficult to determine exactly what was done at times. The use of specialist knowledge in pressure damage prevention and management is not documented. It is unclear if staff understood the need to escalate issues for specialist help and advice, or if specialist help was not available”.³⁰⁹

Deficiencies in pressure management

The following issues were identified by the nursing experts:

- Failures to assess a patient for the risk of pressure damage
- Failures in documentation of the risk which included incorrect scoring
- Failures to review assessments appropriately when assessments were made
- Failures to prepare appropriate care plans when there was a risk
- Failures to identify patients with early but significant signs of pressure damage
- Failures to obtain a pressure relieving mattress where it was required
- Failures to use the appropriate products
- Failures to document wounds appropriately
- In one patient who was critically ill there was no assessment of the risk of pressure damage and no recorded assessment of pressure points³¹⁰

Turning charts

A turning chart allows nursing staff to record positional changes to patients who have sustained, or are at risk of sustaining, pressure damage. The chart provides a plan of care that is dedicated to a turning programme appropriate for the patient. Positional changes are clearly recorded by all those dealing with the patient.

309 EXP00390022; [TRA00110067-71](#)

310 EXP00660001; EXP00680007; EXP00720008; EXP00730007; EXP01050002; [TRA00350130-131](#); [TRA00180057](#); [TRA00220114](#); [TRA00160156-157](#); [TRA00160136-138](#); [TRA00240057](#); [TRA00350131](#)

Turning charts were not in use at the VOLH during the early and focus periods.³¹¹ One SCN provided the evidence that although there were no turning charts available “patient turning was seen as a basic nursing duty”.³¹² It was suggested that references to turning would be made in the patient’s care plan.³¹³ Sister Fox said that she did not consider that it was within her remit to introduce turning charts to her ward or to the hospital, despite her role as TVN for the hospital.³¹⁴ That is a perfectly understandable position because she was not a dedicated TVN. A turning chart is now included in the care bundle for tissue viability.³¹⁵

The clear message from the nurses’ evidence was that despite the absence of turning charts patients were turned regularly and appropriately. This meant that the nurse had to remember when a patient had been turned and what the previous position had been.³¹⁶ Nurses did not accept that any patient sustained pressure damage as a result of failure by a nurse to institute and follow a proper turning regime.

Tissue Viability Nurse

The VOLH did not have a dedicated TVN during the early and focus periods. The role of TVN was performed between January 2007 and June 2008 by Sister Fox,³¹⁷ who was given a job description for the position.³¹⁸ She was also the SCN for ward 6, a busy medical ward, and accepted that she could not provide the service a dedicated TVN³¹⁹ practitioner would provide. Nor did she have formal training for such a role.³²⁰

Around June 2008 the role of the TVN at VOLH was reviewed and thereafter Sister Fox resigned from the position, which was then shared between TVN specialists from the IRH and the RAH.³²¹

311 [TRA00300032](#); [TRA00380089-90](#); [TRA00430021](#); [TRA00450043](#)

312 [WTS01870009](#)

313 [WTS01870009](#)

314 [TRA00300033-34](#)

315 [INQ01070001](#); [WTS01870009](#)

316 [TRA00320096-99](#); [TRA00410014](#); [TRA00430022](#); [TRA00450044-45](#)

317 [WTS01870001](#); [TRA00290005](#)

318 [INQ01020001](#)

319 [TRA00300033](#)

320 [TRA00300044](#); [TRA00300044-45](#)

321 [WTS01870004](#)

The use of pressure relieving mattresses

Nursing staff said that they had access to pressure relieving mattresses and had no difficulty in obtaining such mattresses.

It was accepted that where a pressure relieving mattress was in use this should be evident from the patient records.³²² On review of the patient records it was often impossible to ascertain if a specialist mattress was ordered, when this type of mattress was used, and for how long the mattress was in use.³²³

Number of patients with pressure damage

The nursing experts were able to identify 37 patients in the focus group of patients who suffered pressure damage. The number is likely to be higher because poor record keeping meant that the experts could not ascertain the position for a significant number of patients. Nor is it possible to say how many patients were suffering from some pressure damage on admission to the VOLH.

Conclusions on pressure damage in the focus period

Pressure and tissue management at the VOLH was poor. Inevitably this would have had an impact on care. Sister Fox was placed in a very difficult position because she had responsibility for a busy medical ward in addition to her duties as a TVN, and the Inquiry considers that it would be unfair to criticise her for failures in pressure damage management. As SCN and as TVN for the hospital, however, Sister Fox should have known that a failure to follow the Waterlow system of assessment was unacceptable.

Given the importance of tissue viability, a nurse who was a SCN on a busy ward should not have been selected as the TVN for the VOLH. There also appears to have been a lack of any assessment of her work in the role of TVN. The nurse selected for the role of TVN ought to have had the appropriate experience and training and to have been provided with sufficient time to perform the role properly.

Nursing Management and ultimately the NHSGGC Board have to accept responsibility for the failures identified in this Section.

322 [TRA00410015](#)

323 [TRA00300038-39](#); [TRA00340092-94](#)

12.10 Nursing care in the early period

Similar trends

The work undertaken by Mrs Phair in connection with the early period has already been described. Mrs Phair had access to 33 sets of patient records. Sixty-eight patients tested positive for CDI during the early period.

The trends evident on basic aspects of nursing care were also present in the early period.

Nursing care assessments

The review of the nursing assessments carried out disclosed that in 32 of the 33 patient records the nursing assessment was either poorly completed or not present when it should have been.³²⁴

Nutritional assessments

Nutritional assessments in the early period were only completed to a satisfactory standard for three patients. Ten patients had poorly completed assessments and a further 20 had no assessment or care plan.³²⁵ This was a similar pattern to that found in the focus period.

Moving and handling assessments

Only five patients in the patient records reviewed had satisfactory moving and handling assessments.³²⁶ There were no records of assessments for 25 patients who should have had assessments.³²⁷

Falls risk assessments

Only four patients had a satisfactory falls risk assessment.³²⁸ There was no evidence of falls risk assessments for 26 patients and falls risk assessments for a further three patients were inadequate.³²⁹

Care planning for patients with CDI

Mrs Phair also looked at care planning for CDI for patients in the early period. She was of the view that only two patients had a satisfactory care plan in place for the management of the infection. Nine patients

had no care plan in place at all and 22 had care plans that were inadequate.³³⁰

Stool and fluid balance charts

Mrs Phair concluded that in the cases she reviewed stool charts did not exist or were not completed correctly for 32 patients out of the 33 patient records examined.³³¹ Fluid balance charts were either not completed properly or did not exist.

Pressure management

It was clear from the review of pressure risk assessment that there were deficiencies similar to those discovered in the focus period. Only three patients had a satisfactory pressure risk assessment. Fifteen patients had an inadequate assessment and/or no care plan. Fifteen had no assessment or care plan at all.³³²

12.11 Staffing issues and care

Apparent shortage of nurses

A number of relatives expressed the view that there appeared to be a shortage of nurses and that nurses were “run off their feet”.³³³ This is considered in Chapter 11. Nursing staff also contended that deficiencies in record keeping could be explained, at least in part, by the fact that they were busy.³³⁴

The importance of adequate staffing

Adequate staffing of nurses on wards is not only dependent on having the correct number of nurses but also on having the correct skill mix to carry out the care appropriate to the level of patient dependency. There are no nationally set mandatory nursing levels.

Adequate nurse staffing levels are important for ensuring patient safety and quality of care. There is a direct link between low staffing and increased levels of pressure ulcers, medication errors, falls and healthcare associated infections.³³⁵ Conversely, good staffing levels promote good levels of care.

324 [EXP02790005](#); [EXP02790008](#); [TRA00480052-53](#)

325 [EXP02790005](#)

326 [EXP02790005](#)

327 [EXP02790011](#)

328 [EXP02790011](#)

329 [EXP02790011](#)

330 [EXP02790005](#)

331 [EXP02790005](#)

332 [EXP02790005](#)

333 [TRA00030070](#); [TRA00040097](#); [TRA00010029](#);
[TRA00010107](#)

334 [TRA00370065-66](#); [TRA00460033](#); [TRA00460081-82](#)

335 [EXP02820008](#); [INQ03810007](#); [INQ03810028](#)

Tools used as a guide to assessment of nurse staffing levels and ratios

There is a variety of methods that can be used to guide nurse staffing levels and ratios. A commonly applied tool in the UK is the Hurst Model.³³⁶ The 2006 Royal College of Nursing report, "Setting Appropriate Ward Nurse Staffing Levels in NHS Acute Trusts",³³⁷ recommends a skill mix of 65% registered nurses and 35% nursing assistants.³³⁸ Apart from the correct skill mix, available staffing levels will vary depending on vacancies due to turnover of staff, maternity leave and sickness. To account for this and for protected time for training and development, the Royal College of Nursing (RCN) also recommends that a predictable absence allowance of 25% is built into ward nursing numbers.³³⁹

Evidence of the ward nurses on staffing

The evidence of nurses was that they were extremely busy on the wards. One SCN accepted in evidence that there could be a delay in patients being cared for because the staff were so busy.³⁴⁰ Other SCNs said there were absences and they relied heavily on bank staff.³⁴¹ One SCN stated that she had regular discussions with her manager about the fact that staff on her ward were overly busy.³⁴²

One of the SCNs described the position on staff in the following way:

"We could have done with more staff yes. Our patients were very dependent, even when not medically unwell. Due to stroke or dementia our patients would require input that took a lot of time. It was very heavy work, both physically and mentally demanding".³⁴³

Review of whether the issue of lack of staff had previously been raised as a problem

As mentioned on several occasions in this Chapter, the SCNs argued that the burden

on nursing staff could explain the significant failures identified in record keeping and apparent deficiencies in care. This explanation for poor record keeping was first raised when the SCNs gave evidence. The Inquiry is not aware of any meeting where it was suggested that nurses could not complete records due to lack of staff.

Neither the NHSGGC Internal Investigation report³⁴⁴ nor the Independent Review³⁴⁵ chaired by Professor Cairns Smith suggested that poor staffing levels were seen as having an adverse impact upon record keeping or care. When the Internal Investigation Team interviewed the SCNs for wards 3, 4, 6, 14, 15 and F. SCNs did not raise staffing levels as an issue preventing them from performing all their duties. The following extract has been taken from the Internal Investigation report:

"WARD STAFFING LEVELS

The purpose of this Section is to confirm that the VOL had no problem with nurse staffing levels.

This can be evidenced from the interviews with all Ward Managers (SCNs) and Lead Nurses/CSMs (Clinical Service Managers) who confirmed:

- They did not have staffing problems
- They had a low turnover of staff
- Their sickness absence was well controlled
- They never had cause to raise staffing issues to the general management level"³⁴⁶

Expert review of staffing levels

Mrs Perry reviewed the staffing ratios for all wards and considered that they were acceptable for the number and nature of patients on the ward.³⁴⁷ She prepared a Table setting out the staffing levels in wards from January 2007 to April 2008 which is reproduced in Table 12.4.

336 [EXP02820007](#)

337 [INQ01990001](#)

338 [INQ01990005-06](#); [EXP02820012](#)

339 [EXP02820007](#)

340 [TRA00290017-18](#)

341 [TRA00360009](#); [TRA00450030-31](#); [TRA00460150](#)

342 [TRA00310130-131](#)

343 [WTS02250019](#)

344 [GGC00610001](#)

345 [GOV00030001](#)

346 [GGC00610017](#)

347 [EXP02820008](#)

Table 12.4 Mrs Perry's review of staffing levels

Ward	Whole time equivalent nursing staff budget	Number of beds	Skill mix (%) registered/unregistered
3	25.33	20	61/39
4	18.87	10	71/29
5	26.71	20	66/34
6	27.40	22	61/39
F	22.18	16	52/48
14	27.30	24	45/55
15	27.23	24	40/60
Fruin	23.36	24	36/64

The staffing levels demonstrate that the scheduled number of nurses to beds did not fall below one nurse to four patients with the exception of night duty, where it is common across the NHS to have lower staffing numbers.³⁴⁸ The figures for staffing at VOLH did include a 22.5% allowance in numbers for predictable absence. According to Mrs Perry the ratio of one nurse to four patients for day shifts is accepted professionally as a reasonable benchmark.³⁴⁹

Mrs Perry's view was that the ratio of registered/trained to untrained staff on the medical wards was appropriate, aligned to the RCN benchmarks, and therefore unlikely to have contributed to poor clinical care and spread of infection.³⁵⁰

Mrs Perry also looked at levels of sickness absence and the use of bank and agency staff. She concluded that the use of bank and agency staff was at the level expected in the NHS and that bank and agency staff were used appropriately.³⁵¹

The staffing ratio does not, however, take account of a situation where a number of patients become unwell with profuse diarrhoea

and require additional nursing input.³⁵² In particular, the ratios for the Rehabilitation and Assessment wards do not take account of the fact that some patients in those wards were medically unwell and required nursing rather than rehabilitation care.

Staff morale

Some nursing staff described morale as low due to overwork. The nurses were aware that there was uncertainty over the future of the hospital. Yet nursing staff did not believe that low morale or uncertainty about the future of the VOLH affected the quality of patient care.

An SCN had this to say on the uncertainty over the future of the VOLH:

"I don't think it impacted on morale on a day to day basis when the staff were working. I think it was just a threat that was hanging over them over a period of a long time, and they were almost used to it. But when they came into work, it certainly didn't reflect on their performance when they were there".³⁵³

The Deputy SCN of Fruin ward, when asked if she thought that staff morale was affected by the dissolution of Clyde, expressed the following view:

348 [GGC24580001](#)

349 [EXP02820008](#)

350 [EXP02820013](#)

351 [EXP02820012](#)

352 [TRA01040009-13](#)

353 [TRA00440069](#)

“Yes, we were all scared for our jobs. We thought we would be transferred to Gartnavel. We stated our case to Cabinet Secretary for Health Nicola Sturgeon and after she came back and said we could stay where we were. We felt the hospital was getting down graded all the time. The hospital was getting run-down”.³⁵⁴

Appropriate staffing levels

The definition of a safe level of nursing staff varies in different situations. There must be a balance between the level of the nursing staff and the needs of the patients on the wards. It is not simply an issue of numbers. It is also critical that the nursing staff are competent to provide the care required by the patients on their particular ward.

The issue of safe and adequate nurse staffing is a controversial one and is the subject of significant debate. Studies³⁵⁵ do demonstrate a direct correlation between inadequate nurse staffing levels and

- Patient mortality
- Patient satisfaction
- Adverse patient outcome
- Patient recovery
- Errors in treatment³⁵⁶
- Where staffing levels are inadequate this also can have an affect on nursing morale and increased nurse turnover rates.

Conclusions on staffing

The staffing levels at the VOLH were in accordance with nationally approved standards in 2007 and 2008 but that does not mean that staffing levels were safe. At times when there are outbreaks of infections such as CDI the demands upon staff are increased. Also, where patients in a rehabilitation ward are acutely unwell and are kept in that ward rather than transferred to an acute ward, it is highly likely that the staffing levels will be inadequate. Some nurses working in a rehabilitation setting may not have the necessary skills to nurse

acutely ill patients. When staffing levels are inadequate, or nurses do not have the necessary skills to nurse patients, it is the responsibility of the SCN to raise this with Nursing Management.

Nursing Management must be directly involved in the wards for which they have responsibility. They must be aware when staffing levels require to be addressed.

12.12 Overall conclusions on nursing care

This Chapter has identified a catalogue of failures in fundamental aspects of nursing care.

The Inquiry accepts the evidence of the nursing experts. They carried out a careful and detailed examination of the patient records and many of the deficiencies they identified were not disputed by the nurses in their evidence. Each nursing expert identified similar failures across different wards in the VOLH, a consistency that reinforces the soundness of their conclusions.

The focus of the Report is of course on CDI, and the review of patient records has disclosed serious deficiencies in the nursing care given to patients with CDI in the VOLH. Care was deficient at the most basic levels, and also in more specialised management of patients. It is worthy of note that the deficiencies identified were not restricted to one particular ward. Nor were they restricted to the focus period. Standards of nursing care had been permitted to lapse over a period of time. The SCNs must be primarily to blame for the deficiencies on their own wards. Indeed in some cases it is clear that SCNs participated in the poor care. The SCNs should have led by good example. They had a duty to identify deficiencies in nursing care on their wards.

The conclusion that the standard of nursing care was poor is supported by other deficiencies noted in other Chapters of this Report. For example, in Chapter 11 evidence of failures in basic care, including faeces found under nails, has been identified. Furthermore, as discussed in Chapter 13,

354 [WTS02200019](#)

355 [INQ03810001](#)

356 [INQ03810001](#)

there were serious delays in commencing treatment for CDI even after a diagnosis had been confirmed.

Having reviewed patient records prior to giving evidence, the SCNs accepted that there were deficiencies. They sought to explain the deficiencies by the levels of activity on the wards. It may be that on occasion notes were not made because staff were busy, but that explanation does not excuse the significant deficiencies found. It is simply not a convincing explanation that, notwithstanding the serious failures identified in this Chapter, the care was in fact given.

It would be simplistic, however, to suggest that all blame should lie with the SCNs. For proper care to be delivered Nursing Management also has a role to play. That role must be a proactive one. There was no evidence that Nursing Management was proactively involved in the management of the wards for which they had responsibility. Their total ignorance of the extent of the problems discovered on analysis of the patient records is demonstrative of their lack of involvement on the wards. Had Nursing Management been more proactively involved on the wards under the managers' care, and ensured that regular auditing of records was undertaken, deficiencies could have been identified.

Ultimately, NHSGGC must accept responsibility for the failures identified in this Chapter.

12.13 Recommendations

Recommendation 13: Health Boards should ensure that there is a clear and effective line of professional responsibility between the ward and the Board.

Recommendation 14: Health Boards should ensure that the nurse in charge of each ward audits compliance with the duty to keep clear and contemporaneous patient records. Health Boards should ensure that there is an effective system of audit of patient records, and that there is effective scrutiny of audits by the Board.

Recommendation 15: Health Boards should ensure that nursing staff caring for a patient with CDI keep accurate records of patient observations including temperature, pulse, respiration, oxygen saturation and blood pressure.

Recommendation 16: Health Boards should ensure that the nurse in charge of each ward reports suspected outbreaks of CDI (as defined in local guidance) to the Infection Control Team.

Recommendation 17: Health Boards should ensure that where there is risk of cross infection, the nurse in charge of a ward has ultimate responsibility for admission of patients to the ward or bay. Any such decision should be based on a full report of the patient's status and full discussion with site management, the bed manager, and a member of the Infection Control Team. The decision and the advice upon which the decision is based should be fully recorded contemporaneously.

Recommendation 18: Health Boards should ensure that there is an agreed system of care planning in use in every ward with the appropriate documentation available to nursing staff. Where appropriate they should introduce pro forma care plans to assist nurses with care planning. Health Boards should ensure that there is a system of audit of care planning in place.

Recommendation 19: Health Boards should ensure that where Infection Control Nurses provide instructions on the management of patients those instructions are recorded in the patient notes and are included in care planning for the patient.

Recommendation 20: Health Boards should ensure that where a patient has, or is suspected of having, *C. difficile* diarrhoea a proper record of the patient's stools is kept. Health Boards should ensure that there is an appropriate form of charting of stools available to enable nursing staff to provide the date, time, size and nature of the stool. Stool charts should be continued after a patient has become asymptomatic of diarrhoea in order to reduce the risk of cross infection. Health Boards should ensure that all nursing staff are properly trained in the completion of these charts, and that the nurse in charge of the ward audits compliance.

Recommendation 21: Health Boards should ensure that a member of nursing staff is available to deal with questions from relatives during visiting periods.

Recommendation 22: Health Boards should ensure that any discussion between a member of nursing staff and a relative about a patient which is relevant to the patient's continuing care is recorded in the patient's notes to ensure that those caring for the patient are aware of the information given.

Recommendation 23: Health Boards should ensure that a nurse appointed as Tissue Viability Nurse (TVN) is appropriately trained and possesses, or is working towards, a recognised specialist post-registration qualification. Health Boards should ensure that a trainee TVN is supervised by a qualified TVN.

Recommendation 24: Health Boards should ensure that where a TVN is involved in caring for a patient there is a clear record in the patient notes and care plan of the instructions given for management of the patient.

Recommendation 25: Health Boards should ensure that every patient is assessed for risk of pressure damage on admission to hospital using a recognised tool such as the Waterlow Score in accordance with best practice guidance. Where patients are identified as at risk they must be reassessed at the frequency identified by the risk scoring system employed. Compliance should be monitored by a system of audit.

Recommendation 26: Health Boards should ensure that where a patient has a wound or pressure damage there is clear documentation of the nature of the wound or damage in accordance with best practice guidance, including the cause, grade, size and colour of the wound or damage. The pressure damage or wound should be reassessed regularly according to the patient's condition. Compliance should be monitored by a system of audit.

Recommendation 27: Health Boards should ensure that where a patient requires positional changes nursing staff clearly record this on a turning chart or equivalent. Compliance should be monitored by a system of audit.

Recommendation 28: Health Boards should ensure that all patients have their nutritional status screened on admission to a ward using a recognised nutritional screening tool. Where nutritional problems are identified further assessment should be undertaken to determine an individual care plan. Appropriate and timely referrals should be made to dieticians for patients identified as being in need of specialist nutritional support.

Recommendation 29: Health Boards should ensure that there is appropriate equipment in each ward to weigh all patients. Patients should be weighed on admission and at least weekly thereafter and weights recorded. Faulty equipment should be repaired or replaced timeously and a contingency plan should be in place in the event of delays.

Recommendation 30: Health Boards should ensure that where patients require fluid monitoring as part of their clinical care, nursing staff complete fluid balance charts as accurately as possible and sign them off at the end of each 24-hour period.

Recommendation 31: Health Boards should ensure that the staffing and skills mix is appropriate for each ward, and that it is reviewed in response to increases in the level of activity/patient acuity and dependency in the ward. Where the clinical profile of a group or ward of patients changes (due to acuity and/or dependency), an agreed review framework and process should be in place to ensure that the appropriate skills base and resource requirements are easily provided.

Recommendation 32: Health Boards should ensure that there is a straightforward and timely escalation process for nurses to report concerns about the staffing numbers/skill mix.

Recommendation 33: Health Boards should ensure that where a complaint is made about nursing practice on a ward this complaint is investigated by an independent senior member of Nursing Management.

Chapter 13

Antibiotic prescribing

Introduction

This Chapter explores the background to the recognition of the importance of prudent antibiotic prescribing and whether action could have been taken before June 2008 to address the prolonged, excessive and inappropriate prescription of certain antibiotics at the VOLH. The Chapter also considers the timescales involved in the creation of an Antimicrobial Management Team (AMT) by NHS Greater Glasgow and Clyde (NHSGGC) and the impact of the VOLH experience on antibiotic prescribing after June 2008.

13.1 Antimicrobial policy and prudent prescribing

A starting point

An important milestone in addressing antibiotic policy in the UK is the House of Lords Select Committee on Science and Technology Report dated 17 March 1998, “Resistance to Antibiotics and other Antimicrobial Agents”.¹ Another important milestone is the report produced by the Standing Medical Advisory Committee of the Department of Health for England and Wales, “The Path of Least Resistance”, also in 1998.² In the latter report the following observations are made about *C. difficile* and about antibiotic prescribing practice in general:

“*Clostridium difficile* can become established in the gut only when the normal bacterial flora has been disrupted by antibiotics”.³

“Taking antibiotics unnecessarily does you no good and damages them for anyone else”.⁴

“It makes sense to cherish your bacterial flora”.⁵

1 [INQ04790001](#)
2 [INQ05080001](#)
3 [INQ05080102](#)
4 [INQ05080100](#)
5 [INQ05080100](#)

The position in Scotland in 1999

In a letter⁶ dated 21 May 1999 addressed to Health Board General Managers and Chief Executives of NHS Trusts, among others, the Scottish Office Department of Health set out the action to be taken by the NHS in Scotland in response to the House of Lords report. The goals for NHSScotland included:

- A reduction in ill-health from communicable disease, including hospital acquired infection; and
- A contribution to the control of antimicrobial resistance

Annex 1 to the letter described the strategy as one that needed to address three key elements:⁷

- Infection control;
- Prudent antimicrobial use; and
- Surveillance of resistant organisms and antimicrobial usage

One of the particular steps highlighted as part of that strategy was the reduction of “inappropriate antimicrobial prescribing”.⁸

The Antimicrobial Resistance Strategy and Scottish Action Plan 2002

After devolution, the then Scottish Executive produced a report in 2002 with the title “Antimicrobial Resistance Strategy and Scottish Action Plan”⁹ (the 2002 Action Plan). The 2002 Action Plan took account of the sources mentioned earlier as well as recommendations from the World Health Organization (WHO) and the European Conference on “The Microbial Threat”.¹⁰ It was a three-year plan¹¹ and its aims included:

- The reduction of unnecessary and inappropriate use of antimicrobials; and
- The monitoring and provision of data on resistant organisms, associated morbidity and antimicrobial usage¹²

6 [INQ04540001](#)
7 [INQ04540003](#)
8 [INQ04540004](#)
9 [GOV00360072](#)
10 [GOV00360077](#)
11 [GOV00360077](#)
12 [TRA01100113](#)

The strategy set out in the 2002 Action Plan comprised three elements:

- Prudent antimicrobial use;
- Surveillance, including surveillance of antimicrobial usage; and
- Infection control to reduce the spread of infection¹³

This was in effect a repetition of the strategy set out in the Scottish Office Department of Health letter of 21 May 1999.

As part of that strategy the Scottish Medicines Consortium was established to co-ordinate across Scotland work done to evaluate new medicines, new formulations and new indications for existing medicines, including antimicrobial agents, in terms of clinical and cost effectiveness.¹⁴

The guide to Antimicrobial Prescribing Policy and Practice in Scotland – 2005

A guide to the prudent use of antibiotics, “Antimicrobial Prescribing Policy and Practice (APP&P) in Scotland”¹⁵ (the 2005 guide), was produced for NHSScotland by the Scottish Medicines Consortium in August 2005. It highlighted a number of challenges faced in antimicrobial prescribing, including:

- Evidence of wide variation in antimicrobial prescribing and practice;
- Concern about insufficient liaison between microbiologists, clinicians, and pharmacists; and

- Concern about inadequate supervision of prescribing and the inappropriate choice, duration of treatment and records of administration by junior doctors.¹⁶

By letter dated 5 September 2005¹⁷ the then Scottish Executive made Boards aware of the availability of the 2005 guide, describing the recommendations contained in it as “a key clinical governance issue and a major public health imperative”.¹⁸

Key areas

The 2005 guide identified several key areas of practice and made a number of recommendations. One of those recommendations was that a multi-disciplinary Antimicrobial Management Team (AMT) should be formed by each Health Board¹⁹ to be responsible for implementing antimicrobial policy and practice. One of the key areas identified was the importance of auditing as a tool in maintaining the safe and cost-effective use of antibiotics,²⁰ and the AMT was to play a critical role in the evaluation of appropriate auditing systems. Ward-based antimicrobial pharmacists were to take the lead in co-ordinating the implementation and audit of antimicrobial practice and to report to the Chief Pharmacist.²¹ Figure 13.1 sets out the proposed structure.²²

13 [GOV00360079](#)

14 [GOV00360090](#)

15 [GOV00360003](#)

16 [GOV00360009](#)

17 [GOV00360001](#)

18 [GOV00360002](#)

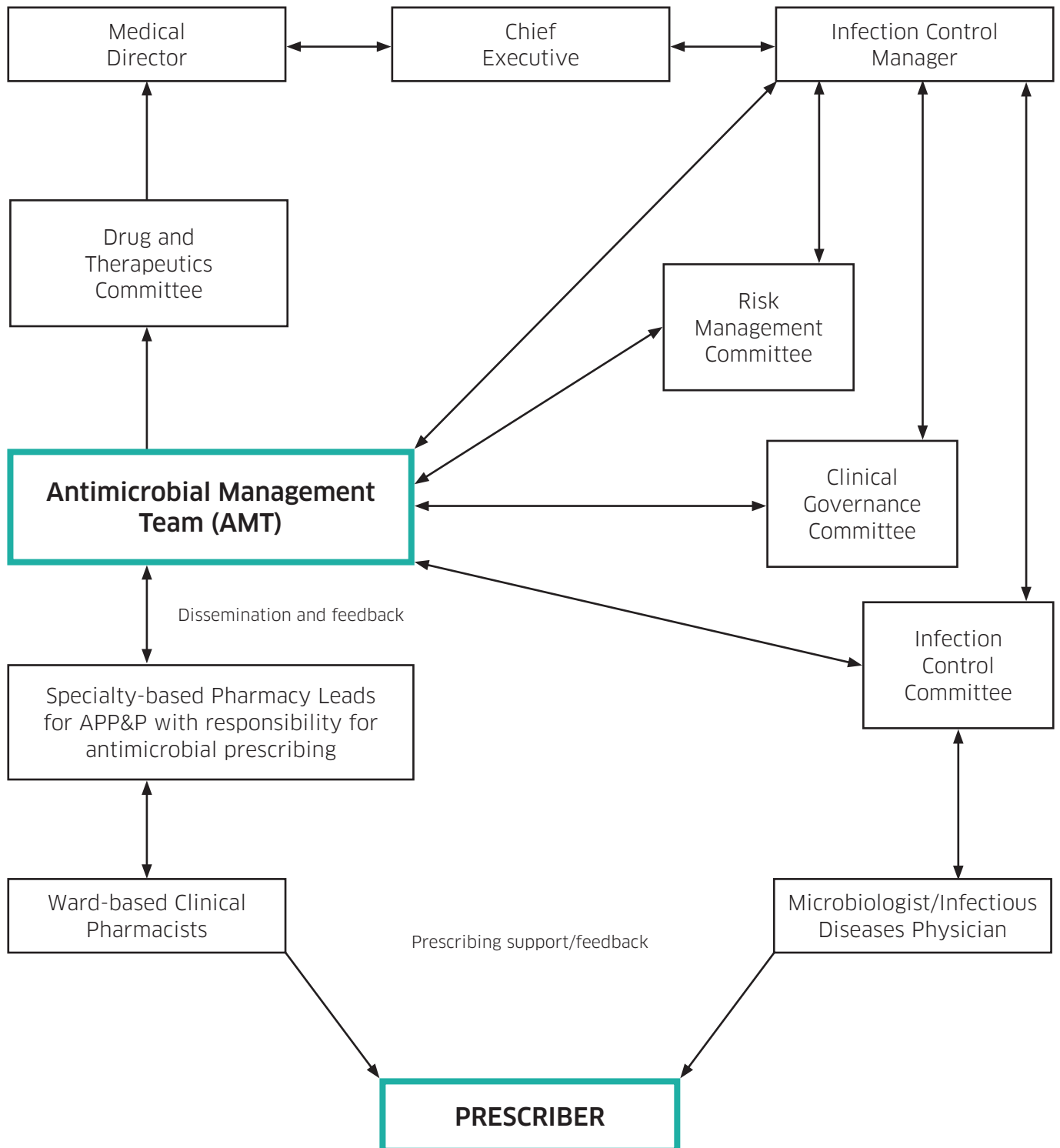
19 [GOV00360012](#)

20 [GOV00360017](#)

21 [GOV00360022](#)

22 [GOV00360022](#)

Figure 13.1 Model antimicrobial prescribing practice pathway in acute hospitals



Another key area of practice identified was to:

“Define the minimum dataset requirements and standard procedures for collecting information related to antimicrobial consumption and quality of prescribing at an organisational level and/or ward specific level”.²³

The 2005 guide noted that monitoring of hospital consumption of antibiotics was one of the key recommendations of the 1998 House of Lords report.²⁴ It also noted that six years on from that report the UK had no routine data on antimicrobial use in hospitals, in contrast to 23 out of 31 other European countries,²⁵ and recommended that all acute hospitals should analyse and report antimicrobial use. It also recommended that a national agency should collate and report antimicrobial utilisation trends across Scotland,²⁶ and the National Medicines Utilisation Unit (NMUU) was set up in 2005 for this purpose.

A letter from the Scottish Executive Health Department to Chief Executives of NHS Boards dated 5 September 2005 introduced the 2005 guide and described the intention behind it as follows:

“Antimicrobial Prescribing Policy and Practice in Scotland sets out recommendations for good practice relating to health care structures and lines of responsibility, data requirements for monitoring resistance and antimicrobial use at local and national levels, issues relating to audit and performance management, and requirements for education and training. It also provides guidance on the development and monitoring of local antimicrobial prescribing policies and formularies”.²⁷

13.2 The 2008 Action Plan

Background

In December 2005 the Healthcare Associated Infection (HAI) Task Force decided to reconvene a Steering Group²⁸ to update the 2002 Antimicrobial Resistance Strategy and Scottish Action Plan. The intention was to invite comments from all interested parties with a view to producing a consultation document. The remit²⁹ of that group included the following areas:

- Assessing the progress of the implementation of the 2002 Action Plan, and producing a successor document;
- Assessing the progress of the 2005 guide and identifying outstanding actions required to achieve a number of goals including the promotion of prudent antimicrobial prescribing; and
- The development of an updated Antimicrobial Resistance Strategy and Action Plan for delivery to NHSScotland by April 2007³⁰

The first meeting of the Steering Group took place on 30 January 2006,³¹ and at that meeting the impact of the 2002 Action Plan was described in the following way:

“Problems encountered in the implementation of ARSSAP (Antimicrobial Resistance Strategy and Scottish Action Plan) 2002, include the fact that it was launched without specific responsibilities or overseeing group being identified; lack of progress on prescribing information systems for secondary care; no single focus for driving the agenda forward; and rapidly growing antimicrobial resistant threats since 2002”.³²

In his evidence, Dr Kevin Woods, Director General for Health, Scottish Government, agreed that the 2002 Action Plan “had not really produced much by way of results”.³³

23 [GOV00360016](#)

24 [GOV00360016](#)

25 [GOV00360016](#)

26 [GOV00360016](#)

27 [GOV00360001](#)

28 [GOV00360126](#)

29 [GOV00360049](#)

30 [GOV00360165](#)

31 [GOV00360119](#)

32 [GOV00360120](#)

33 [TRA00970089](#)

The launch of the 2008 Action Plan

The Steering Group completed its work in November 2006 and produced “The Scottish Management of Antimicrobial Resistance Action Plan” (ScotMARAP), which was submitted to the then Scottish Executive.³⁴ The peer review draft of that document was circulated by Mr Paul Martin, then Chief Nursing Officer, Scottish Government, by letter dated 7 December 2007.³⁵ Included on the circulation list were the area drug and therapeutic committees and Infection Control Managers.³⁶ In the peer review draft³⁷ the following observations were made:

“It is known that a significant proportion of current antimicrobial usage in hospitals is not ‘prudent’; this is mainly an issue of excessive use (use of an antimicrobial where not necessary or prolonged courses), or inappropriate choice of (or incorrect dosing of) antimicrobial agent for treatment or prevention of the relevant infection”.³⁸

In March 2008 the then Cabinet Secretary for Health and Wellbeing launched the “Scottish Management of Antimicrobial Resistance Action Plan”³⁹ (the 2008 Action Plan), which was to replace the 2002 Action Plan. The description on practice just quoted from the peer review draft was repeated in the final version.⁴⁰

The 2008 Action Plan and prudent prescribing

The 2008 Action Plan again emphasised the importance of prudent prescribing and proposed that all Boards should immediately set up Antimicrobial Management Teams (AMTs)⁴¹ where these were not already in place. It noted that NHS Boards were “moving towards implementing some of the major recommendations” contained in the 2005 guide and that the Steering Group had observed that progress in this area had been “slow and patchy”.⁴²

The original Task Force target of delivery of an updated Antimicrobial Resistance Strategy and Action Plan to NHSScotland by April 2007 was not met.

The 2008 Action Plan echoed the theme that had emerged in Scotland by at least 1999,⁴³ and had persisted over the years,⁴⁴ that it was known that antibiotic prescribing was not being carried out in a “prudent”⁴⁵ way. It also recorded that, although a key role for the NMUU since its establishment in 2005 had been to develop systems to collect and collate information on antimicrobial prescribing, particularly within hospitals:⁴⁶

“The UK lags behind much of Europe in being able to access these hospital data, and in Scotland this represents the major outstanding task within (the 2002 Action Plan)”.⁴⁷

The expectation of the 2008 Action Plan was that the NMUU would work closely with the Scottish Medicines Consortium and Health Protection Scotland to carry out a number of specific tasks, including reporting the usage of “agreed key antimicrobials in target groups across NHS Boards”.⁴⁸

One of the initiatives in the 2008 Action Plan was the establishment of the Scottish Antimicrobial Prescribing Group (SAPG),⁴⁹ which was set up as a national clinical multi-disciplinary forum with representation from Boards. It was formed in March 2008,⁵⁰ and its primary function was to co-ordinate and deliver a national framework for antimicrobial stewardship in Scotland so as to improve the quality of antimicrobial prescribing and management.

34 [GOV00360166](#)

35 [GOV00360168](#)

36 [GOV00360169](#)

37 [GOV00360170](#)

38 [GOV00360175](#)

39 [GOV00360040](#)

40 [GOV00360045](#)

41 [GOV00360061](#)

42 [GOV00360049](#)

43 [INQ04540001](#)

44 [GOV00360079](#); [GOV00360009](#)

45 [GOV00360045](#)

46 [GOV00360058](#)

47 [GOV00360058](#)

48 [GOV00360058](#)

49 [GOV00360053](#)

50 [TRA01100113](#)

13.3 Significant failures in implementation and monitoring

The Scottish Government letter of 8 July 2008

After the problem with *C. difficile* infection (CDI) at the VOLH came to light, the Scottish Government wrote to NHS Board Chief Executives and others on 8 July 2008 highlighting the following points among others:

“One key intervention in managing both problems (MRSA and *C. difficile*) is to robustly address the issue of prudent prescribing of antimicrobials within NHS Scotland, and this Letter seeks the immediate implementation of our national policies in this area”.⁵¹

“SAPG has advised that not every Board has an established Antimicrobial Management Team (AMT) as set out in APP&P (Antimicrobial Prescribing Policy and Practice) and ScotMARAP (Scottish Management of Antimicrobial Resistance Action Plan), and some of those which have been set up do not cover primary care prescribing. As an immediate intervention to reduce the risks from *C. difficile*, we accept SAPG’s recommendation that all Boards should immediately establish an AMT which covers primary and secondary care prescribing activities”.⁵²

Failure of the message on prudent prescribing

The message on the importance of prudent prescribing had certainly not reached the VOLH prior to June 2008, despite its repetition over the preceding years. Dr Seaton explained the position in the following way:

“My take on the situation was that what had happened or was happening, in the Vale of Leven, was applicable to all our hospitals in Greater Glasgow and Clyde and, indeed, almost certainly all our hospitals in Scotland. That was the big important message to me. So this was the catalyst for me, for change of not just guidance for that specific hospital, but for all our hospitals and board”.⁵³

It is not within the Inquiry’s remit to dwell on what was happening in other hospitals across Scotland. Dr Seaton was, however, in a position to speak about the general position with some authority.

As Dr Seaton explained, a culture had developed in which clinicians had come “under the spell of broad spectrum antibiotics”⁵⁴ and were using them in situations where broad spectrum antibiotics were not any more effective against those infections that were sensitive to narrow spectrum antibiotics. The VOLH experience became a catalyst for change, but change in antimicrobial practices should have happened long before it did. As explored in Chapter 18, the reports into the CDI outbreaks at the Stoke Mandeville and Maidstone and Tunbridge Wells Hospitals published in 2006 and 2007 should in any event have prompted an examination of antibiotic prescribing practice. As documented elsewhere in this Report in relation to other aspects of infection prevention and control, a pattern had developed of policy and/or guidance being issued on behalf of the Scottish Government and of significant delay in its implementation.

It may be that financial constraints played some part in such delays. There is no reason to doubt either the assertion of Dr Brian Cowan, Board Medical Director and Medical Director of the Acute Division, that new guidance provided by NHSScotland on infection prevention and control after June 2008 “invariably”⁵⁵ came with supportive finance, or his suggestion that that was something that did not “tend to happen before”.⁵⁶ An example of that approach is the instruction in the Scottish Government’s letter of 8 January 2008 to Boards which did not have an AMT in place to establish an AMT “immediately”.⁵⁷ This instruction was accompanied by a pledge of supportive funding.⁵⁸

The recognition of the need for prudent antibiotic prescribing and the implementation

51 [GOV00360037](#)

52 [GOV00360038](#)

53 [TRA01150114](#)

54 [TRA01150117](#)

55 [TRA01220146](#)

56 [TRA01220146](#)

57 [GOV00360038](#)

58 [GOV00360038](#)

of that policy produced an ineffective response by the NHSGGC Board over a period of several years. The failure to implement the prudent prescribing message should have been identified and remedied at an earlier stage by the Scottish Executive and later the Scottish Government. These failures are made more acute by the inadequate response to the warnings on imprudent antibiotic prescribing contained in the reports of the outbreaks at Stoke Mandeville (2006) and Maidstone and Tunbridge Wells (2007) Hospitals, discussed more fully in Chapter 18.

13.4 The Antimicrobial Management Team

The AMT in Greater Glasgow and Clyde

As already mentioned, the recommendation to set up AMTs was contained in the 2005 guide⁵⁹ published in September of that year.⁶⁰ Dr Seaton had been a member of the working group that drafted the 2005 guide as had Mr Scott Bryson, a pharmaceutical advisor to Greater Glasgow Health Board.⁶¹ Thereafter Dr Seaton formed a short-life working group⁶² together with Dr Bill Anderson, then Infection Control Manager for GGHB, Mr Bryson and Ms Ysobel Gourlay, a Pharmacist,⁶³ to develop a business case for the funding of their AMT.

In January 2006 a proposal for AMT funding was submitted to the GGHB Prescribing Management Group. In June 2006 the final business case for the establishment of the AMT was submitted to Mr Robert Calderwood, then Chief Operating Officer, Acute Services and currently Chief Executive, NHSGGC.⁶⁴ The conclusion of the business case emphasised that the creation of an AMT was “critical to prudent use of antimicrobials within NHS hospitals”.⁶⁵

Mr Calderwood confirmed that he had received a business case for the AMT in late June or early July 2006.⁶⁶ This was

considered in September 2006 by the Acute Strategic Management Group,⁶⁷ which concluded that the issue was too important to defer until the next financial year even although the budget for 2006 to 2007 had already been set, and the decision was taken to release funds so that the team could be established. Approval was given in about November 2006,⁶⁸ and interviews for the AMT posts took place in around April 2007.⁶⁹ By June 2007 the members of the core team, including Dr Seaton, were in place, although the team of antimicrobial pharmacists necessary for the development of the programme⁷⁰ was not in place.

The AMT timescale – no undue delay

The NHSGGC AMT was not established until June 2007, but the timetable set out previously shows that there was no undue delay on the part of the NHSGGC Board in its creation. That was largely due to Dr Seaton’s diligence in following through the recommendations of the working group, of which he had been a member, and to the Board’s provision of the necessary support.

Dr Seaton thought that NHSGGC was ahead of other Health Boards in the appointment of its AMT.⁷¹ In fact Dr Martin Connor, a microbiology expert commissioned by the Inquiry, gave evidence that NHS Dumfries and Galloway had established its AMT earlier, with a first minuted meeting on 18 April 2006.⁷² Dr Seaton also pointed out that it was only after the VOLH problem became apparent that the Scottish Government instructed categorically that every Board had to have an AMT, and that central funding was not available until that point.⁷³

The priority for the AMT

From June or July 2007 the priority for the NHSGGC AMT was to unify antibiotic prescribing guidance across the Health Board.⁷⁴ This led to production of the

59 [GOV00360003](#)

60 [GOV00360001](#)

61 [GOV00360035](#)

62 [INQ04070001](#)

63 [WTS01620001](#)

64 [GGC15970044](#); [TRA01150094](#)

65 [GGC06070009](#)

66 [TRA01240102](#)

67 [TRA01240103](#)

68 [TRA01240103](#)

69 [INQ04070002](#)

70 [TRA01150098-99](#)

71 [TRA01150148](#)

72 [TRA00630091](#)

73 [TRA01150148](#)

74 [TRA01150099](#)

“Infection Management Guideline: Empirical Antibiotic Therapy”.⁷⁵ Those guidelines were approved in December 2007⁷⁶ and available in the VOLH in February 2008,⁷⁷ and were designed to improve the consistency of antimicrobial prescribing. There was, however, no antimicrobial pharmacist employed to promote, monitor and encourage adherence to the guidelines,⁷⁸ and only one of the senior doctors at the VOLH seemed to be using them.

The position after June 2008

Following the discovery of the CDI problem in the VOLH an Outbreak Control Team was set up and met for the first time on 10 June 2008.⁷⁹ Later that day Dr Syed Ahmed, Consultant in Public Health Medicine and Clinical Consultant in the Public Health Protection Unit, NHSGGC, who had chaired that first meeting, contacted Dr Seaton to invite input from the AMT in addressing the issues faced at the VOLH. The AMT was asked to undertake three tasks:

- Review of prescribing practices in the VOLH in order to ascertain the volume of prescribing;
- Assessment of whether treatment of *C. difficile* infected patients could be improved; and
- Rapid review of guidance and the introduction of more restrictive prescribing guidelines⁸⁰

Revised guidelines

By 19 June 2008 the prescribing guidelines had been revised and new guidelines put into immediate effect. Among the main modifications to existing guidelines were the following:

- Emphasis given to considering whether antimicrobial therapy was required;
- Prescribers had to review the need for antimicrobial therapy on a daily basis;
- Cephalosporins were to be avoided except on the advice of a microbiologist;
- Empirical co-amoxiclav was to be restricted to severe community acquired pneumonia, infected human or animal bites, peri-anal infections and spontaneous bacterial peritonitis;
- Empirical oral ciprofloxacin was to be restricted for use in pyelonephritis; and
- Clindamycin was to be restricted to severe Group A streptococcal infections, necrotising fasciitis and severe soft tissue infections in parenteral drug users.⁸¹

The AMT’s reaction was swift and effective. Figure 13.2⁸² illustrates the dramatic impact on the number of CDI cases in the Board area even in the relatively short term. This resulted from, at least in part, the introduction of the new antibiotic policy.

75 [GGC22180001](#)

76 [TRA01150099](#)

77 [TRA01150100](#)

78 [TRA01150135](#)

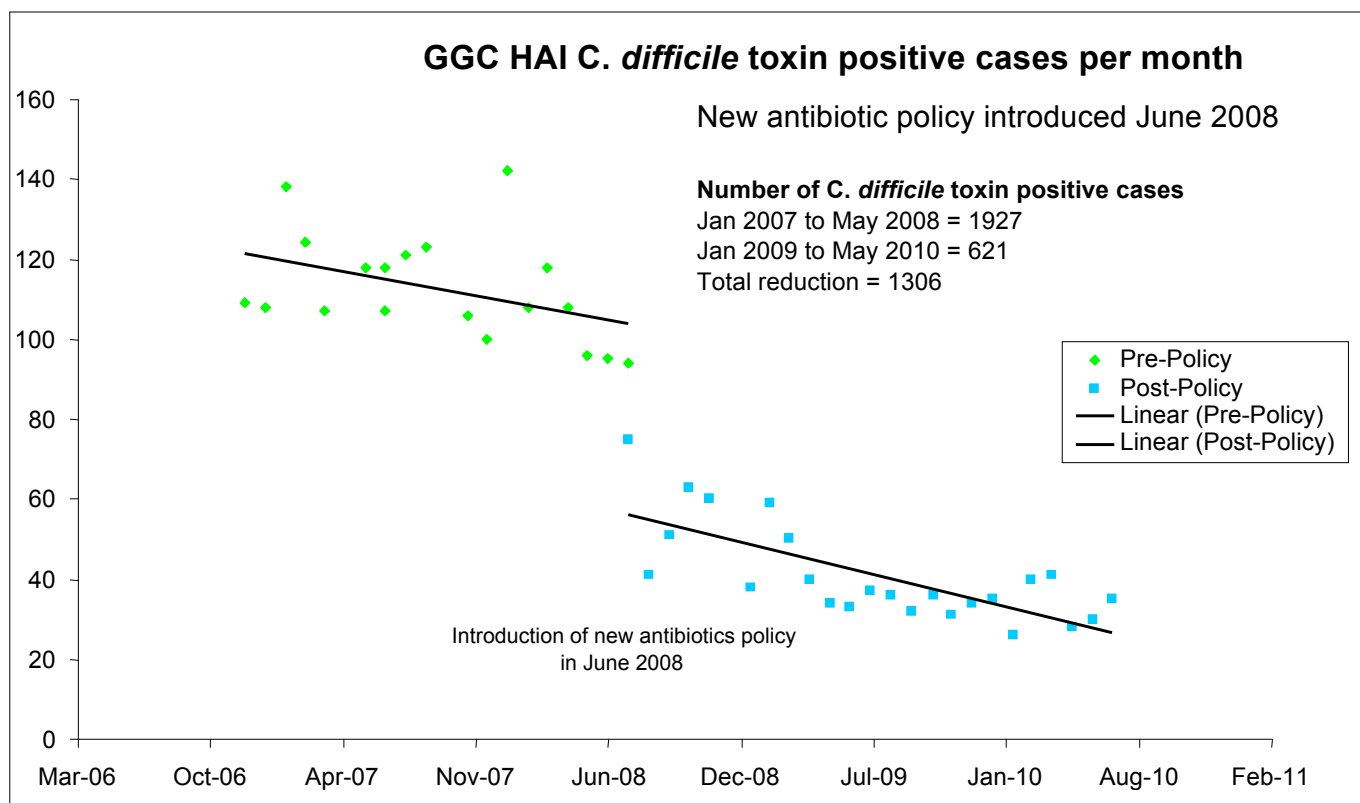
79 [GGC11140001](#)

80 [TRA01150112-113](#)

81 [GGC13550002-03](#)

82 [INQ00630001](#)

Figure 13.2 Greater Glasgow and Clyde Health Board *C. difficile* toxin positive cases



Largely due to the impetus provided by Dr Seaton, the recommendation for the creation of an AMT made in the 2005 guide was implemented by the Board in a reasonably expeditious manner. The fact that the AMT was not in place until June 2007 was due to the process involved, including finding the financial resources necessary for its creation. Because auditing was linked to the role to be played by the AMT and the appointment of antimicrobial pharmacists, there was no auditing of antibiotic prescribing in the VOLH in the period 1 January 2007 to 1 June 2008. Nevertheless NHSGGC was clearly ahead of many other Health Boards in Scotland. Even in July 2008 the Scottish Government had to instruct Health Boards to establish AMTs “immediately”.⁸⁵ That instruction itself highlights the mismatch between expectation and implementation, a mismatch that must be remedied.

13.6 Recommendations

Recommendation 34: Health Boards should ensure that changes in policy and/or guidance on antimicrobial practice issued by or on behalf of Scottish Government are implemented without delay.

Recommendation 35: Scottish Government should monitor the implementation of policies and/or guidance on antibiotic prescribing issued in connection with healthcare associated infection and seek assurance within specified time limits that implementation has taken place.

Chapter 14

Medical care

Introduction

This Chapter of the Report examines the evidence provided to the Inquiry by medical staff at the VOLH, with particular emphasis on the focus period, 1 December 2007 to 1 June 2008. It also examines the medical expert evidence on the quality of care given by the medical staff at the VOLH to the patients suffering from *C. difficile* infection (CDI), including antibiotic prescribing and aspects of the testing of stool specimens relevant to medical care.

14.1 Inquiry medical experts

Nursing experts

The Inquiry commissioned independent medical experts to provide a professional opinion on the quality of medical care given to patients who suffered from CDI at the VOLH in the focus period, including the use of antibiotics.

The Inquiry's medical experts can be divided into two broad groups: physicians and medical microbiologists.

The Inquiry Team met individually with each of the medical experts. In addition there were meetings with groups of experts. The discussions at these meetings included the identification of key themes and conclusions.

The approach adopted with the nursing experts to the manner in which individual cases were distributed was also followed with the medical experts. The cases were distributed so that each expert could review patient records from a number of different wards rather than focusing on one particular ward.

The physicians are detailed in Table 14.1 as are the number of cases each expert examined.

Table 14.1 Physicians commissioned by the Inquiry and their reports by ward

Name	Ward 3	Ward 4/HDU	Ward 5	Ward 6	Ward F	Ward 14	Ward 15	MAU	Fruin	Total
Mary Harrington	1	1		2		3	2	1		10
Mike Jones	4		1	5	1		1	1		13
James Reid		1	1	4	3	2	1			12
Ray Sheridan	2			3	2	3	1			11
Henry Woodford	1	1	2	4	2	2	3		2	17
Total	8	3	4	18	8	10	8	2	2	63

Table 14.2 Microbiologists commissioned by the Inquiry and their reports by ward

Name	Ward 3	Ward 4/HDU	Ward 5	Ward 6	Ward F	Ward 14	Ward 15	MAU	Fruin	Total
Martin Connor	1		1	4	4	3	4	1		18
Kevin Kerr	2	1	1	3		1	1			9
Alan MacDonald	2		1	2	1					6
Louise Teare	2			3		1	3			9
Rod Warren	1	2	1	4	3	3	2	1	2	19
Tim Wyatt				2		2				4
Total	8	3	4	18	8	10	10	2	2	65

Dr Jones was based in Scotland. The other physicians were based in England. Table 14.2 lists the microbiologists and the number of cases examined by each expert. Dr Wyatt worked in Northern Ireland. Doctors MacDonald and Connor were in practice in Scotland and the other microbiologists were based in England.

The difference in the total numbers in Tables 14.1 and 14.2 arises because there were insufficient patient records for the physicians to carry out an assessment of the medical care for two patients in the focus group. The patient records did allow the microbiologists to arrive at some conclusions on why and where the CDI was contracted.

Instruction given to medical experts

The medical experts were given the full patient records and Infection Control Cards of the patients allocated to them. A template¹ was provided identifying areas upon which the Inquiry wished the experts to focus. Again, as with the nursing experts, this was to ensure consistency of focus and review among the experts and to ensure compliance with the Terms of Reference of the Inquiry.

The experts were not given access to the statements obtained from medical or nursing staff. Nor were they present during the evidence of those staff. The expert opinion given was based solely on the patient records.

The Inquiry also asked the medical experts not to discuss their opinions with each other during the preparation of their reports.

14.2 Record keeping

General Medical Council standards

The medical experts were asked to use the professional standards issued by the General Medical Council (GMC) as a benchmark for the standard of care expected from medical staff. The GMC published “Guidance for Doctors” effective from 13 November 2006,² and for the purpose of this Chapter the following instructions contained in that guidance are worthy of note:

1 [INQ05400001](#)
2 [INQ00270003](#)

“2 Good clinical care must include:

- (a) adequately assessing the patient’s conditions, taking account of the history (including the symptoms, and psychological and social factors), the patient’s views, and where necessary examining the patient”.³

“3 In providing care you must:

- (f) keep clear, accurate and legible records, reporting the relevant clinical findings, the decisions made, the information given to patients, and any drugs prescribed or other investigation or treatment”.⁴

“Maintaining and improving your performance

- 17 You must make sure that all staff for whom you are responsible, including locums and students, are properly supervised”.⁵

Use of patient records to audit patient care

As already mentioned, the medical experts based their views on an analysis of the patient records, the approach that was also followed by the nursing experts when analysing nursing care. The observation made in Chapter 12 that retrospective audit of patient records against pre-determined criteria is a recognised and accepted approach in the analysis of adverse events⁶ applies equally to this method of assessing medical care.

The difficulties experienced in the use of patient records have been fully explained in Chapter 12. Suffice to say at this point that the standard of record keeping and the fact that there were missing records and pages out of sequence made analysis of the records particularly difficult. All these factors mean that caution must be exercised when seeking to draw conclusions from the medical records alone. The medical experts did recognise the need for caution when only the patient records were being used to draw conclusions.⁷ The issue was explained by Professor Kerr in the following way:

3 [INQ00270009](#)
4 [INQ00270010](#)
5 [INQ00270016](#)
6 [INQ05150001](#); [INQ05140001](#)
7 [TRA00530197](#); [TRA00570116](#)

“The ability to assess the quality of care provided from the patient records does rely on the accuracy and completeness of the record, although accurate and complete medical notes are certainly a part of good quality care as defined in “Duties of a Doctor” (GMC 2006).⁸

Overall quality of record keeping

There was unanimity among the Inquiry expert physicians, however, that although there were clear examples of very good documentation the overall quality of the documentation was poor.⁹ Although the recording of a patient’s condition and assessment made by the consultants was generally adequate, the recording by junior doctors was poor.

The message for doctors who want to show that care of the necessary quality has been given is to make an accurate and complete record of that care. The interrelationship between care of the necessary quality and record keeping cannot be overemphasised. Good record keeping is an integral aspect of good care.

14.3 Medical staffing

Background

The decline of clinical services at the VOLH in the years prior to June 2008 has been considered in Chapter 8. Over that period different strategies were considered, including the Lomond Integrated Care Model, in an attempt to retain a level of unscheduled medical admissions at the VOLH.

Despite such efforts, years of uncertainty had a significant impact upon the recruitment of medical staff.¹⁰ Even as early as 2002, when Dr Stephanie Dancer, the resident microbiologist, left the VOLH,¹¹ her post was advertised but it was not filled.¹² Instead the work was undertaken by locums until the stopgap arrangement set out in Chapter 15 was devised in 2006. The uncertainty over the future of the VOLH became even more acute after the dissolution of NHS Argyll and Clyde on 1 April 2006.

Grades of doctor

In 2005 a programme entitled “Modernising Medical Careers” was introduced in the United Kingdom. The programme replaced the traditional grades of doctor below the level of consultant, and was a major reform which had a significant impact on the manner in which doctors are trained. Table 14.3 provides a summary of the changes.

8 [TRA00530197](#)

9 EXP01840001; EXP01850005; EXP01850014; EXP02050007; EXP02050007; EXP0204001-2; EXP02170005-06; EXP021700095

10 [INQ03390001](#)

11 [TRA00850003](#)

12 [TRA00850015](#)

Table 14.3 NHS medical career grades

	Old system Pre-2007		New system (Modernising Medical Careers)	
Year 1	Pre-registration House Officer (PRHO) (Junior House Officer) - one year		Foundation House Officer - two years (FY1 then FY2)	
Year 2	Senior House Officer (SHO)		Specialty Registrar (StR) in a hospital speciality: six years	
Year 3	A minimum of two years, although often more			
Year 4	Specialist registrar - four to six years	GP registrar - one year	Specialty Registrar (GPST) in general practice: three years	
Year 5	General practitioner (Total time in training: four years)		General practitioner (Total time in training: five years)	
Years 6-8				
Year 9	Consultant (Total time in training: minimum seven to nine years)		Consultant (Total time in training: minimum eight years)	

Doctors at the VOLH

Table 14.4 sets out the consultants employed at the VOLH who gave oral evidence. It also identifies their particular specialisms and the

wards/department they were mainly concerned with in the period 1 January 2007 to 1 June 2008.

Table 14.4 Consultants employed at the VOLH and their specialisms

Name	Position	Specialism	Wards
Dr Fiona Johnston	Consultant	Elderly medicine	14, 15, 3, 4, 6, MAU
Dr Hugh Carmichael	Consultant	Gastroenterology	3, 4, 6, MAU
Dr Douglas McCrudden	Consultant	Diabetes and Endocrinology	3, 4, 6
Dr Musa Al-Shamma	Consultant	Respiratory medicine	3, 4, 6
Dr Patricia Clarke	Consultant	Haematology	All wards (including the laboratory)

In addition to the consultants listed in Table 14.4 Dr Lance Forbat was employed at the VOLH up to December 2007 as a locum consultant specialising in cardiology.¹³ Between 1 January 2007 and 1 June 2008 Dr Javed Akhter was employed at the VOLH as a locum consultant specialising in care of

the elderly,¹⁴ and was also responsible for stroke patients.¹⁵ During the focus period Dr Akhter was primarily responsible for wards 14 and F (the stroke ward) but could also be responsible for patients in the acute wards.¹⁶

13 [WTS00950001](#); [GGC21720003](#)

14 [TRA00730054](#); [TRA00730056-57](#); INQ03110006

15 [TRA00730057](#)

16 [TRA00730057](#)

Role of General Practitioners

Between 1 January 2007 and June 2008 Dr Gordon Herd, a GP, had a commitment to ward 15 at the VOLH of three to three and a half hours per day, Monday to Friday.¹⁷ He looked upon Dr Johnston as his supervisor.¹⁸ Each Tuesday his partner in the GP practice, Dr Mark Garthwaite, would do a session in the morning.¹⁹ Dr Herd gave oral evidence to the Inquiry.

Dr Afaq Khan

Dr Afaq Khan was employed at the VOLH from 2 July 2007 to 14 March 2008 as a locum Senior House Officer (SHO).²⁰ He was based mainly in ward 14 assisting Dr Akhter, although from time to time he also assisted other consultants in other wards.²¹ Dr Khan also gave oral evidence.

Junior doctors

Table 14.5 sets out the junior doctor staffing numbers at the VOLH and their commitments.

Table 14.5 Junior medical staffing numbers at VOLH

Grade	Level of supervision	Number	Cover provided	Wards
FY1	Junior Supervised	6	Day and evening only	3, 4, 6, F, 14
FY2	Junior Supervised ²²	3	24 hour – provided GP on site	3, 4, 6, F, 14

Lack of middle grade medical staff

The Inquiry heard evidence from Drs Johnston, McCrudden, Al-Shamma, Carmichael and Akhter of how, as consultants, they managed their respective workloads and responsibilities. A major problem for them was the lack of middle grade clinicians, which meant that a significant burden was borne by the junior doctors at FY1 or FY2 level.

In explaining the difficulties in working at the VOLH with no middle grade doctors, Dr Johnston provided the following explanation:

“I found it extremely difficult. I’d been a consultant in three different places. When I was a consultant in a hospital in Glasgow, I had the full team. We had ITU, my own registrar, and ward rounds were well informed. When I was a consultant in the Vale, carrying out all these duties across the patch, when I was on my medical receiving day, for example, I would often have to go to MAU to see patients with the juniors because they were very junior”.²³

17 [TRA00820001](#); [TRA00820005-06](#)

18 [TRA00820008](#)

19 [TRA00820006](#)

20 [TRA00760003](#); [TRA00760005](#); INQ03070002

21 [TRA00760005](#)

22 [TRA00790131](#)

23 [TRA00770018](#)

Dr Johnston contrasted this with her post as a consultant physician in geriatric medicine at Inverclyde Royal Hospital (IRH) at the time she gave her evidence:

“... my current allocation for rehabilitation patients, it’s still about seven minutes per patient, but I currently have one or two junior doctors supporting the ward round, I have a clinical pharmacist who has already gone through all the medications right back to primary care, and I have a nurse who has all the information and various tools ready on the ward round. So it is a much more effective ward round than I was able to do at the Vale”.²⁴

Dr Al-Shamma was also in a position to contrast his position as a consultant physician at the IRH with his earlier position in the VOLH as follows:

“The problem with our on call, when we are on call, all patients admitted would be under our care. So if it was a cardiology problem or GI or liver disease, or whatever, endocrine, they would be under my care until they are discharged, and I would follow them up, unless they are really complicated and require special input, I would follow them up at my medical clinic...

Now, comparing that with the current situation in IRH, so when I am on call, I would be in the medical ... I would be based in the medical assessment unit and what I normally do, when the patient is admitted, I would manage him initially and then say ‘Divert to the’ ... so if it was a gastrointestinal problem, I would say ‘Divert this patient to the gastro ward’, if it was cardiology, ‘Send him to the cardiology ward’, respiratory ‘Send him to my ward’.

So I can get 30 admissions in IRH, but probably, of those, three or four will end up on the respiratory ward and the rest will be diverted to different wards, and my sort of input towards those patients would finish by that time”.²⁵

The position in the VOLH was that the on-call physician admitting an acute medical patient retained responsibility for that patient throughout the period of the patient’s stay irrespective of the ward in which the patient was located.²⁶ This included Drs Johnston and Akhter, whose specialism was care of the elderly. Dr Johnston also contrasted the position in the VOLH at the time with other hospitals in Scotland:

“I was a consultant geriatrician at the Vale of Leven; the difference being that in most hospitals in which geriatricians have some involvement in medical receiving, that involvement stops at 24 hours and the patients are handed on to the next medical unit. So this is, I think, a unique position in Scotland at the time”.²⁷

Reasons for lack of middle grade doctors

Dr Carmichael explained that the reason there were no middle grade doctors such as registrars in the VOLH was that there were fewer such doctors available. The departure of the different specialist services from the VOLH also meant that the VOLH was being regarded less and less as a potential source of senior education.²⁸ The reality was that the VOLH was not seen as an attractive hospital in which to gain appropriate experience. The difficulties with recruitment and the uncertainty over the future of the VOLH have already been mentioned.

Dr McCrudden explained that for a time there was a first year specialist registrar at the VOLH. This grading was removed by the Post-Graduate Deanery because the volume of activity doctors had to undertake on the rota at the VOLH prevented them from furthering their medical career in other ways, for example by carrying out research.²⁹ The Deanery is responsible for overseeing post-graduate medical training and ensuring that training is delivered to the standards set by the GMC.

24 [TRA00770056](#)

25 [TRA00710023-24](#)

26 [TRA00710024](#)

27 [TRA00770005](#)

28 [TRA00830004](#)

29 [TRA00790126](#)

Lack of continuity of care

Dr Al-Shamma explained that in a 24-hour period in the VOLH more than 20 patients could be admitted for whom he would remain responsible and who would be “scattered all over the hospital”.³⁰ At the time he gave evidence Dr Al-Shamma was working at the IRH and he drew a comparison between that post, where junior doctors worked as part of a team, and the position in the VOLH, where the junior doctors tended to be based on particular wards and would be involved in the ward rounds with any consultant who had patients in that ward.³¹ Dr Al-Shamma expressed concern that the set-up in the VOLH led to a lack of continuity of care.³² This problem was recognised and according to Dr Al-Shamma was raised many times at meetings, but because of the circumstances at the VOLH there was no way round it.³³ Dr Al-Shamma did agree that because of this lack of continuity and care, note-taking by doctors was of particular importance. The clinical position needed to be expressed as clearly as possible for the incoming doctor, who might not know the patient at all.³⁴

Dr Johnston said that from her perspective there was a layer of medical staffing missing “that would have ensured more continuity of care”.³⁵

Junior doctor rotation and availability

The problem in the VOLH with lack of continuity of care was compounded by the fact that junior doctors allocated to the VOLH were there for a period of only three or possibly four months’ rotation before moving on to another hospital. This was in contrast to the position in the IRH at the time that Dr Al-Shamma gave his evidence, where junior doctors would remain for six months and indeed sometimes a whole year.³⁶ It seems, however, that rotations of three to four months in Scottish hospitals may not in fact be unusual because, as Dr Brian Cowan, Board Medical Director, explained,

NHS National Education Scotland imposed a national training scheme that changed the rotation periods from six months to either three or four months.³⁷

The factors which affected the recruitment of middle grade medical staff in the VOLH also had an impact upon the availability of junior doctors. Dr McCrudden explained the position in the following way:

“Junior doctors’ posts in hospital were largely determined by national needs for the training of doctors, rather than the local service, but in order to provide service ... We received ... I think it was two extra new jobs to make the rotas work”.³⁸

He went on to say that the rotas were not “comfortable” for junior doctors, who were perhaps not getting enough experience and yet were very busy when on call.³⁹ It was for that reason that, after surgical and A&E services were withdrawn from the VOLH in the years prior to 2007, final year medical students from Glasgow University were no longer allocated to the VOLH for clinical teaching. The absence of such specialties meant that their education would have been prejudiced.⁴⁰

Dr McCrudden also explained that it was not possible to achieve a one-year allocation for any of the rotating junior doctors at the VOLH because of the limited experience to which they would be exposed due to the limited number of specialties.⁴¹ Again this was in contrast to hospitals such as the IRH and the RAH, where there were examples in the core medical training rotation of doctors being appointed for a year at a time. Any change in the frequency of rotation would have involved the Post-graduate Deanery.⁴²

The rotation arrangements for junior doctors was focused on the individual training needs of those doctors, rather than reflecting patient need.⁴³ The Post-graduate Deanery

30 [TRA00710024](#)
31 [TRA00710024](#)
32 [TRA00710025-26](#)
33 [TRA00710026](#)
34 [TRA00710028](#)
35 [TRA00770084](#)
36 [TRA00710031-32](#)

37 [TRA01230001-02](#)
38 [TRA00790119-120](#)
39 [TRA00790120](#)
40 [TRA00790073](#); INQ03230005
41 [TRA00790138](#)
42 [TRA00790141](#)
43 [TRA00790142](#)

only allocated the number of posts it did at the VOLH based on a short rotation of three to four months. Furthermore, without such a time restriction, applicants would not have applied for the posts because the training would have been inadequate.⁴⁴

Consultants' general responsibilities

The consultants who had greatest contact with patients who contracted CDI generally had fixed ward rounds twice a week.⁴⁵ Dr Johnston only had a formal weekly ward round on Mondays, but Dr Herd carried out an additional ward round on Thursdays in ward 15.⁴⁶ Consultants also had outpatient responsibilities.

The consultants' staff rota

The rota system in the VOLH involved six consultants covering the whole hospital when on call. In reality, because of holidays, the commitment to being on call was one in four or five.⁴⁷ The effect of the on-call commitment was that each of the six consultants (including locum consultant Dr Akhter) had a commitment of being on call one weekday and every fourth or fifth weekend.

Dr Carmichael was responsible for the organisation of the rota.⁴⁸ As he explained, the rota was primarily based on days when the individual consultants were best placed to undertake the duties involved. The weekday rota was from Monday to Thursday and the on-call weekend rota was from Friday to Sunday.⁴⁹ Dr Carmichael described the task of organising the rota as "an onerous and difficult juggling act at times".⁵⁰ If the proposed on-call duty clashed with another commitment, then it was for the consultant who had the clash to raise it with him in the first instance. According to Dr Carmichael, this was something that often occurred.⁵¹

Dr Carmichael explained that the on-call system meant that the consultant on call

would go into the VOLH on Saturday and Sunday mornings so that all new patients admitted over the weekend would have a consultant assessment following admission.⁵²

Clash between ward rounds and on-call duties

The pressures placed on the senior doctors because of their on-call duties for acute medical receiving have already been discussed in this Chapter. The position was particularly acute in the case of Dr Akhter, who also had responsibilities for elderly patients and for stroke patients in the VOLH. The impact of his on-call duties was such that he was not able to fulfil his ward round responsibilities as often as scheduled. The Inquiry was given a copy of Dr Akhter's monthly diary shortly before he gave evidence.⁵³ This was designed to show the extent to which his on-call duties clashed with his ward round responsibilities for wards 14 and F.

On the basis of that record, Dr Akhter's on-call duties during the focus period certainly did have a significant impact upon his ability to conduct ward rounds. Dr Akhter's expectation was that, at least for ward 15, Dr Herd, the GP allocated to that ward, would be carrying out a ward round on the day that Dr Akhter should have been there.⁵⁴ From the patient records examined, however, it does appear to be the case that ward rounds were missed in a number of wards. Dr Johnston described Dr Akhter's position as "unworkable".⁵⁵ Dr McCruden said that it did seem that Dr Akhter was under "substantial pressure".⁵⁶

Dr Johnston also made the point that in the VOLH the consultant did not know what was happening outwith visits to the ward.⁵⁷ Senior medical staff were dependent upon being told by junior medical staff and nursing staff of any patient who needed to be reviewed.

44 [TRA00790142](#)
 45 [TRA00710006](#); [TRA00820155-157](#)
 46 [TRA00770013](#)
 47 [TRA00820159](#)
 48 [TRA00830009](#)
 49 [TRA00830009](#)
 50 [TRA00830016](#)
 51 [TRA00830016](#)

52 [TRA00830008](#)
 53 [INQ03100001](#)
 54 [TRA00750035-36](#)
 55 [TRA00770086](#)
 56 [TRA00800019](#)
 57 [TRA00770059-60](#)

Weekend cover

At weekends the only medical cover provided at the VOLH during the day was by two doctors; one at FY1 level and the other above the level of FY2.⁵⁸ Overnight one junior doctor (FY2) and a GP would be in attendance.⁵⁹ As just mentioned, however, the consultant on call did attend the VOLH on Saturday and Sunday mornings.

Dr McCrudden explained that “staffing at the weekend was recognised as being at a level that was desirable to be increased”.⁶⁰ The level of cover had remained unchanged over a long period.⁶¹

Furthermore, as discussed later, Dr McCrudden said that if the staff on duty had trouble coping he was called in to assist.⁶²

Staffing problems

A number of the medical witnesses gave evidence of a general shortage of medical staff. Dr Al-Shamma said that they were working “under tremendous pressure” and had “too many patients to see”.⁶³ Dr Carmichael described the staffing problem as having arisen in the following way:

“...almost a threefold increase in admissions, and these admissions were becoming more elderly, more complicated, more co-morbidities, more interventions had developed over the years. So, all in all, the workload for medical and nursing staff had steadily increased, and I have to accept that the staffing, to some extent, had not kept up with that increased need”.⁶⁴

One of the difficulties identified by Dr Patricia Clarke was that of staffing the laboratory. Recruitment had been “frozen for five years”⁶⁵ with the filling of full-time posts not being permitted. This meant that people were “acting up”⁶⁶ over prolonged periods of time.⁶⁷

58 [TRA00800001](#)
59 [TRA00780145](#); [TRA00800001](#)
60 [TRA00800002](#)
61 [TRA00800002](#)
62 [TRA00790123-124](#)
63 [TRA00720153](#)
64 [TRA00830007](#)
65 [WTS01600008](#)
66 [TRA00500014-15](#)
67 [WTS01600008](#)

When the most senior person in haematology in the laboratory left, uncertainty over its future led to the second most senior person taking over that role, although not permanently appointed to the post.⁶⁸ There was a general policy that posts were not to be refilled so long as there was uncertainty over the future.⁶⁹

In describing the VOLH as an example of one where “management were trying to sell the unsellable”,⁷⁰ Dr Clarke provided the following explanation:

“...the official assurances that we appeared to be getting were that no-one was wanting to shut the Vale, that it would continue to be an important hospital, that services would be retained there, while, at the same time, we weren’t allowed to fill posts because there was uncertainty about whether we were going to keep those posts. So the two messages coming across seemed to be inconsistent”.⁷¹

Dr McCrudden described the level of medical staffing as “not generous”⁷² and gave the example of being called at home on occasions with the plea “We’re having trouble coping with the amount of work”.⁷³ The result was that he could find himself working in the MAU on a Saturday night to help to clear the backlog of cases.⁷⁴ It seems that the consultants accepted that they had to manage their workloads as well as they could in circumstances where recruitment of additional staff was difficult.

Wards 14 and 15

The consultants responsible for wards 14 and 15 during the focus period were Drs Johnston and Akhter. The profile of these wards, part of the Rehabilitation and Assessment Department (RAD), was designed to be one of patients who were at a stage in their recovery at which they were being prepared for discharge. That profile was

68 [TRA00500015](#)
69 [TRA00500015](#)
70 [TRA00500016](#)
71 [TRA00500016](#)
72 [TRA00790123](#)
73 [TRA00790123-124](#)
74 [TRA00790124](#)

suitable for the type of GP input to ward 15 provided by Dr Herd, and in his absence by Dr Garthwaite. Prior to April 2007 there was also a GP hospital practitioner with commitments to ward 14, but he retired and was not replaced.⁷⁵ Dr Khan was then employed as a locum SHO from 2 July 2007, a post he held until 14 March 2008. He assisted Dr Akhter in particular, and although he attended other wards when necessary his primary commitment was to ward 14.⁷⁶

As Dr Johnston explained, the level of medical cover for wards 14 and 15 suited: “a rehabilitation unit that was quietly turning over with not much contact with acute medicine...”.⁷⁷

Generally the staffing of wards 14 and 15 was “mainly geared to rehabilitation”⁷⁸ and not to looking after acutely ill patients. As discussed in Chapter 12, during the focus period acutely ill patients were transferred to these wards,⁷⁹ and in the absence of middle grade doctors there was increased pressure on Dr Johnston and on Dr Akhter.⁸⁰ Therefore, as Dr Johnston was concerned, the medical staff available for the RAD was inadequate.⁸¹ She felt under pressure because of the amount of work she had to do and the areas within the hospital she had to cover.⁸² Dr Johnston was of the view that the pressure that she was under would affect “the follow-through of the care”.⁸³

Staff morale

Some senior doctors who gave evidence did consider that the uncertainty over the future of the VOLH affected morale.⁸⁴ The threat of closure meant that morale was low.⁸⁵ According to Dr Johnston “uncertainty was the biggest problem with morale” because “They were waiting for the big answer for years ...”.⁸⁶

Dr Clarke also was of the opinion that the morale of staff was “very low”.⁸⁷ There had been changes in the VOLH and there was real uncertainty over whether the VOLH had any future at all.⁸⁸

Management awareness

The fact that Dr Akhter was not able to carry out ward rounds because of pressure of work was not communicated to management or to the Clinical Directors who had responsibilities for the VOLH.⁸⁹ That was unfortunate because at least that aspect of medical staffing could have been addressed.⁹⁰ Nor was any real concern over the provision of an appropriate level of care communicated to Dr John Dickson, the Associate Medical Director for Clyde who took over in September 2007.⁹¹ As set out in Chapter 2, his predecessor, Dr Liz Jordan, was unable to assist the Inquiry.

Senior managers were aware that a number of staffing issues had the potential to put the care of patients at the VOLH at risk. A paper by Mrs Deborah den Herder, Director for Clyde, dated 28 February 2008 addressed to the Acute Division Senior Management Group proposed measures to be put in place:

“to assure the Board that services at the Vale are safe until such time as permanent decisions are taken regarding its future”.⁹²

The background to that proposal was the continued uncertainty for the future of the VOLH. Under reference to “Staffing” Mrs den Herder went on to say:

“There are a number of staffing issues which contribute to fragility, and these affect each of the key groups of staff employed there”.⁹³

In the paper Mrs den Herder set out the difficulties in the recruitment of medical staff, in particular anaesthetists. She stated that junior staffing at the VOLH was “a significant

75 [TRA00770009](#)
 76 [TRA00760005-07](#)
 77 [TRA00770015-16](#)
 78 [TRA00830006](#)
 79 [TRA00770014-15](#)
 80 [TRA00770018](#)
 81 [TRA00770083-84](#)
 82 [TRA00770085](#)
 83 [TRA00770087](#)
 84 [TRA00800090-91](#)
 85 [TRA00710111](#)
 86 [TRA00770069](#)

87 [TRA00500014](#)
 88 [TRA00500014](#)
 89 [WTS02280002](#); [WTS02270002](#)
 90 [WTS02290001-02](#)
 91 [WTS02290001-02](#)
 92 [GGC04520001](#)
 93 [GGC04520001](#)

cause for concern”,⁹⁴ although that was not elaborated upon. She also highlighted the “significant vacancy level” in the laboratory.⁹⁵ The proposal at that stage was that the Clyde senior management team together with the Board’s Medical Director, Nurse Director and the VOLH physician would meet on a monthly basis to consider all relevant issues.

Mrs den Herder’s paper was considered at a meeting of the Acute Strategic Management Group on 28 February 2008⁹⁶ chaired by Mr Robert Calderwood, then the Chief Operating Officer, and the proposed arrangements were discussed.⁹⁷ An update report on the issues identified by Mrs den Herder in her paper of 28 February 2008 noted that, as regards junior medical staff at the VOLH:

“The level of seniority, competence, ability to contribute to the out of hours rota and vacancies combine to create considerable risk”.⁹⁸

It is clear, therefore, that at least by February 2008 steps were being taken by management to monitor the provision of care at the VOLH while a decision on the future of the VOLH was awaited.

It is apparent to the Inquiry that the medical staff were working under a significant degree of pressure during the period of the Inquiry’s remit. As discussed later in this Chapter, the result was that certain aspects of patient care, such as the medical review and assessment of patients suffering from CDI, were below an adequate standard.

Conclusion on medical staffing

On inheriting the VOLH, NHS Greater Glasgow took over a hospital that for a number of years had suffered losses of services and serious mismanagement. Problems over the recruitment of medical staff had persisted long before NHS Greater Glasgow took over responsibility. The background to the dissolution of NHS Argyll and Clyde is considered in Chapter 8, but by April 2006

a layer of medical staffing was missing, the consultants were overstretched, and junior doctors bore the brunt of the ongoing day to day care of the patients suffering from CDI. The plan put in place in February 2008 was in effect a holding exercise, as the future of the VOLH had not been determined at that time.

The fact that this state of affairs existed should not be seen as a criticism of NHSGGC. The need for doctors to receive proper training, combined with the uncertainty over the future of the VOLH and the consequential difficulty in recruiting staff, placed NHSGGC in a difficult position. The plan adopted in February 2008 did recognise that careful monitoring of the situation was necessary if any impact on patient care was to be avoided. Notwithstanding such efforts, there were deficiencies in medical review and assessment, discussed later in this Chapter, that had a real impact on the care of patients suffering from CDI.

14.4 Medical management of CDI

The management of CDI generally

The thrust of the expert physicians’ evidence was that CDI was not well managed.⁹⁹ Antibiotic practices are considered later in this Chapter, as are delays in producing results and delays in commencing treatment of CDI patients. These matters aside, two areas of practice particularly commented upon by the medical experts were the frequency of review of patients and the nature of any review carried out.

Initial review of patients on diagnosis and assessment

There should be prompt review of a patient who tests positive for CDI. “Prompt” means that the patient should be seen that same day.¹⁰⁰ That review should include a clinical assessment of the patient’s condition. Although at the time a severity markers scoring chart was not available in the VOLH, that did not mean that a clinical assessment to assess the severity of the condition

94 [GGC04520001](#)

95 [GGC04520002](#)

96 [GGC02410001-02](#)

97 [GGC02410001](#); [GGC04510003](#)

98 [GGC04510003](#)

99 [TRA00530151-153](#); [TRA00510155-157](#); [TRA00590117](#); [TRA00510146-148](#); [EXP02040001-10](#)

100 [TRA00570088](#); [TRA00530152-153](#)

should not take place.¹⁰¹ Such an assessment would include an abdominal examination. A recurring theme that emerged from the medical experts' examination of the patient records was that of delays in medical intervention for patients who had tested positive for CDI. The impression gained was that the medical staff perhaps did not really recognise the severity of CDI as an illness.¹⁰² Dr James Reid advanced the following conclusion:

“They perhaps hadn't been alerted to the fact that *Clostridium difficile* was a life threatening infection, rather than just a nuisance and a minor complication of antibiotic therapy”.¹⁰³

To an extent this chimed with some of the oral evidence given to the Inquiry by the doctors at the VOLH who were asked about the nature of CDI as an illness. This was Dr Johnston's evidence:

“I think our experience of *C. difficile* led us ... not have a ... you know, not that our approach was poor; but we simply hadn't seen what *C. difficile* can do. It's an important diagnosis. But until we went through that experience at the Vale, we were not aware of the potential”.¹⁰⁴

She went on to say that she was not necessarily told at the time of diagnosis that one of her patients had contracted CDI, although she would have expected to be contacted at an early stage thereafter.¹⁰⁵ In the post she held at the time of giving evidence she would be contacted when a diagnosis had been made.¹⁰⁶ Dr McCrudden said that a patient diagnosed with CDI should be medically reviewed as soon as possible,¹⁰⁷ but he would not have expected to be called to review the patient at the time of diagnosis.¹⁰⁸

Medical review and assessment

There was a general acceptance by the VOLH consultants who gave evidence on the point that patients suffering from CDI should be reviewed regularly, which could mean on a daily basis.¹⁰⁹ Such a review should include an assessment of the severity of the infection.

The following summaries set out some examples of patients whose treatment was considered by the VOLH consultants during their oral evidence to the Inquiry, and for whom they accepted there had been a lack of medical review and assessment.

Mary Broadley was admitted to ward 15 on 23 November 2007¹¹⁰ and was thought to be suffering from CDI on 4 December 2007.¹¹¹ A note in the patient records for 5 December 2007 confirmed that she had tested positive for CDI.¹¹² A clinical examination of the patient should have been carried out at that time. There was no record in the clinical notes of such an examination. Following upon a short entry on 6 December 2007 “For sc.fluid”¹¹³ there was no further medical input until 13 December 2007.¹¹⁴ There was also a gap of two weeks between consultant ward rounds, a gap that could not be explained.¹¹⁵ This level of medical review was not acceptable care.¹¹⁶ The systematic management of an infection such as CDI required daily review.¹¹⁷ This patient tested positive for CDI again on about 17 December 2007. There was no evidence of a medical review of the patient's condition at that time. There was evidence of some medical input because there was a nursing note that a discussion took place with a microbiologist on 19 December 2007 to the effect that the patient was to be commenced on oral vancomycin.¹¹⁸ After

101 [TRA00770053](#)
 102 [TRA00590117](#)
 103 [TRA00530153](#)
 104 [TRA00770032](#)
 105 [TRA00770099-100](#)
 106 [TRA00770099](#)
 107 [TRA00800083](#)
 108 [TRA00810025](#)

109 [TRA00710093](#); [TRA008300063](#); [TRA00810030](#);
[TRA00810071-72](#); [TRA00770101](#); [TRA00770141](#)
 110 [TRA00770096](#)
 111 [TRA00770098](#)
 112 [TRA00770099](#)
 113 [GGC00050030](#); [TRA00770100](#)
 114 [GGC00050031](#); [TRA00770101](#)
 115 [TRA00770101-102](#)
 116 [TRA00770102](#)
 117 [TRA00770103](#)
 118 [TRA00770114](#); [GGC00050127](#)

17 December 2007 the next consultant review was on 31 December 2007. There was no evidence from the clinical notes that Mrs Broadley was medically reviewed in connection with her CDI prior to 31 December 2007.¹¹⁹ Mrs Broadley tested positive again for CDI, and the ward was aware of this on 14 January 2008.¹²⁰ There was no evidence from the clinical notes that a clinical assessment of the patient's condition was carried out.¹²¹ There were blood results relating to this patient in respect of a specimen collected on 19 December 2007.¹²² There should have been further blood sampling carried out, particularly as she had tested positive for CDI on three occasions, to allow the clinician some insight into the severity of the infection. That was not done. This should have been identified on ward rounds.¹²³

John Boyle, who was admitted to ward 15 on 10 January 2008¹²⁴ was known by the ward to be positive for CDI on 25 January 2008. That same day there was a note in the clinical notes indicating that the patient has been started on metronidazole.¹²⁵ That note was made by an FY1. There was no evidence of a medical review being carried out and in any event such review should have been by a more senior doctor.¹²⁶ There was no evidence of any medical review from the notes between 25 January 2008 and 28 January 2008.¹²⁷ There should have been further medical review during that time.¹²⁸ Because this patient's condition was deteriorating despite receiving metronidazole, antibiotic treatment should have been reviewed after discussion with a microbiologist. There was no evidence that that happened from the clinical notes.¹²⁹ This patient should also have had blood tests carried out by 18 January

2008 in order to assess the severity of his condition and manage any risks of dehydration. There was no evidence in the clinical notes to that effect.¹³⁰ There was no dispute that the standard of record keeping for this patient was poor.¹³¹

Evelyn Scott-Adamson was admitted to ward 15 on 17 December 2007.¹³² There were no entries in the clinical notes between 1 January 2008 and 9 January 2008.¹³³ The entry for 9 January 2008 records the fact that the patient fell and sustained injury. During that time the patient was suffering from diarrhoea and a sample was collected on 5 January 2008¹³⁴ because it was suspected that the patient might have been suffering from CDI. There was no evidence from the records that she was medically reviewed in relation to the diarrhoea. A doctor should have been involved with the patient in circumstances where the nursing staff were sending a sample for *C. difficile* toxin testing.¹³⁵

Agnes Burgess was admitted to the VOLH on 20 December 2007 and tested positive for CDI through a sample collected on 22 December 2007. The positive result was known to the ward in the evening of 24 December 2007. That should have prompted a medical review and an assessment of whether any medication should be stopped or changed.¹³⁶ There was no evidence that that happened.¹³⁷ There was no evidence of a medical review prior to 27 December 2007. There should have been a medical review after the positive result was known.¹³⁸ A junior doctor was contacted to write up a prescription for metronidazole but there was no evidence that the patient was examined.¹³⁹

119 GGC00050031-32

120 [TRA00770118](#)

121 [TRA00770119](#)

122 [TRA00770125](#)

123 [TRA00770126](#)

124 [TRA00770135](#)

125 GGC00030016

126 [TRA00770140](#)

127 GGC00030016-17

128 [TRA00770141](#)

129 [TRA00780011-12](#)

130 [TRA00780025-27](#)

131 [TRA00780028](#)

132 [TRA00780045](#)

133 GGC27020014; GGC27020018; [TRA00780049-50](#)

134 GGC27920039

135 [TRA00780052-53](#)

136 [TRA00780086](#)

137 [TRA00780087](#)

138 [TRA00780086-87](#)

139 [TRA00780091](#)

Elizabeth Valentine was admitted to ward 6 on 8 February 2008¹⁴⁰ and was known to be positive with CDI on 22 February 2008.¹⁴¹ A colonoscopy carried out on 21 February 2008 diagnosed that she was suffering from a severe pseudomembranous colitis of the entire colon.¹⁴² There was no reference in the clinical notes covering the period 22 to 25 February 2008 to the colitis. The colitis was a serious condition and should have been recorded in the clinical notes prior to 25 February 2008.¹⁴³ A clinical assessment should have been carried out on the patient by a doctor on 22 February 2008. There was no record that that happened.¹⁴⁴

Patient B was admitted to ward 6 on 7 December 2007¹⁴⁵ and developed loose stools by about 14 December 2007.¹⁴⁶ On 17 December 2007 the ward was made aware that she was suffering from CDI.¹⁴⁷ There was no senior doctor involvement with this patient between 8 December 2007 and 24 December 2007.¹⁴⁸ There was a note in the clinical notes that she was seen by a doctor on 17 December 2007 and that she was *C. difficile* toxin positive. There was no record at that time that a medical examination to assess the patient's condition was carried out.¹⁴⁹ Over that period Patient B should have been seen on four occasions by a senior doctor.¹⁵⁰ The lack of senior review was not appropriate.¹⁵¹ Although there was no record of an examination when the positive result was confirmed there had been an examination, including an abdominal examination, earlier that same day.¹⁵²

Mary Hamilton was admitted to the VOLH on 27 December 2007 and transferred to ward 6. She was known to be positive for *C. difficile* toxin on 22 January 2008.¹⁵³ There was no record of a medical review between 18 January and 23 January 2008.¹⁵⁴ She should have been assessed at the time the CDI diagnosis was confirmed.¹⁵⁵ She was seen on 23 January 2008 and it was noted in the clinical notes that the patient was suffering from CDI. It was only then that metronidazole was prescribed for that condition.¹⁵⁶ Had the patient been seen sooner then the treatment would have commenced earlier.¹⁵⁷ Mrs Hamilton tested positive for *C. difficile* toxin again, a result of which the ward was aware on 13 February 2008. There was no clinical acknowledgement of that positive result until 14 February 2008 when a note made by an FY1 doctor records that the patient was *C. difficile* toxin positive and metronidazole was prescribed.¹⁵⁸ She should have been seen on 13 February when the positive result was known.¹⁵⁹ There was no evidence of a clinical examination. Thereafter, the patient was reviewed by a senior doctor on 15 and 22 February 2008.¹⁶⁰ However, there was no record of a medical review contained in the clinical notes between 22 February 2008 and 11 March 2008.¹⁶¹ There should not have been such a gap. From the nursing notes it did appear that there were multi-disciplinary team meetings in relation to this patient on 26 February 2008 and 4 March 2008.¹⁶²

Muriel Waddell, who was admitted to the VOLH on 22 April 2008, was known to be *C. difficile* toxin positive from 1 May 2008.¹⁶³ On that date she was seen by a junior doctor but there was no evidence in the record made that a medical

140 [TRA00710112](#)

141 [TRA00710144-145](#)

142 [GGC00800067](#)

143 [TRA00710144](#)

144 [TRA00710155](#); [TRA00710159](#)

145 [TRA00720038](#)

146 [GGC26380058](#)

147 [GGC26380060](#)

148 [TRA00720048](#); [TRA00720051](#)

149 [GGC26380017](#)

150 [TRA00720050](#)

151 [TRA00720053](#)

152 [GGC26380017](#)

153 [TRA00810015](#); [GGC00260055](#)

154 [TRA00810025](#)

155 [TRA00810025](#)

156 [GGC27230009](#)

157 [TRA00810026](#)

158 [GGC00260012](#)

159 [TRA00810027](#)

160 [TRA00810029-30](#)

161 [TRA00810029-30](#)

162 [GGC00260048](#); [GGC00260047](#)

163 [TRA00810038](#); [TRA00810042](#)

examination was carried out.¹⁶⁴ The patient was seen the following day by a senior doctor and, although there was no note made of an abdominal examination, his view was that he would have carried out such an examination.¹⁶⁵

Rosa Rainey was admitted to the VOLH on 27 December 2007.¹⁶⁶ She was known to be positive for *C. difficile* toxin on 21 January 2008 when a note to that effect was made in the clinical notes.¹⁶⁷ The next medical review did not take place until 23 January 2008. There should have been a further review before that date.¹⁶⁸ This patient was known to be *C. difficile* toxin positive again on 1 April 2008. On that date there was a note in the clinical records by a junior doctor confirming the positive result. The next entry was dated 8 February (sic) (it is clear that that should have been 8 April 2008) and it would have been desirable if there had been more frequent review.¹⁶⁹ This patient again tested positive for *C. difficile* toxin on 22 April 2008 and there was a note to that effect in the clinical notes made by a junior doctor. Again there was no note that a clinical examination was carried out.

Patient C was admitted to the VOLH on 9 December 2007, initially to ward 6, and then transferred to ward F.¹⁷⁰ She was known to be positive for CDI on 24 December 2007¹⁷¹ when in ward F.¹⁷² The patient was seen by a senior doctor on 18 December 2007 and seen again by a junior doctor (FY1) some time before 20 December 2007.¹⁷³ There was no evidence from the patient records that the patient was seen again until 8 January 2008.¹⁷⁴ There was no evidence of any medical review either by a senior or junior doctor. The dates of the normal weekly ward rounds may have coincided

with holiday periods¹⁷⁵ but it was not disputed that this patient should have been seen by a doctor and should have been medically assessed. The failure so to do was unacceptable practice.¹⁷⁶ Patient C was known to be *C. difficile* toxin positive again on 9 January 2008.¹⁷⁷ She was seen by a junior doctor on that date. There was no record made of a medical examination, although it was noted that the patient was not unwell.¹⁷⁸ The patient was not seen again until 14 January when a note was made by a junior doctor.¹⁷⁹ At that time she was described as “not improving”.¹⁸⁰ Once again there was no note made of a medical examination. This patient should have been seen on a more regular basis over this period.¹⁸¹ She was seen by a senior doctor on 15 January 2008 but there was no record made of an abdominal examination.¹⁸² The examination may have been carried out but not recorded.¹⁸³ After 15 January 2008 there was a gap of one week before the patient was seen again on 22 January 2008, according to the records. There should have been more regular medical reviews of this patient.¹⁸⁴ This patient again tested positive for *C. difficile* toxin, the result of which is known on 6 February 2008.¹⁸⁵ She was seen on that day but there was no record of a medical review after that date until 11 February 2008.¹⁸⁶ That would not be an acceptable level of medical review.¹⁸⁷ The patient was seen on 12 February but thereafter there was a gap of six days where there was no evidence of medical review.¹⁸⁸ During that period she continued to suffer from diarrhoea.¹⁸⁹ This patient was known to be positive for *C. difficile*

164 [TRA00810042-43](#)

165 [TRA00810043](#)

166 [TRA00810049](#)

167 GGC00490013

168 [TRA00810070-71](#)

169 [TRA00810072](#)

170 GGC26340019; [TRA00740008](#)

171 GGC26340172

172 [TRA00740010-11](#); SPF01390001

173 [TRA00740009-10](#); GGC26340025

174 [TRA00740010](#)

175 [TRA00740011-12](#)

176 [TRA00740016](#)

177 GGC26340025

178 GGC26340025

179 GGC26340026

180 GGC26340026

181 [TRA00740023](#)

182 [TRA00740029](#)

183 [TRA00740029](#)

184 [TRA00740034](#)

185 [TRA00740036-37](#)

186 [TRA00740041](#)

187 [TRA00740042](#)

188 [TRA00740043](#)

189 [TRA00740043](#)

toxin on 25 February 2008.¹⁹⁰ Despite that knowledge there is no evidence in the patient records of the patient being seen or examined on that day. The patient should have been medically reviewed on 25 February 2008 when the diagnosis was confirmed.¹⁹¹ Patient C was seen by a doctor on a ward round on 26 February 2008 but there was no evidence from the note made that a medical examination was carried out. The doctor considered that a clinical examination would have been carried out, although not recorded.¹⁹² According to the patient records the patient was not seen again until 4 March 2008, in the course of a ward round.¹⁹³ This patient should have been seen and clinically assessed between 26 February and 4 March 2008.¹⁹⁴ In the course of the month of March this patient was only seen on four occasions (4, 11, 18 and 25 March 2008).¹⁹⁵ There was no dispute that that was not acceptable practice.¹⁹⁶

Patient Isobel Cameron was admitted to ward 14 in the VOLH in October 2007 and was known to be positive on 26 October 2007 for *C. difficile* toxin.¹⁹⁷ There was a record that she was seen by a doctor on that date. But there was no record made of a clinical examination to assess the severity of the CDI.¹⁹⁸ There was no evidence of a further medical review until 29 October 2007. The patient should have been seen by a doctor over that period.¹⁹⁹ This patient was known to be positive again for *C. difficile* toxin on 5 December 2007.²⁰⁰ There was no record of a medical examination being carried out on that date. Such an examination should have been carried out.²⁰¹ Mrs Cameron was seen on 6 December 2007 but thereafter there was no note made in the patient records until 10 December 2007 when she was

seen in the course of a ward round.²⁰² She should have been reviewed by a doctor during that four day period.²⁰³ After 10 December 2007 there was no record made in the patient records of the patient being seen until 17 December 2007, a period of a week.²⁰⁴ On that occasion also she was seen in the course of the weekly ward round.²⁰⁵ Mrs Cameron continued to suffer from CDI over that period.²⁰⁶ Thereafter there was a gap of ten days where there was no entry in the records that this patient was seen by a doctor. The next entry on 27 December 2007 coincided with a ward round.²⁰⁷ The failure to review this patient over that period of time was unacceptable practice.²⁰⁸ This patient was known to be positive again on 4 January 2008, although there appears to be some confusion over the result.²⁰⁹ Despite that result Mrs Cameron was not seen by a doctor between 31 December 2007 and 7 January 2008.²¹⁰ The patient should have been medically reviewed over that period.²¹¹ When she was seen on 7 January 2008 there was no evidence in the record made that a clinical examination was carried out.²¹² Mrs Cameron was once again known to be *C. difficile* toxin positive on 8 January 2008.²¹³ She was not seen until 9 January 2008 when a note was made in the patient records that the patient was *C. difficile* toxin positive. There was no evidence in the record made that the doctor carried out a medical examination of the patient.²¹⁴ Such an assessment should have taken place.²¹⁵ The patient was next noted as having been seen in the course of a ward round on 14 January 2008, some five days later. At that time the note made included "Remains unwell.

190 [TRA00740056](#)

191 [TRA00740057](#)

192 [TRA00740057](#)

193 [TRA00740058](#)

194 [TRA00740058](#)

195 [TRA00740060](#)

196 [TRA00740061](#)

197 [TRA00740064](#); GGC00070031

198 [TRA00740064](#)

199 [TRA00740066](#)

200 [TRA00740067](#)

201 [TRA00740068](#)

202 GGC00070027

203 [TRA00740069](#)

204 [TRA00740069](#)

205 GGC00070027

206 [TRA00740070](#)

207 [TRA00740070](#)

208 [TRA00740072](#)

209 [TRA00740073](#)

210 [TRA00740074](#)

211 [TRA00740074](#)

212 GGC00070025

213 [TRA00740076](#)

214 [TRA00740076](#)

215 [TRA00740076-77](#)

For TLC”²¹⁶ Mrs Cameron died later that same day.²¹⁷ At no point in the records made in respect of this patient was there any evidence of a clinical review of the patient’s symptoms.²¹⁸ The only cause of death entered on the patient’s death certificate was *Clostridium difficile* colitis.²¹⁹

Sarah McGinty was admitted to the VOLH on 3 December 2007,²²⁰ having suffered a stroke and was noted by 21 January 2008 to be “much improved”.²²¹ By 25 January she was known to be *C. difficile* toxin positive. A note in the clinical notes on that date recorded the positive result but the FY1 doctor did not record whether a clinical examination of the patient was carried out.²²² At this time Mrs McGinty was beginning to become unwell.²²³ On 26 January 2008 she was seen by a doctor but there was no record made of a clinical assessment.²²⁴ This was unacceptable practice.²²⁵ As at 27 January 2008 the patient was becoming very unwell.²²⁶ She continued to deteriorate and died on 1 February 2008.²²⁷ This was a patient who in light of the deterioration, ought to have had a medical review by a senior doctor.²²⁸ There was no evidence from the records that Mrs McGinty was seen by a senior doctor after having contracted CDI, although there was a note that the day before she died a doctor did discuss the patient with a senior doctor.²²⁹

Ellen Pirog was a patient who had suffered serious orthopaedic injuries and who tested positive for *C. difficile* toxin in the RAH. She was transferred to the VOLH on 9 July 2007.²³⁰ This patient was admitted to ward 15. Although she

developed loose stools in the VOLH,²³¹ she was not tested for *C. difficile* toxin. This patient did suffer from CDI when in the VOLH.²³² Mrs Pirog died on 3 October 2007, having been a patient in the VOLH for almost three months. Over that period there were significant gaps in the patient’s clinical records where no record was made as to whether or not the patient was medically reviewed. There was no record of a medical review being carried out in the last eight days of Mrs Pirog’s life.²³³ This represented unacceptable practice.²³⁴ The patient was only seen by a consultant on two occasions during the patient’s stay in the VOLH, a situation which was totally unacceptable.²³⁵

Conclusion on medical management of CDI

It was the junior doctors who had by far the most involvement with patients. The repeated failure to note that an assessment of the patient’s condition had been made when CDI was contracted was a trend that suggested that no such assessment had been made. Examples of failures to carry out blood sampling to assess a patient’s condition also support the conclusion that the level of medical assessment was inadequate.

The frequency of medical review of this group of patients with CDI was also inadequate, at least according to the records. It may be that in some cases there was more regular review than has been recorded,²³⁶ although it is clear that there was a significant number of instances where there was no review. In addition, because junior doctors were to the forefront of care their inexperience resulted in failures to notify senior medical staff when senior medical involvement was necessary. The inadequacy of medical review and assessment is likely to have compromised patient care.

It is clear that the junior doctors at the VOLH were not properly supervised. This is not a criticism of the senior medical staff but

216 GGC00070025; [TRA00740077](#)

217 [TRA00740080](#)

218 [TRA00740082](#)

219 [TRA00740083](#)

220 [TRA00740104](#)

221 GGC00420013

222 GGC00420014; [TRA00740153](#)

223 [TRA00740153](#)

224 [TRA00740153](#)

225 [TRA00740153-154](#)

226 [TRA00740156](#)

227 SPF00250001

228 [TRA00750004](#)

229 [TRA00750004-05](#)

230 [TRA00750023](#)

231 [TRA00590021-24](#)

232 [TRA00590058-59](#)

233 [TRA00750034](#)

234 [TRA00750035](#)

235 [TRA00750037-38](#)

236 [TRA00820041](#)

simply a state of affairs brought about by the status of the VOLH as a hospital with an uncertain future. Services had dwindled and the VOLH had become a hospital that was unattractive both to medical staff with appropriate experience and to junior staff looking for that experience. The senior medical staff were exposed to pressures that limited their ability to provide the supervision that was necessary.

It is difficult to escape the conclusion that junior doctors were placed in a hospital where the training they received did not comply with necessary standards. Deficiencies in training can only result in compromised patient care. Good training is essential to good clinical care when junior doctors are providing the care. Ultimate responsibility for the situation in the VOLH rests with NHSGGC. While the Inquiry acknowledges that it may not be easy for a Board to scrutinise the levels of medical care provided, particularly where clinical judgement may be involved, nonetheless through appropriate systems, a Board can obtain assurance that the quality and safety of care meet the requisite standard. The VOLH did provide the Board with a real challenge, but that challenge should not have led to the standards of medical care provided to *C. difficile* infected patients being at unacceptable levels.

14.5 Do Not Attempt Resuscitation orders

Purpose

A Do Not Attempt Resuscitation (DNAR) order is a written record of a decision that if the patient suffers a cardiac arrest he or she will not be resuscitated.

The NHSGGC DNAR policy provided that a “DNAR decision” applied solely to cardiopulmonary resuscitation (CPR).²³⁷ All other treatment and care should be continued and should not be influenced by the DNAR decision.²³⁸ Furthermore, such a decision could only be taken in the best interests of the patient. Establishment of DNAR status was the responsibility of the consultant in charge. Even if the responsibility was

delegated to another senior doctor, the decision was to be discussed and agreed with the consultant.²³⁹

The policy also provided that a DNAR decision had to be reviewed regularly, which was defined as “no greater than seven days in Acute Areas or 28 days in Specialist Areas”.²⁴⁰ A review date had to be documented and signed.²⁴¹ The DNAR order form itself provided that a DNAR decision should be reviewed by the:

“consultant/lead GP at the earliest opportunity and should be reviewed 48-hourly for the first week and thereafter at least weekly...”.²⁴²

The policy also required that clinical practice in relation to DNAR decisions be “audited regularly, at least twice a year”.²⁴³

Do Not Attempt Resuscitation orders in the VOLH

Of the 63 patients in the focus group 36 patients had DNAR orders in their patient records. Of that number, 26 DNAR orders had been incorrectly completed. The following are examples of the deficiencies.

- The reason for the DNAR decision is not recorded in the order in at least two cases²⁴⁴
- A significant number of DNAR orders did not have a review date noted²⁴⁵
- Sections of the DNAR order designed to show if there had been discussion with family members were often left blank²⁴⁶

The families’ view on communication over this aspect of care is mentioned in Chapter 11.

239 [GGC04470016](#)

240 [GGC04470017](#)

241 [GGC04470017](#)

242 [GGC00090007](#)

243 [GGC04470017](#)

244 [GGC00030004](#); [GGC26340227](#)

245 [GGC00050010](#); [GGC00580223](#); [GGC00110005](#); [GGC00220012](#); [GGC00240004](#); [GGC00270065](#); [GGC00320056](#); [GGC00330003](#); [GGC21690003](#); [GGC00520005](#)

246 [GGC00020003](#); [GGC00030010](#); [GGC00500010](#); [GGC00580223](#); [GGC22480018](#); [GGC00080047](#); [GGC00110005](#); [GGC00160005](#); [GGC00170003](#); [GGC00190215](#); [GGC00220012](#); [GGC00270065](#); [GGC00280005](#); [GGC00330003](#); [GGC00340003](#); [GGC00420024](#); [GGC00460040](#); [INQ02360001](#); [GGC21690003](#); [GGC00520005](#); [GGC00530053](#)

237 [GGC04470015](#)

238 [GGC04470016](#)

There are instances where it was not apparent from the DNAR orders whether senior doctors were involved in the decision making process,²⁴⁷ although in the majority of cases senior doctors were directly involved or consulted.

There was no evidence that the auditing envisaged by the DNAR policy ever took place. Auditing would have identified the deficiencies that were apparent. The failure to audit is one for which management and ultimately NHSGGC are responsible.

14.6 Antibiotic prescribing

A culture of over-prescribing

The relevance of antibiotic therapy to *C. difficile* infection (CDI) is examined in Chapter 3, and the failure to heed the message of prudent prescribing is considered in Chapter 13. This Section considers first the guidelines and policies on the prescription of antibiotics available to the medical staff in the VOLH in the period from 1 January 2007 to 1 June 2008 and second the prescribing practices adopted by the medical staff at the VOLH for CDI and other conditions during the focus period. The prevailing evidence was of a culture of over-prescribing at the VOLH, and some detailed examples of prescribing practices are set out in this Section.

This Section also examines the delays between samples being obtained from patients, positive results being received, and treatment commencing.

Guidelines and policies

A number of different guidelines and policies on antibiotic prescribing were available to the VOLH medical staff including:

- The Argyll and Clyde Drug Formulary (2006)²⁴⁸
- The Infection Management Guideline – Empirical Antibiotic Therapy (2007) (the Infection Management Guideline)²⁴⁹

- The North Glasgow Acute Hospitals Prescribing Handbook 2007-2008²⁵⁰
- The Guide to First Line Antimicrobial Prescribing (1997 and 2000)²⁵¹
- The Greater Glasgow and Clyde Formulary (2007)²⁵²
- The British National Formulary (BNF) (2006)²⁵³

Use of guidelines and policies by the medical staff

Senior medical staff can rely on their own experience in the prescription of antibiotics. In contrast, junior staff have a greater need for guidelines and supervision. The evidence of the senior medical staff on the guidance available to them during this period can be summarised in the following way.

Dr McCrudden thought that the Argyll and Clyde Drug Formulary 2006 looked familiar and that he did use it “from time to time”.²⁵⁴ He also used the BNF,²⁵⁵ and referred to guidelines called the “Guide to First Line Antimicrobial Prescribing”, apparently produced by Dr Dancer and revised by her in January 2000. He said that he had seen the Infection Management Guideline in draft but did not think that that document had reached the wards much before May 2008.²⁵⁶

Dr Carmichael also thought that the Argyll and Clyde Drug Formulary 2006 looked familiar but he was unsure when it was available.²⁵⁷ He had no recollection of using the Infection Management Guideline prior to June 2008, although he thought that there was an earlier version and that one would have been available to him.²⁵⁸ He did recall there being “several different types of guidelines around over that year or two” but he was unsure “which one was the formally accepted, current one”.²⁵⁹

247 GGC00580022; GGC00580313; GGC00240004; GGC00300016; GGC00340003; GGC27470001; GGC00530052; GGC00550003

248 [GGC21790001](#)

249 [GGC22180001](#)

250 [GGC21760001](#)

251 [INQ01300001](#); [INQ01310001](#)

252 [GGC18270001](#)

253 [INQ02940001](#)

254 [TRA00800045](#)

255 [TRA00800051](#)

256 [TRA00800050-51](#)

257 [TRA00830020](#)

258 [TRA00830020-21](#)

259 [TRA00830019](#)

Dr Johnston said that there were a number of guidelines available but that from October 2007 she used the Infection Management Guideline.²⁶⁰ That guideline was then in draft form²⁶¹ and was not issued in the VOLH until early February 2008,²⁶² and there is no suggestion that any other member of the senior medical staff used it prior to that date. She also identified the Greater Glasgow and Clyde Drug Formulary 2007 as a document that was available, and indeed said that it was kept in her office.²⁶³

Dr Al-Shamma said he used the Greater Glasgow and Clyde Formulary, the Argyll and Clyde Drug Formulary 2006 and the BNF.²⁶⁴ He did not use the Infection Management Guideline document before June 2008 and thought it was not available before then.²⁶⁵

Dr Akhter said he used the NHS Argyll and Clyde Drug Formulary 2006, although the version he had did not contain the appendices to the version previously made available to the Inquiry.²⁶⁶ He also used the BNF, but did not use any other guidance.²⁶⁷

Dr Herd said that he used the Greater Glasgow and Clyde Formulary and the BNF.²⁶⁸ He said that the Infection Management Guideline became available “latterly”²⁶⁹ but he could not remember when that was.

This summary of the evidence of senior medical staff discloses that in the period 1 January 2007 to 1 June 2008 a variety of different guidelines was in use at the VOLH. There was a lack of uniformity in approach from the senior medical staff and there were some differences between the guidelines. This situation should not have developed, and in a hospital like the VOLH clinicians should have been following one common agreed policy.

Junior medical staff

With the exception of Dr Khan, the picture for the junior medical staff is a more consistent one. Prior to February 2008, junior doctors were provided on induction with the North Glasgow Acute Hospitals Prescribing Handbook, the BNF and the Greater Glasgow and Clyde Formulary.²⁷⁰ In February 2008, junior doctors were provided with the Infection Management Guideline available at that time.²⁷¹ No member of the senior medical staff said that the North Glasgow Acute Hospitals Prescribing Handbook was being used.

The exception among the junior doctors was Dr Khan. He did not have an induction²⁷² and was not supplied with the junior doctors’ handbook that was normally supplied then.²⁷³ Nor was he provided with any of the prescribing guidelines that were available. During his period of employment at the VOLH he relied on his own experience and followed the guidance provided by the BNF (2006)²⁷⁴ or the guidance given by the consultant supervising him.

Empirical antibiotic therapy guidelines

From February 2008 the Infection Management Guideline was available in document and laminated poster form at the VOLH.²⁷⁵ According to Mr Scott Nicol, the Pharmacy Manager, the launch took place after a medical meeting attended by senior and junior medical staff.²⁷⁶ Mr Nicol expected that all doctors at the VOLH would use these guidelines, but the only clear evidence that these guidelines were in use by the senior medical staff prior to June 2008 came from Dr Johnston, who in fact had been using them even when they were in draft form.

It is important to note that the introduction of the Infection Management Guideline in February 2008 did not produce a real change in the prescribing of the more provocative

260 [TRA00770019-20](#)

261 [TRA00880059](#)

262 [TRA00880064](#)

263 [TRA00770023](#)

264 [TRA00710010-13](#)

265 [TRA00710011](#)

266 [TRA00730059](#)

267 [TRA00730070](#)

268 [TRA00820011](#)

269 [TRA00820010](#)

270 [TRA00880057-58](#)

271 [TRA00880064](#); [TRA01150100](#)

272 [TRA00760005](#)

273 [TRA00760005](#)

274 [TRA00760011-12](#)

275 [TRA00880059-60](#); [TRA01150100](#)

276 [TRA00880060](#)

antibiotics that predispose patients to CDI.²⁷⁷ That change came after June 2008.

Antibiotic prescribing prior to admission to the VOLH

So far as was possible, the Inquiry examined the pattern of antibiotic prescribing in the community for patients in the focus group for the six months prior to admission of each patient to the VOLH. As far as can be determined,²⁷⁸ at least 24 patients in the focus group received antibiotics in the community which may have predisposed them to CDI. Six of these patients were prescribed the narrow spectrum antibiotic, trimethoprim. Three of those six had been prescribed antibiotics some five months prior to admission. At least three additional patients had been prescribed predisposing antibiotics at the RAH before admission to the VOLH and received no further antibiotic treatment in the VOLH.

Antibiotics in the VOLH

The Inquiry has been able to ascertain from the patient records that 60 of the 63 patients in the focus group did receive antibiotics while in the VOLH. The three remaining patients did not receive any antibiotic therapy in the VOLH, although they did have antibiotics prescribed to them prior to their admission. While the picture is far from clear, it is therefore likely that more than half of the patients in the Inquiry's patient focus group were first prescribed antibiotics which predisposed them to CDI while they were in the VOLH. The antibiotics involved in the VOLH included third generation cephalosporins, quinolones and broad spectrum penicillins such as amoxicillin and co-amoxiclav (Augmentin).

A mixed pattern

Because of this mixed pattern of community and hospital prescribing, the role played by antibiotics prescribed outwith the VOLH also has to be recognised. There must have been cases where antibiotic prescribing in the community caused patients to become susceptible to contracting CDI following admission to the VOLH. Nevertheless, the

prescribing of antibiotics in the VOLH played a significant role in many of the patients in the focus group contracting CDI.

Antibiotics for conditions other than CDI – the expert evidence

The Inquiry medical experts, and in particular the microbiologists who examined the patient records of the focus group patients, identified some common areas for criticism in relation to antibiotic prescribing for conditions other than CDI. Once again, these criticisms have to be put in context, since the experts based their views on the patient records alone. One of the common themes that emerged was the inappropriate choice of antibiotic, although the poor documentation of the reasons for the choice of certain antibiotics might to some extent have contributed to this. In addition, the initial prescription of antibiotics in the VOLH was largely carried out by junior doctors, and as one of the Inquiry medical experts, Dr Harrington pointed out:

“there was an enthusiasm for starting antibiotic therapy before a clear diagnosis had been established which is understandable in inexperienced junior staff who are afraid that their patient will deteriorate unless treated immediately with powerful antibiotics”.²⁷⁹

Another expert, Dr Reid, drew this conclusion from his examination of the cases allocated to him:

“It was striking that there was a tendency to sort of, you know, shoot first and ask questions later when it came to antibiotics for suspected urinary tract infections”.²⁸⁰

From Dr Sheridan's perspective there was “scant evidence of any attempts to pursue a prudent antibiotic usage approach”.²⁸¹

Although senior review ought to have identified errors in prescribing by junior staff, the pressures on the senior medical staff already highlighted reduced the effectiveness of senior medical supervision.

277 [TRA00880050-51](#)
278 [INQ04700001](#)

279 [EXP02050005](#)
280 [TRA00530149](#)
281 [EXP01850001](#); [TRA00570078-79](#)

Some aspects of antibiotic practice

There was a significant number of instances where the reason for the choice of antibiotic was not apparent, or where it was evident that the antibiotic chosen was inappropriate. There was a general acceptance by the VOLH senior medical staff who gave evidence that the recording of the reasons why a particular antibiotic was chosen should have been better. There was also some acceptance that in certain cases the patient should not have been prescribed the antibiotic that was chosen. The following summaries set out some examples taken from the oral evidence in which the senior medical staff accepted criticism of the antibiotic treatment.

Elizabeth Valentine was prescribed and given ciprofloxacin when no such prescription should have been made. According to the oral evidence of the senior doctor responsible for the patient:

“that shouldn’t have happened ...Again this stems from the fact that junior doctors, middle grade, will change all the time and somebody will take an action without passing on the message to another person”.²⁸²

A urine sample taken from Mrs Valentine was reported as normal and at least at that stage the opportunity should have been taken to stop the antibiotic.²⁸³ The ciprofloxacin was continued for several days.²⁸⁴ Had the junior doctor recorded the prescription in the clinical notes the senior doctor would have become aware and stopped it.²⁸⁵ The subsequent change to Augmentin was likely to have been on the advice of the microbiologist, but the advice and the change were not recorded in the clinical notes.²⁸⁶ It also seems that this patient received lactulose after the diagnosis of *C. difficile* and that should not have happened.²⁸⁷

A decision taken in relation to Margaret Gaughan to change the antibiotic

therapy by prescribing ciprofloxacin, would not have been approved by the senior doctor if discussed with him.²⁸⁸ A combination of broad spectrum antibiotics prescribed while the patient was a patient in the Royal Alexandra Hospital (RAH) (moxifloxacin and cefaclor) was continued in the VOLH and that should not have happened.²⁸⁹ When the plan was changed to start ceftriaxone, an antibiotic recommended for a hospital-acquired pneumonia, the cefaclor was stopped but the moxifloxacin was not and that was an error.²⁹⁰

Sarah McGinty, who had a specimen of urine taken from her catheter, was prescribed trimethoprim when it was likely that she had asymptomatic bacteriuria.²⁹¹ Once the course had been completed and the report of a urine specimen indicated that the bacteria were resistant to trimethoprim, she was prescribed amoxicillin even although there were no clinical signs that she was suffering from a urinary tract infection. It was likely that Mrs McGinty had continuing asymptomatic bacteriuria.²⁹² The senior doctor in charge of this patient accepted in evidence that if the antibiotic prescription had been properly reviewed the antibiotic would have been stopped. Subsequently this patient was prescribed co-amoxiclav and clarithromycin for a chest infection. That combination may have been appropriate for a severe chest infection.²⁹³ There was no evidence of a severe chest infection and a narrower spectrum antibiotic would have been more appropriate.²⁹⁴ Once Mrs McGinty had been diagnosed with CDI, that antibiotic treatment should have been stopped or at least reviewed and modified.²⁹⁵ This was also a patient who was prescribed lactulose when she may have been suffering from diarrhoea. That should not have happened or at least the medication

282 [TRA00710117](#)

283 [TRA00710121](#)

284 [TRA00710122](#)

285 [TRA00710124](#)

286 [TRA00710131-132](#)

287 [TRA00710161](#)

288 [TRA00720016](#)

289 [TRA00720020-22](#)

290 [TRA00720023](#)

291 [TRA00740110-111](#)

292 [TRA00740113](#)

293 [TRA00740142](#); GGC00420012

294 [TRA00740144](#)

295 [TRA00740152](#)

should have been stopped when she had diarrhoea.²⁹⁶

Jessie Jones was prescribed ciprofloxacin for possible renal colic that was to be treated as if it were a complicated urinary tract infection.²⁹⁷ The results of tests should have led to the antibiotic being stopped or changed to a less broad spectrum antibiotic.²⁹⁸ The ciprofloxacin was in fact prescribed for eight days – the normal duration would be three days or five days for a severe infection.²⁹⁹

Ellen Gildea was prescribed co-amoxiclav for a suspected urinary tract infection on admission to the VOLH. The report on the urine sample was negative and the antibiotics should have been stopped once that information was available.³⁰⁰ There was an issue as to whether there was a delay in the information being made available to the ward. The patient continued to be prescribed co-amoxiclav from 30 January 2008 to 5 February 2008. The antibiotic was then stopped when she was reviewed by a senior doctor.

Mary Hamilton was prescribed ciprofloxacin and vancomycin with no reason given.³⁰¹ The ciprofloxacin should not have been started and furthermore, after a Laboratory Report showed that the bacteria were resistant to ciprofloxacin, it should have been stopped.³⁰² It was in fact continued for several days after production of the Laboratory Report.³⁰³

John Miller was appropriately started on co-amoxiclav for a suspected urinary tract infection. However, he continued to receive that antibiotic for ten days even although a Laboratory Report dated a week earlier indicated that the bacteria isolated were resistant to co-amoxiclav.³⁰⁴ There may have been undue delay in the

Laboratory Report becoming available, but the junior medical staff should have taken steps to determine the result.³⁰⁵

Dureena Chandayly was started on trimethoprim on admission to the VOLH for a suspected urinary tract infection. The Laboratory Report dated the following day indicated the culture was negative. She continued to receive trimethoprim for five days although the normal period according to the existing guidelines was three days.³⁰⁶ There may have been a delay in the Laboratory Report being available. Had the senior doctor involved been made aware of the result he would have stopped the antibiotic.³⁰⁷ Subsequently, the patient was prescribed co-amoxiclav for a pyrexia of unknown origin. The duration was too long and the opportunity should have been taken to review the prescription and stop it sooner.³⁰⁸

Janet Fitzsimmons, who presented with a number of problems, was prescribed Augmentin (co-amoxiclav) shortly after admission. There was no reference in the patient records to the potential sources of any infection.³⁰⁹ A Laboratory Report of a urine sample taken on admission disclosed that a fungal urinary tract infection was isolated.³¹⁰ It was not clear when that result was communicated to the ward but the Augmentin therapy should have been stopped. That did not happen for several days after the date of the Laboratory Report. Subsequently this patient was prescribed clarithromycin, a decision which was also debatable.³¹¹

296 [TRA00750022](#)

297 [TRA00750052-53](#)

298 [TRA00750058](#)

299 [TRA00750061](#)

300 [TRA00750074-77](#)

301 [TRA00810017](#)

302 [TRA00810018](#)

303 [TRA00810018](#)

304 [TRA00830070-72](#)

305 [TRA00830072](#)

306 [TRA00830095](#)

307 [TRA00830096](#)

308 [TRA00830099-100](#)

309 [TRA00830136](#)

310 [TRA00830138](#)

311 [TRA00830141](#)

Summary of trends of antibiotic prescribing for conditions other than CDI

There were many examples of appropriate prescribing of antibiotics for conditions other than CDI, particularly by the senior medical staff. There were also, however, many examples of inappropriate prescribing for such conditions. The trends can be summarised as follows.

- Poor documentation of choice, duration and reason for the prescription of antibiotics
- Continued prescription of antibiotics in cases where a laboratory test demonstrated the organism was resistant
- Prescription of antibiotics in cases where no antibiotic was necessary, for example, asymptomatic bacteriuria
- The prescription of loperamide and lactulose to patients who were suspected of having contracted CDI or indeed who had tested positive for *C. difficile* toxin
- The omission of doses from drug kardexes without explanation and the significant number of instances when an antibiotic was not given because it was not available

- Instances in which, even where antibiotics were appropriately prescribed, the course of treatment was protracted without any reason being recorded
- Failure to stop or to review antibiotic therapy once a patient had tested positive for *C. difficile* toxin

Antibiotic prescribing review

In response to the CDI problem that became apparent in June 2008, a rapid review of antibiotic use in Clyde hospitals was carried out by Dr Andrew Seaton, Consultant Physician in Infectious Diseases and General Medicine, and by pharmacist Ms Ysobel Gourlay in June and July 2008.³¹² Their analysis was constrained by time and lack of personnel and was limited to a review of commonly known agents known to predispose to CDI.³¹³ Nonetheless, they found higher volumes of co-amoxiclav, quinolones and cephalexin were dispensed in the VOLH compared with the other hospitals in Clyde relative to bed numbers.³¹⁴ The co-amoxiclav analysis³¹⁵ produced by their review is reproduced in Figure 14.1.

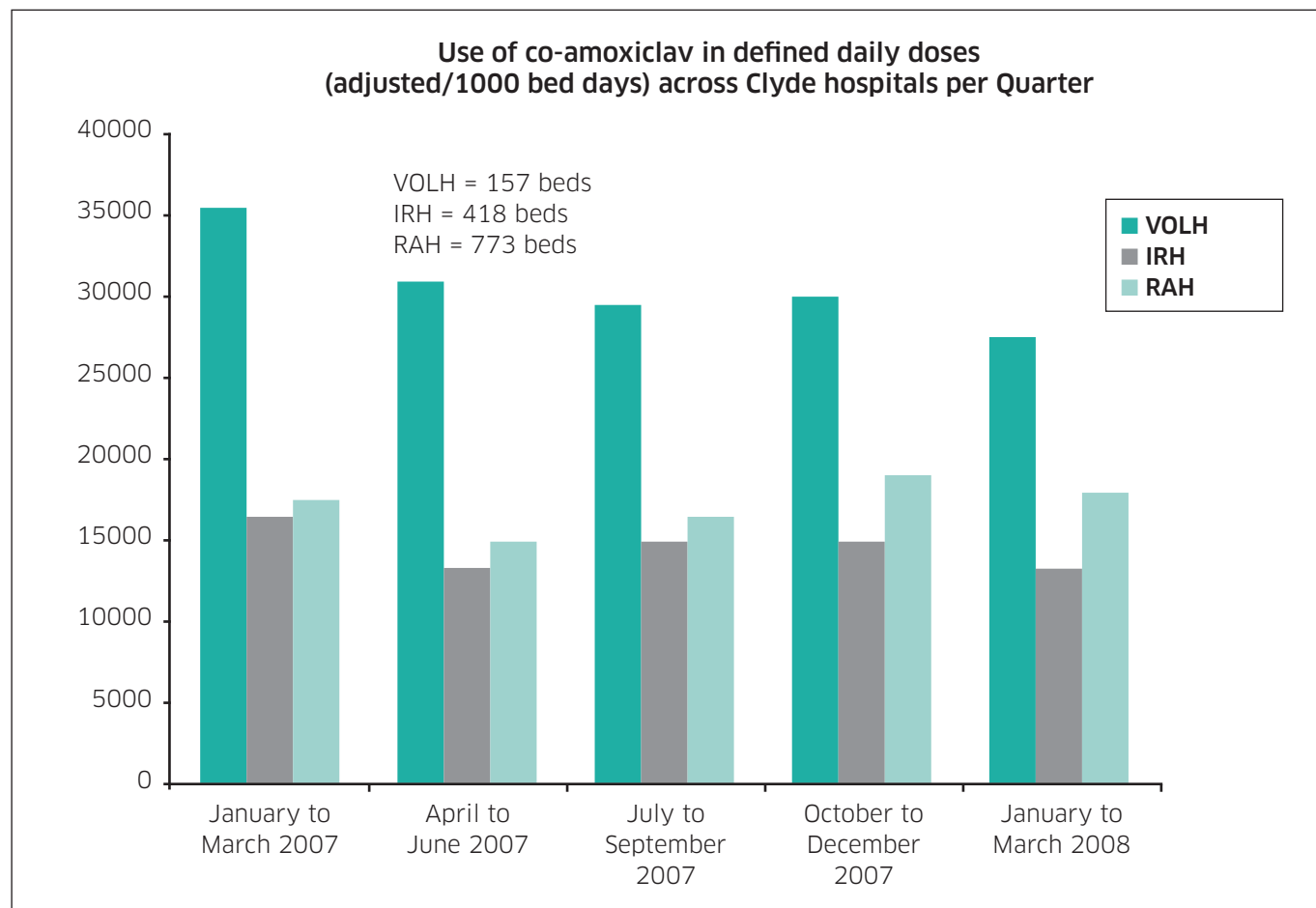
312 [GGC11060001](#)

313 [GGC11060003-04](#)

314 [GGC11060003-04](#)

315 [GGC11060006](#)

Figure 14.1 Co-amoxiclav use in Clyde hospitals



The VOLH has many fewer beds than either the IRH or the RAH. Figures have been adjusted for all three to represent an assumed figure of 1000 beds in each hospital and thus give an accurate basis for comparison. Figure 14.1 illustrates that throughout 2007 and into 2008 the rate of co-amoxiclav use at the VOLH was typically around double that of either of the other Clyde hospitals.

This analysis supports the conclusion arrived at by the Inquiry experts that there was inappropriate use of antibiotics at the VOLH for conditions other than CDI. After stricter controls were introduced in June 2008 there was a “precipitous reduction”³¹⁶ in the use of co-amoxiclav in hospitals in NHSGGC, including the VOLH.³¹⁷

Antibiotic treatment of *C. difficile* infection

The general consensus of the expert medical witnesses was that in most cases, once the treatment was started, appropriate antibiotic treatment by the prescription of metronidazole or vancomycin was given. The regularity of medical review and of assessment of symptoms has already been discussed. There were instances where ongoing monitoring should have led to a re-assessment of treatment with greater input from a microbiologist,³¹⁸ but there were also examples documented where the medical staff (generally the junior staff) did consult with a microbiologist and where advice on treatment was given and followed.³¹⁹

316 [TRA01150125](#)

317 [TRA01150125-126](#)

318 [TRA00640111](#); [TRA00630053](#)

319 [TRA00690026](#)

Some aspects of practice

There were instances where doses of the antibiotic prescribed for CDI were missed or at least not recorded on the drug kardex or the appropriate dosages were not given.³²⁰ This meant that the patient was receiving a sub-therapeutic dose.

In one case a patient only received half the recommended dose of vancomycin although a microbiologist had advised a more appropriate dose. This patient was inclined to wander, thereby increasing the risk of her infecting other patients. The expert microbiologist who looked at this case was not surprised that her CDI did not respond to the treatment.³²¹ A subsequent treatment plan devised by a microbiologist was not followed. The patient ended up suffering from a prolonged episode of CDI until eventually the correct dose was given to which she responded.³²² The doctor involved with this patient had a poor recollection of the reason for failure to follow the plan devised by the microbiologist.³²³

Consultation with consultant microbiologists

Because there was no microbiologist based at the VOLH in the period 1 January 2007 to 1 June 2008, it was necessary for medical staff at the VOLH seeking advice on antibiotic prescribing to telephone either the IRH or the RAH. The general impression gained by the experts who looked at the patient records of the patients in the focus group was that more use could have been made of the services of the medical microbiologists.

14.7 The process for testing for *C. difficile* toxin

Laboratory management

Certain aspects of the management and operation of the laboratory are considered in Chapter 15.

From 1 January 2007 to 1 June 2008 Mr Charles Kinloch³²⁴ was the Technical Head of

the Laboratory Support Services department at the VOLH.³²⁵ He had held that post since May 2005,³²⁶ and was responsible for all non-clinical aspects of the laboratory.³²⁷ Ms Marie Martin, General Manager, Diagnostics for Clyde, was his line manager.³²⁸

Laboratory hours

Mr Kinloch said that the VOLH laboratory was open from 08:40 to 17:00 Monday to Friday and 09:00 to 12:30 on Saturdays,³²⁹ although the VOLH Laboratory Manual provides slightly different times.³³⁰ There was also a 24 hour seven day service for the processing of emergency samples.³³¹ What constituted an emergency was a decision for medical staff. There were two collections of specimens on week days. One batch arrived at the laboratory at lunch time and the second batch arrived at around 15:00 hours,³³² and according to Mr Kinloch the general practice was that all specimens would be tested together just after the second batch arrived.³³³ If a Biomedical Scientist was available earlier, however, the testing of earlier samples could take place before 15:00 hours.³³⁴

Specimen collection process

Each ward had a collection point³³⁵ where stool specimens were kept pending collection by porters. For example, ward 6 had wall compartments located within the ward close to the entrance. Some wards had trays.³³⁶

If a specimen was taken from a patient on Saturday afternoon or Sunday, that specimen would not be received by the laboratory until Monday morning unless identified as an emergency specimen.³³⁷ There was evidence from one nurse that samples taken at night or at the weekend after Saturday morning

320 GGC21070188; [TRA00530028](#); [TRA00600129](#)

321 [TRA00600129](#)

322 [TRA00600131](#)

323 [TRA00760108](#)

324 [TRA00860096](#)

325 [TRA00860095-96](#)

326 [TRA00860097](#)

327 [TRA00860098-99](#)

328 [TRA00860099](#)

329 [TRA00860110](#)

330 [GGC24480007](#)

331 [TRA00860110-111](#)

332 [TRA00860119](#)

333 [TRA00860139-140](#)

334 [TRA00860139](#)

335 [TRA00310007](#)

336 [TRA00380143](#); [TRA00450074](#); [TRA00410134](#)

337 [TRA00860135](#)

could remain on the ward for some time.³³⁸ There was no facility for refrigeration or storage of specimens pending collection.³³⁹ There was some inconclusive evidence of a fast track procedure, particularly in ward F, which involved contacting the porter after the specimen had been collected³⁴⁰ from the patient, and such a system might have been in place for a period after the problem with *C. difficile* in the VOLH had been identified,³⁴¹ but Mr Kinloch did not know what was meant by the fast track procedure.³⁴²

Receipt by the laboratory

The laboratory operated a computerised Laboratory Information Management System (LIMS) system for recording the information which ultimately was entered onto the hard copy Laboratory Report Form. When a stool specimen was taken from the ward to the laboratory it was accompanied by a two part Request Form comprising a front copy and a carbon back copy.³⁴³ The front copy was retained at the laboratory reception area for entry on the LIMS system, and the back carbon copy went with the specimen into the laboratory itself.³⁴⁴ The date on which the specimen was taken was written on the Request Form by ward staff. That date was entered into the LIMS system. It was that date which generally thereafter appeared on the Laboratory Report Form.

The date of receipt by the laboratory was also entered on the LIMS system. According to Mr Kinloch, that date would nearly always reflect the date of actual receipt.

There were, however, occasions when the information was not entered into the LIMS system until the day after actual receipt.³⁴⁵ Dr Clarke thought that this was “often” the case,³⁴⁶ and in that event the date of receipt entered into the LIMS system was the default date generated by the computer, which was

the current date.³⁴⁷ This would explain why, for example, in one case the laboratory appeared to have made the ward aware of the positive result for *C. difficile* toxin before they had even received the sample.³⁴⁸

Testing methodology

The *C. difficile* toxin test used by the laboratory in 2007 to 2008 was known as the Techlab TOX A/B QUIK CHEK³⁴⁹ test. This type of test was in common use at that time,³⁵⁰ and its sensitivity, by which is meant the ability to detect a positive, was around 80%.³⁵¹ The Standard Operating Procedure for the *C. difficile* toxin test³⁵² envisaged that toxin positive results would be phoned to the ward and to the Infection Control Team, but in practice the Infection Control Nurse was the first port of call and the ward was contacted only if she was not available.³⁵³ The test itself (usually done in a batch)³⁵⁴ took approximately 45 minutes.³⁵⁵ According to Mr Kinloch, the general expectation was that all specimens received by the laboratory by 12:30 and 15:00 hours would be tested the same day and reported either to the Infection Control Team or the ward.³⁵⁶

Impact of a delay in treatment of CDI

When there is a suspicion of CDI it is important that a specimen taken is tested without undue delay and treatment started as soon as CDI is confirmed. Delay in the prescription and administration of appropriate antibiotic therapy for CDI can have a significant impact on the management of the condition. A delay in treatment tends to make the outcome worse, particularly if the patient continues to receive broad spectrum antibiotics.³⁵⁷ With few exceptions, the general practice adopted in the VOLH was that treatment for CDI was not started until a positive result was communicated by the laboratory. That represents normal practice,

338 [TRA00310010](#)
339 [TRA00310010](#); [TRA00380146](#)
340 [TRA00410134-135](#)
341 [TRA00370072-73](#)
342 [TRA00870118](#)
343 [TRA00870001-02](#)
344 [TRA00870002](#)
345 [TRA00870003](#)
346 [TRA00500089](#)

347 [TRA00870003](#)
348 GGC00090080-81; GGC00090202
349 [GGC28100004](#)
350 [TRA01050095](#)
351 [TRA00600102](#)
352 [GGC28100006](#)
353 [TRA00860143](#)
354 [TRA00860146](#)
355 [TRA00860146](#)
356 [TRA00860146-147](#)
357 [TRA00860150](#) [TRA00530068](#)

but it means that the time between taking a specimen and the result of that specimen being communicated to the ward and acted upon is of extreme importance to the appropriate management of a CDI patient.

Specimens in the focus period

The Inquiry has identified from patient records and from data from the LIMS system³⁵⁸ that in the period from 1 December 2007 to 1 June 2008 90 specimens tested positive for *C. difficile* toxin. For three of these results there is inadequate information available to allow an analysis of whether there was any delay between the taking of the specimen and the treatment commencing, but there was sufficient information available for the other 87.

Patient records had to be relied upon in analysing whether there were any significant delays between the taking of specimens and starting treatment, and the deficiencies identified in many of the patient records must be acknowledged. Nonetheless, assuming that those entries that are in the records are reasonably accurate, some trends can be observed.

Types of delay

The analysis carried out by the Inquiry revealed that there were delays in 32 out of the 87 positive results. That number included 15 specimens taken at weekends, when the laboratory did not process the specimens. In only six of those weekend cases, however, could the delay be attributed to the reduced weekend service. The other nine cases

included a day or more on either side of the weekend in addition to the weekend delay. It follows that, although in the majority of cases there were fewer than 24 hours between collecting specimens and commencing treatment, there was a significant number of cases in which a delay of some sort occurred.

There are potentially three types of delay:

1. A process delay: Such a delay could be caused while either transporting or processing the specimen. Here the approach taken was that a delay occurred where there was more than 24 hours between the specimen being taken from the patient and the ward becoming aware of the CDI result.
2. A delay in treatment: The task here was one of examining the patient records to see if there was any significant delay between the ward becoming aware of a positive CDI result and the patient commencing treatment.
3. A combined process and treatment delay: A delay in the transport or processing of specimens and a further delay in commencing treatment.

Delays in process

The Inquiry's analysis revealed 22 individual process delays where there were more than 24 hours between the specimen being collected from the patient and the ward becoming aware of the CDI result. That includes five instances of a process delay of four days. Table 14.6 sets out the delays in processing samples.

Table 14.6 Delays in process

Patient	Date specimen collected	Date ward aware of CDI result	Total delay
Isobel Cameron	03/12/07	05/12/07	2 days
Patient B	15/12/07 (Saturday)	17/12/07	2 days
Agnes Burgess	22/12/07	24/12/07	2 days
Isobel Cameron	02/01/08	04/01/08	2 days
Mary Broadley	12/01/08	14/01/08	2 days
Rosa Rainey	19/01/08 (Saturday)	21/01/08	2 days
David Somerville	07/02/08	11/02/08	4 days
Jean Beattie	09/02/08 (Saturday)	11/02/08	2 days
Mary Hamilton	11/02/08	13/02/08	2 days
Margaret Gaughan	14/02/08	18/02/08	4 days
Jessie Jones	16/02/08 (Saturday)	18/02/08	2 days
Elizabeth Valentine	21/02/08	25/02/08	4 days
David Somerville	29/02/08	04/03/08	4 days
Allan Lynch	07/03/08 (Friday pm)	10/03/08	3 days
David Somerville	16/03/08	18/03/08	2 days
Mary McDougall	10/04/08	14/04/08	4 days
David Somerville	04/05/08	07/05/08	3 days
Moira McWilliams	06/05/08	09/05/08	3 days
Charles Cook	07/05/08	09/05/08	2 days
Charles Cook	07/05/08	09/05/08	2 days
Muriel Waddell	14/05/08	16/05/08	2 days
George Drummond	17/05/08 (Saturday)	19/05/08	2 days

Delays in treatment after ward aware of CDI result

So far as the Inquiry could ascertain from the patient records, there were 18 instances

where there was a delay in treatment after the ward became aware of the positive CDI result. Table 14.7 sets out when these delays occurred, and the nature of the delays.

Table 14.7 Delays in treatment

Patient	Date ward aware of positive CDI result	Date treatment started	Total delay
Isobel Cameron	05/12/07	06/12/07	1 day
Agnes Burgess	24/12/07	25/12/07	1 day
Isobel Cameron	04/01/08	09/01/08	5 days
Isobel Cameron (x 2 samples)	08/01/08	09/01/08	1 day
Mary Broadley	14/01/08	15/01/08	1 day
Margaret Thompson	17/01/08	18/01/08	1 day
Mary Hamilton	22/01/08	23/01/08	1 day
Matthew Macfarlane	12/02/08	13/02/08	1 day
Mary Hamilton	13/02/08	14/02/08	1 day
Margaret Gaughan	18/02/08	21/02/08	3 days
Anne Gray	26/02/08	28/02/08	2 days
Coleman Conroy	10/03/08	11/03/08	1 day
David Somerville	18/03/08	19/03/08	1 day
Coleman Conroy	24/03/08	25/03/08	1 day
Margaret Kelly	15/04/08	17/04/08	2 days
David Somerville	07/05/08	08/05/08	1 day
Margaret Stevenson	15/05/08	16/05/08	1 day

Combined delays in process and treatment

There were a number of cases where there were combined delays in processing samples and in commencing treatment after the ward

became aware of the positive CDI result. Table 14.8 sets out eight instances of such delays including some delays of three to seven days.

Table 14.8 Combined process and treatment delays

Patient	Date specimen Collected	Date ward aware	Process delay	Date treatment started	Treatment delay	Total combined delay
Isobel Cameron	03/12/07	05/12/07	2 days	06/12/07	1 day	3 days
Agnes Burgess	22/12/07 (Saturday)	24/12/07	2 days	25/12/07	1 day	3 days
Isobel Cameron	02/01/08	04/01/08	2 days	09/01/08	5 days	7 days
Mary Broadley	12/01/08 (Saturday)	14/01/08	2 days	15/01/08	1 day	3 days
Mary Hamilton	11/02/08	13/02/08	2 days	14/02/08	1 day	3 days
Margaret Gaughan	14/02/08	18/02/08	4 days	21/02/08	3 days	7 days
David Somerville	16/03/08 (Sunday)	18/03/08	2 days	19/03/08	1 day	3 days
David Somerville	04/05/08 (Sunday)	07/05/08	3 days	08/05/08	1 day	4 days

Negative results

Between 1 January 2007 and 30 November 2007 (the early period) there were 432 negative results for *C. difficile* toxin. Ninety-five of those negative results were for patients who did test positive for *C. difficile* toxin at some point, either earlier or later.

Between 1 December 2007 and 1 June 2008 (the focus period) there were 298 negative results. Of those, 80 were results for patients who did test *C. difficile* toxin positive at some point.

The practice adopted for negative results was that the laboratory did not telephone the Infection Control Nurse or the ward to notify them of the result. Instead the negative result was entered into the computer system where it could be accessed. Once available and printed off, the report was placed in the patient records.

Generally, nursing and medical staff were unaware of a negative result until the hard copy Laboratory Report was received on

the ward. It should have been the general practice for nurses and doctors to contact the laboratory or access the computer system to check on a result. Reliance on receipt of the formal Laboratory Report increased the delay in the ward becoming aware of the negative result, which meant that any decision to re-test was delayed as was any consideration of an alternative diagnosis.

Process delays with negative specimens

It was possible to make some assessment of process delays in 68 of the 80 negative results for the focus group patients. Here the picture was very similar to that of the positive CDI results. There appeared to be frequent delays in transport, for in 41 of the 68 negative results the specimen did not reach the laboratory the same day as it was collected. This exercise has been carried out by reference to laboratory records only, and is subject to the reservation that those records were not always accurate, but on the information available there were apparent transport delays of two to six days in 19 out of 68 negative results.

Handling of samples – false negatives

As already mentioned, the test in use in the VOLH laboratory normally had the ability to detect toxin positive results in about 80% of cases. This would indicate therefore, that there were false negative results produced in at least 20% of cases.³⁵⁹ But in addition to that, delays in transporting stool specimens from the ward to the laboratory could cause specimens to degrade and produce a higher rate of false negative results.³⁶⁰ Although there were refrigerated storage facilities in the laboratory, there was no evidence that specimens were ever refrigerated when on the ward. Indeed, the contrary seems to have been the case.³⁶¹ Yet according to the Standard Operation Procedure for the *C. difficile* toxin test:

“Optimal results are obtained with samples which are < 24 hours old. Most specimens may be stored at 2-8°C for up to 72 hours before significant degradation of toxin is noted”.³⁶²

It is therefore highly probable that the lack of refrigeration, in conjunction with the delays in specimens reaching the laboratory, contributed to the number of false negative results produced. In examining the records of CDI patients during the focus period, the Inquiry’s microbiology experts were able to identify 16 separate instances where in their view a false negative result was produced³⁶³ but because of the way specimens were managed, especially on the wards, there were more false negative results than identified by the experts.

Conclusion on antibiotic prescribing

Chapter 13 explores the mismatch between the regular issuing of policy and guidance on prudent antibiotic prescribing in the years prior to the emergence of the CDI problem at the VOLH and the implementation of policy and guidance. In this Inquiry the scrutiny of antibiotic prescribing for conditions other

than CDI has disclosed that the message on prudent prescribing had not reached the VOLH. Subject to the specific exceptions set out in this Chapter, in general the prescribing practice for CDI in the VOLH was appropriate.

There should have been a more effective system in place for the prompt reporting of *C. difficile* toxin positive results. The weekend should not have meant that the system of collection, testing and reporting was in any way compromised. Patients are as liable to become symptomatic on weekend days as on any other days. The treatment and care of patients suffering from CDI demand a seven-days-a-week programme of care. The existence of a system of reduced weekend sampling, combined with the practice in the VOLH of not isolating patients prior to the production of a positive *C. difficile* toxin result, only served to increase the risk of cross infection.

The delays identified in commencing treatment after positive results were known by the ward are inexcusable. These were patients who were suffering from a serious and potentially life threatening infection. Furthermore, a delay in treatment for CDI means that no assessment is made of the existing antibiotic treatment the patients might be receiving. This Chapter has also identified delays in the processing of specimens that produced false negative results.

The 32 separate delays between obtaining a specimen and commencing treatment occurred for 23 patients. Fifteen of those patients died and according to Professor George Griffin, the Inquiry’s infectious diseases expert, for 13 of those patients *C. difficile* was the cause or a contributory factor in their deaths. These were patients with co-morbidities and it is likely that their survival would not have been greatly extended had they not contracted CDI. Nonetheless, the delay in treatment of such patients reflected an extremely poor standard of nursing and medical care.

359 [TRA00600101-102](#)

360 [TRA00640028-29](#); [TRA00600101](#)

361 [TRA00310010](#); [TRA00380146](#)

362 [GGC28100006](#)

363 EXP01460010; EXP01470010; EXP01490011; EXP01530012; EXP01570010; EXP01620012; EXP01640011-12; EXP01750010; EXP01760009; EXP01780013; EXP01820010; EXP01980014; EXP01990034; EXP02100006

14.8 Overall conclusion

The overall quality of record keeping by junior doctors was poor. Problems with the recruitment of medical staff and a lack of middle grade medical staff meant that the consultants at the VOLH were overstretched. Junior doctors had the greater involvement with patients. There was a clear trend that assessments of the condition of many patients suffering from CDI were not being recorded which suggests that no assessments were being made. The frequency of the medical review of patients suffering from CDI was inadequate. Because consultants were overstretched, junior doctors at the VOLH were not being properly supervised. Although there were examples of appropriate prescribing of antibiotics for conditions other than CDI there were also many examples of inappropriate prescribing. The delays identified between the obtaining of a stool specimen and the commencement of antibiotic treatment after a positive test, particularly after the results were known, were inexcusable.

The failures identified in this Chapter will have compromised patient care. No doubt there were failures by individuals but the ultimate responsibility for standards having become unacceptable must rest with NHSGGC.

14.9 Recommendations

Recommendation 36: Health Boards should ensure that the level of medical staffing planned and provided is sufficient to provide safe high quality care.

Recommendation 37: Health Boards should ensure that any patient with suspected CDI receives full clinical assessment by senior medical staff, that specific antibiotic therapy for CDI is commenced timeously and that the response to antibiotics is monitored on at least a daily basis.

Recommendation 38: Health Boards should ensure that clear, accurate and legible patient records are kept by doctors, that records are seen as integral to good patient care, and that they are routinely audited by senior medical staff.

Recommendation 39: Health Boards should ensure that medical and nursing staff are aware that a DNAR decision is an important aspect of care. The decision should involve the patient where possible, nursing staff, the consultant in charge and, where appropriate, relatives. The decision should be fully documented, regularly reviewed and there should be regular auditing of compliance with the DNAR policy.

Recommendation 40: Health Boards should ensure that the key principles of prudent antibiotic prescribing are adhered to and that implementation of policy is rigorously monitored by management.

Recommendation 41: Health Boards should ensure that there is no unnecessary delay in processing laboratory specimens, in reporting positive results and in commencing specific antibiotic treatment. Infection control staff should carry out regular audits to ensure that there are no unnecessary delays in the management of infected patients once the diagnosis is confirmed.

Chapter 15

Infection prevention
and control

	Page
Introduction	265
15.1 The constitution of an Infection Control Team	265
15.2 The Infection Control Team for the VOLH	266
15.3 The infection prevention and control management structure	270
15.4 Implementation of policies and training	272
15.5 The Infection Control Manager	280
15.6 The Nurse Consultant	284
15.7 The infection control committee structure	286
15.8 Reporting within the infection control committee structure	294
15.9 The failure of the committee structure	298
15.10 Surveillance systems	301
15.11 Failure to identify outbreaks	306
15.12 Role of the Microbiologists	320
15.13 The Infection Control Doctor	326
15.14 Knowledge of Dr Biggs' failure as Infection Control Doctor	331
15.15 The secondment issue	335
15.16 The reporting of <i>C. difficile</i> data to Health Protection Scotland and the Public Health Protection Unit	341
15.17 Statistical Process Control Charts	343
15.18 The VOLH Laboratory accreditation	345
15.19 Risk registers	346
15.20 Hygiene, environment and audits	349
15.21 Changes after June 2008	361
15.22 Conclusion	367
15.23 Recommendations	368

Introduction

Mr Thomas Divers, the NHSGGC Chief Executive, did not become aware of the longstanding *C. difficile* infection (CDI) problem at the VOLH until June 2008.¹ At the first meeting of the Outbreak Control Team on 10 June 2008 the results of the retrospective investigation into the period from 1 December 2007 to 31 May 2008 (the focus period) were available.² The extent of the current CDI problem was by then apparent and the risk matrix classification already referred to in Chapter 7 was now red.³ The Inquiry's remit, however, also includes the period from 1 January 2007 to 30 November 2007 (the early period). It is clear that the CDI problem also existed during that period, and as set out in Chapter 5 it is highly likely that there were outbreaks of CDI during the early period.

Management at all levels should have become aware of the problem in 2007. In particular the Chief Executive of the Health Board, as the person with ultimate responsibility for infection prevention and control, should have been made aware of the problem. When Mr Divers did become aware of the extent of the problem in June 2008, he did not know in detail what had "brought about such a protracted series of events".⁴ He did, however, realise that:

"things had gone far wrong and that, at a number of levels, there were likely to have been failures in the control and management arrangements".⁵

As set out in this Report, the Inquiry endorses that conclusion.

The intention in this Chapter is to discuss the infection prevention and control arrangements for the VOLH during the period 1 January 2007 to 1 June 2008. The Chapter also explores why the extent of the CDI problem was not identified by senior management until June 2008. The main changes made to the infection prevention

and control arrangements in response to the discovery of the problem are considered. What this Chapter discloses is a catalogue of serious individual and systemic failures that combined to place patients at risk and caused unnecessary suffering and deaths.

15.1 The constitution of an Infection Control Team

Guidance

Clear guidance has been in place on the constitution of an Infection Control Team since at least the publication of the Healthcare Associated Infection Control Standards⁶ by the Clinical Standards Board for Scotland (CSBS) (the CSBS Standards) in December 2001. The overarching Standard statement sets out the need for the creation of a "managed environment which minimises the risk of infection to patients, staff and visitors".⁷

The function of the Infection Control Team

The CSBS Standards required an appropriately constituted and functioning Infection Control Team.⁸ The rationale behind that provision was the importance of having in place a team responsible for the "day-to-day implementation of the Infection Control Programme"⁹ that can provide advice on infection control and manage patients with infection.

The membership of the Infection Control Team

The CSBS Standards stipulated that the Infection Control Team should include an Infection Control Doctor (ICD) and Infection Control Nurses (ICNs). The team was to be supported by dedicated secretarial, IT and audit staff. Members of the team had to be trained in infection control.¹⁰

The Infection Control Doctor as leader of the team

The Watt Group Report of 2002¹¹ also highlighted the importance of the role of the

1 [TRA01250057](#)
2 [GGC11140003](#)
3 [GGC11140004](#)
4 [TRA01250057](#)
5 [TRA01250057](#)

6 [GOV00160001](#)
7 [GOV00160017](#)
8 [GOV00160032](#)
9 [GOV00160032](#)
10 [GOV00160033](#)
11 [GOV00130001](#)

Infection Control Team in the management of healthcare associated infection (HAI), and recommended that the ICD should be the leader of the Infection Control Team.¹² The recommendation on this issue also provided that the ICDs would have “designated sessions” and a clearly defined job description for this component of their work.¹³ The CSBS Standards provided that the “contracted sessions per week”¹⁴ for the ICD were to be defined and agreed.

NHSGGC Infection Control Teams

NHSGGC had Infection Control Teams in place for the sectors that made up the NHSGGC area. The VOLH was in the Clyde Sector as was the RAH and the IRH.

15.2 The Infection Control Team for the VOLH

Infection Control Nurses

From January 2007 to July 2007 Mrs Jean Murray and Mrs Helen O’Neill were respectively Senior Infection Control Nurse and Infection Control Nurse at the VOLH. From July 2007 until her retirement in April 2008 Mrs Murray took on the post of interim Lead Nurse for Infection Control for the Clyde Directorate, taking on responsibility for four ICNs at the Inverclyde Royal Hospital (IRH) and four at the RAH in addition to Mrs O’Neill at the VOLH. Mrs Murray remained based at the VOLH,¹⁵ but the post was a full-time one,¹⁶ and while Mrs Murray retained some hands-on involvement in infection prevention and control at the VOLH the major part of the workload there was borne by Mrs O’Neill.

Infection Control Doctor

The ICD was Dr Elizabeth Biggs. She was also the ICD for the RAH and for the IRH, where she was based. Dr Biggs’ role as ICD was taken over by Dr Linda Bagraade in early February 2008.

12 [GOV00130030](#)
13 [GOV00130030](#)
14 [GOV00160033](#)
15 [TRA01010010](#)
16 [TRA01010012](#)

Non-clinical support staff

In 2006 and up to December 2007 Mr Craig Nixon was attached to the Infection Control Team at the VOLH with the job title of “Quality and Effectiveness Facilitator”.¹⁷ He managed the infection control database¹⁸ and was responsible for producing the quarterly reports on infection rates¹⁹ referred to later in this Chapter. When he left in December 2007 his post was not filled.

Mrs Isobelle McIntyre was the secretary to the Infection Control Team at the VOLH. She had held this post since November 2006,²⁰ and still held it at the time she gave evidence to the Inquiry in March 2012. She shared an office with Mr Nixon prior to his departure in December 2007.²¹

The Infection Control Nurse

Mrs O’Neill qualified as a nurse in 1975²² and has spent her working life in the VOLH. She became an ICN in August 2002.²³ She completed the Cleanliness Champions Programme (CCP) in 2006²⁴ but did not obtain a qualification in infection prevention and control. Her job description²⁵ envisaged that she would hold or would be willing to work towards a post-registration degree or diploma in infection control nursing,²⁶ but despite that provision Mrs O’Neill was unsuccessful in obtaining such a qualification and stopped working towards it in 2006.²⁷ Gaining a qualification in infection prevention and control should have been an essential requirement of Mrs O’Neill remaining in the post of ICN.

Included in Mrs O’Neill’s job description was the duty to:

“Interpret surveillance data and communicate findings via reports and meetings to the appropriate users”.²⁸

17 [TRA00920005](#)
18 [TRA00920010](#)
19 [TRA00920007](#)
20 [TRA00920033](#)
21 [TRA00920034](#)
22 [TRA00950001](#)
23 [TRA00950002](#)
24 [TRA00950004](#)
25 [INQ00380001](#)
26 [INQ00380011](#)
27 [TRA00950017-18](#)
28 [INQ00380004](#)

In her evidence, however, Mrs O'Neill said that she did not carry out that function and left it to Mrs Murray.²⁹ Her job description also envisaged that she would communicate with the ICD in relation to day-to-day infection control issues, placement of patients and information on infection and communicable diseases.³⁰ In practice Mrs O'Neill did not have regular contact with Dr Biggs.³¹

Mrs O'Neill's hours of work were from Monday to Friday from 9am to 5pm. There was no ICN cover at the VOLH at the weekends.³²

The Lead Nurse for Infection Control

Mrs Murray qualified as a registered nurse in 1989. She first took up a post as ICN in 1999 with Liverpool Health Authority, and had infection prevention and control qualifications including the English National Board Qualification for Infection Control. She was appointed to the post of ICN at the VOLH in October 2001,³³ becoming interim Lead Nurse for Infection Control for the Clyde Directorate in July 2007. Her line manager was the Head Nurse for Infection Control, Mrs Annette Rankin. Mrs Murray saw her line manager once or twice a month.³⁴

Mrs Murray thought that there were not many days when she was not present at the VOLH at some point during the day.³⁵ She said it was one of her responsibilities to make herself aware of the number of cases of CDI in the VOLH and to see whether there was an increase in such cases,³⁶ as well as to investigate the possibility of an outbreak.³⁷ Mrs Murray's job description envisaged that she would "Work closely with the relevant Infection Control Doctors ...".³⁸ That did not happen in practice when Dr Biggs was the ICD.³⁹

Mrs Murray commenced a phased retirement process in January 2008, so that over the following three months her working days were reduced. In January she worked four days a week, in February three days a week and in March two days a week. She stopped working on 17 March 2008, although she did not formally retire until April 2008.⁴⁰

The next Lead Nurse for Infection Control

Ms Joan Higgins became interim Lead Nurse for the Clyde Sector on 9 April 2008⁴¹ as the successor to Mrs Murray. Ms Rankin became her line manager.⁴² When she took up her post, Ms Higgins was based at the RAH. Like Mrs Murray, Ms Higgins was responsible for the VOLH, the RAH and the IRH,⁴³ although she only retained responsibility for the VOLH until July 2008.⁴⁴ She had no handover from Mrs Murray, who had already left.⁴⁵

Ms Higgins first visited the VOLH on 11 April 2008 and met Mrs O'Neill and Mrs McIntyre. There was no indication, particularly from Mrs O'Neill, that there was any concern over CDI at that time.⁴⁶ After her first visit to the VOLH on 11 April 2008 Ms Higgins visited the VOLH on a weekly basis until the CDI problem became evident.⁴⁷ She participated in the investigation in May and June 2008.

Dr Biggs

Dr Biggs qualified in 1977 with an MBChB degree from Glasgow University. She became a member of the Royal College of Pathologists in 1984. She became a Consultant Microbiologist in 1986 and since then had worked mainly at the IRH.⁴⁸

As discussed later in this Chapter, Dr Biggs was the ICD for the VOLH in the period from 1 January 2007 to 1 February 2008. As already mentioned she was also the ICD for the RAH and the IRH. The evidence was that Dr Biggs rarely attended at the VOLH. Her line manager, although not her professional

29 [TRA00950011-12](#)
30 [INQ00380009](#)
31 [TRA00950015](#)
32 [TRA00950007](#)
33 [TRA01010001-03](#)
34 [TRA01010017](#)
35 [TRA01010017](#)
36 [TRA01010023](#)
37 [TRA01010024](#)
38 [GGC30480002](#)
39 [TRA01010019](#)

40 [TRA01010016](#)
41 [TRA00990003](#)
42 [TRA00990006](#)
43 [TRA00990007](#)
44 [TRA00990015](#)
45 [TRA00990016](#)
46 [TRA00990023-25](#)
47 [TRA00990026](#)
48 [SPF01460002](#)

line manager, was Ms Marie Martin, General Manager, Diagnostics for Clyde. Ms Martin's position is considered later in this Chapter, as is the position of Dr Biggs' professional line manager.

Dr Biggs' job description⁴⁹ placed her under a duty to take "a lead role in the effective functioning of the Infection Control Team ..."⁵⁰ at the hospitals for which she was the ICD. The job description also provided that the ICD would "attend all meetings" and be "an active member of the Hospital Infection Control Committee".⁵¹ Her responsibilities included investigating outbreaks of hospital infections and supporting the ICNs in their "day-to-day activities".⁵²

As already mentioned, the ICD is the clinical leader of the Infection Control Team. As far as the VOLH was concerned Dr Biggs failed comprehensively to carry out her responsibilities as the ICD. As discussed later in this Chapter, her failure as ICD made a real contribution to the development and undetected continuation of the serious CDI problem at the VOLH.

Dr Bagnade

Dr Bagnade thought she took on the role of ICD for the VOLH on 4 February 2008.⁵³ She also became the ICD for the RAH.⁵⁴

Dr Bagnade qualified as a medical doctor in 1997 from the Medical Academy of Latvia. She acquired some further qualifications, including a professional qualification in medical microbiology, from the Latvian Medical Microbiology Association in 2004.⁵⁵ Dr Bagnade first worked in Scotland as a specialist registrar in medical microbiology in 2006, and took up the post of Consultant Microbiologist at the RAH on 21 January 2008.⁵⁶ The RAH was her base even when she became ICD for the VOLH in early February 2008. Her line manager was Ms Martin.⁵⁷

Dr Bagnade first visited the VOLH in the second half of February 2008,⁵⁸ when she met Mrs Murray, Mrs O'Neill, Mrs McIntyre⁵⁹ and Mr Charles Kinloch, Technical Head for Microbiology at the VOLH.⁶⁰ Dr Bagnade did ask Mrs Murray and Mrs O'Neill if there were any problems,⁶¹ but neither of them identified any during that visit.⁶² Dr Bagnade said that after that first visit she visited the VOLH up to the beginning of May "more or less once a week, sometimes it was even more frequent ...".⁶³

Dr Bagnade remained in ignorance of the numbers of CDI cases in the VOLH after her appointment as ICD in early February. Nevertheless her practice of regular visits to the VOLH was in stark contrast to the attitude previously adopted by Dr Biggs.

Appraisal of Infection Control Team members

Although a process should be in place to regularly discuss and review the work of an employee in the course of a year, formal appraisals are important for a number of reasons. Firstly, the appraisal process presents individual employees with the opportunity to inform their appraiser of how they are finding their work. They can advise whether they are receiving appropriate support in that work and whether they consider that some additional training is necessary. Secondly, appraisals provide more senior staff with the opportunity to review an employee's performance against the agreed job plan and provide feedback on performance. They can identify whether further training may be required and ensure that the employee is fully aware of what is expected in the job.⁶⁴ Thirdly, appraisals provide an opportunity to agree the job plan and set clear priorities and objectives for the year ahead.

As line manager it should have been Mrs Murray's responsibility to carry out

49 [GGC32170001](#); [INQ05180001](#)

50 [GGC32170001](#)

51 [GGC32170001](#)

52 [GGC32170003](#)

53 [TRA01140001](#)

54 [TRA01140002](#)

55 [INQ03560001](#)

56 [TRA01020061](#)

57 [TRA01020084](#)

58 [TRA01020089](#)

59 [TRA01020090](#)

60 [TRA01020093](#)

61 [TRA01020100](#)

62 [TRA01020100-102](#)

63 [TRA01020104](#)

64 [TRA01040017](#)

appraisals of Mrs O'Neill.⁶⁵ Yet in the time she worked as an ICN at the VOLH, from 2002 to 2008,⁶⁶ Mrs O'Neill never had an appraisal carried out.⁶⁷ Mrs Murray said that there was no appraisal system in place during her time at the VOLH,⁶⁸ which was from October 2001⁶⁹ to March 2008.⁷⁰

The absence of a system of appraisals was not limited to the VOLH. Ms Rankin, as Mrs Murray's line manager from April 2007, would have been responsible for carrying out her appraisal, but Ms Rankin also said that there was no formal appraisal system in place.⁷¹ She did, however, assess Mrs Murray's performance through observation and feedback and discuss objectives with her. These were short-term objectives relating to integration with Greater Glasgow Health Board (GGHB) because Mrs Murray was due to retire in April 2008.⁷²

Although Dr Biggs suggested in one of her police statements and to the Internal Investigation that between May 2007 and July 2008 she did not have a line manager,⁷³ or that she did not know who her line manager was, that suggestion is not correct. As discussed in this Chapter, Ms Martin was her line manager and remained so up to June 2008. What Dr Biggs may, however, have been referring to is her professional line management during that period, and what she is noted as saying at her interview by the Internal Investigation panel is in the context of there being no Clinical Director.⁷⁴ This separation of line management roles is because appraisals for medical staff were carried out by another doctor.⁷⁵

Dr Geoffrey Douglas, who was Clinical Director, was Dr Biggs' professional line manager until 15 April 2006, but was then off work due to illness, and on his return

in September 2007 did not resume his professional line management duties.⁷⁶ There is no evidence that Dr Biggs had an appraisal carried out in the period 1 January 2007 to June 2008, and one of the issues identified during the VOLH Laboratory inspection on 18 and 19 September 2007⁷⁷ was that an appraisal for Dr Biggs was "not available".⁷⁸ In contrast, the inspectors were able to conclude that the appraisal for Dr François de Villiers, Consultant Microbiologist at the IRH, was over six months overdue.⁷⁹

The aim of a formal appraisal is at least in part to provide assurance about competence and fulfilment of the requirements of the job. An appraisal of Dr Biggs should have identified that she was not performing her ICD role for the VOLH.

The absence of a formal system of appraisals and the apparent absence of an appraisal of Dr Biggs during this period are just one aspect of the sub-standard management arrangements for the Infection Control Team at the VOLH.

Mrs O'Neill's lack of qualification

As mentioned earlier in this Section, Mrs O'Neill stopped working towards an infection prevention and control qualification in 2006. Her position should certainly have been reviewed by Mrs Murray as her line manager in the light of that, and the absence of a system of appraisals no doubt contributed to that failure to review. Dr Biggs was also aware of the position⁸⁰ and had a professional responsibility as the Infection Control Doctor prior to February 2008 to address this issue. The situation became particularly acute when Mrs Murray was on phased retirement from January 2008. This is discussed later in this Chapter.

65 [TRA00950022](#)

66 [TRA00950002](#)

67 [TRA00950022](#)

68 [WTS01170012](#)

69 [TRA01010001-03](#)

70 [TRA01010016](#)

71 [TRA01000004](#)

72 [TRA01000004](#)

73 [SPF01460003](#); [GOV00890099](#); [GOV00890101](#)

74 [GOV00890099](#)

75 [TRA01250011](#)

76 [TRA01250021-26](#)

77 [GGC30380001](#)

78 [GGC30380001](#)

79 [GGC30380001](#)

80 [SPF01460004](#)

15.3 The infection prevention and control management structure

Infection Control Team set-up

From 1 September 2007⁸¹ wards 14, 15 and F were fully integrated with the NHSGGC Rehabilitation and Assessment Directorate with Ms Anne Harkness as the Director, while the remaining wards, including wards 3, 5 and 6, remained within the Clyde Directorate where Mrs Deborah den Herder was the Director. That meant that in the VOLH two different Directors had parallel but separate responsibilities within the same hospital for different wards.⁸² The two Directorates were served by the same Infection Control Team, however, and had the same infection control line management structure. The Fruin and Christie wards in the VOLH were part of the community healthcare partnership and had a separate Infection Control Team from the rest of the hospital.

Line management – Mrs Murray and Mrs O’Neill

As discussed in the previous Section, Mrs Murray was line manager for Mrs O’Neill until her retirement in April 2008, when Ms Higgins took over that responsibility.

From about 23 April 2007 Ms Annette Rankin became the Infection Control Head Nurse for NHSGGC.⁸³ Prior to that date she had been acting Head Nurse for Infection Control for Glasgow acute services.⁸⁴ As the Head Nurse for Infection Control she became managerially and professionally responsible for all the Lead Nurses for Infection Control⁸⁵ in NHSGGC, which meant that when Mrs Murray became interim Lead Nurse for Infection Control for the Clyde Sector Ms Rankin became her line manager.⁸⁶ When Ms Higgins succeeded Mrs Murray on 9 April 2008⁸⁷ Ms Rankin also became her line manager.⁸⁸

Ms Rankin took up her first post as ICN in 1995.⁸⁹ Her qualifications included an MSc in infection control from the University of the Highlands and Islands.⁹⁰ Ms Rankin’s job description provided that she was to “lead and manage both the infection control nursing service and function”.⁹¹ Thomas Walsh, Infection Control Manager for NHSGGC, was her professional line manager, at least from the time he took up post in June 2007.

Line management – Ms Martin

Subject to the question of her secondment, which is examined later in this Chapter, Ms Martin had been the General Manager of Diagnostic Services for the Clyde Sector since April 2006.⁹² In addition to having responsibilities for radiology, Ms Martin’s remit included infection prevention and control,⁹³ with responsibility to ensure that there was adequate staff in place and that the staff had the resources and the systems in place to allow them to do their job.⁹⁴ Ms Martin reported to Mrs den Herder, who was her line manager. Within the infection control structure for the Clyde Sector Ms Martin was the designated line manager for Dr Biggs and Ms Rankin,⁹⁵ and also became Dr Bagnard’s line manager following her appointment in February 2008.⁹⁶

Line management and phased retirement/absence

No additional resources were made available during the time of Mrs Murray’s phased retirement and there was no evidence that priorities were agreed during this period. Mrs O’Neill was on annual leave from 7 February to 18 February 2008, and there was no direct cover for her. Mrs Murray herself had duties as interim Lead Nurse as well as being in the midst of her phased retirement programme, with reduced working hours. It was at this point that a particular problem with CDI developed in ward F at the VOLH, and this is described in Section 15.4.

81 [TRA01180096](#)

82 [TRA01180099](#)

83 [TRA00990129](#)

84 [TRA00990129](#)

85 [TRA00990130](#)

86 [TRA00990130](#)

87 [TRA00990003](#)

88 [WTS01090001](#)

89 [TRA00990128](#)

90 [TRA00990146](#)

91 [GGC30200001](#); [TRA00990129](#)

92 [TRA01160001](#)

93 [TRA01160001](#)

94 [TRA01160010](#)

95 [TRA01160005](#)

96 [TRA01020084](#)

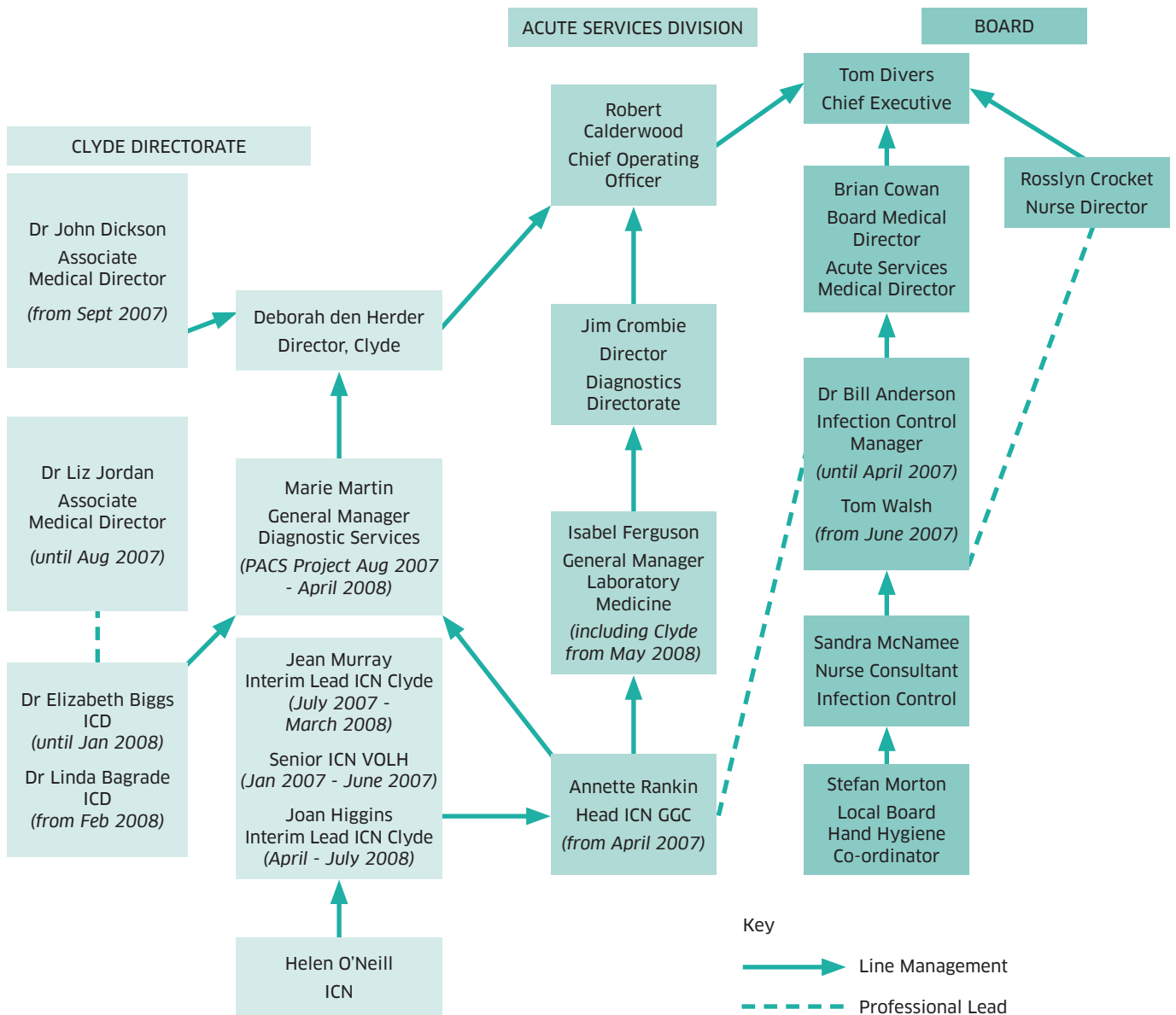
Ms Martin was fully aware of the arrangements for Mrs Murray’s phased retirement.⁹⁷ Given Ms Martin’s responsibility for ensuring that there was an adequate number of staff in place,⁹⁸ she should have addressed the obvious gap created by Mrs Murray’s phased retirement, particularly when Mrs O’Neill did not have an infection control qualification and required supervision. It was only after Mrs Murray

fully retired that cover was provided from the RAH.⁹⁹ The combined impact of Mrs O’Neill’s annual leave and Mrs Murray’s phased retirement created an obvious gap. This gap was a significant one.

Line management – senior management

Figure 15.1 sets out the infection control management structure at the VOLH in the period January 2007 to June 2008.

Figure 15.1 The infection control management structure at the VOLH in the period January 2007 to June 2008



97 [GGC32980001; GGC33010001](#)
 98 [TRA01160009-10](#)

99 [TRA01020030](#)

As Chief Executive Mr Divers had ultimate responsibility for infection prevention and control in the VOLH in the period from 1 January 2007 to 1 June 2008.¹⁰⁰ Within the Clyde Directorate Mrs den Herder as Director had line management responsibility for infection prevention and control with a reporting line to Mr Robert Calderwood, then Chief Operating Officer, Acute Services.

15.4 Implementation of policies and training

Infection Control Manual

The NHSGGC Infection Control Manual¹⁰¹ contained policies relevant to infection prevention and control. In the opinion of Professor Duerden, an infection control expert commissioned by the Inquiry, the policies in place were entirely appropriate.¹⁰² The manual was available in the wards¹⁰³ and was also accessible online on the VOLH intranet.¹⁰⁴ Professor Duerden did say that the manual as a whole was not user friendly, and that in addition laminated documents or posters available in appropriate places would have been more accessible to staff.¹⁰⁵ There is a limit on how many laminated signs can be in use at a given time, but a selection reinforcing important messages would have been appropriate.

Loose Stools Policy

In the two successive versions of the Loose Stools Policy¹⁰⁶ in force from 1 January 2007 to 1 June 2008 the important guidance for present purposes is identical. Loose stools were identified as “potentially infectious diarrhoea”. The precautions to be taken for patients with loose stools included placing such a patient in a single room or, if the patient was clinically unsuitable for isolation, a risk assessment was to be undertaken by the clinical team in conjunction with a member of the Infection Control Team.¹⁰⁷ A care plan was to be prepared for each

patient. All episodes of loose stools and actions taken were to be documented on a stool or fluid balance chart and in the medical or nursing records. A notice was to be put on the door of the patient’s isolation room. Information on loose stools and the prevention of cross-infection was to be provided to the patient and also to the next of kin.¹⁰⁸ The policy also contained a specific instruction to consider the possibility of CDI, especially if the patient was over 65. Importantly, the policy warned that if the precautions set out were not taken then an outbreak could easily occur.

C. difficile Policy

The *C. difficile* Policy¹⁰⁹ provided detailed information on the nature of the infection and the precautions to be taken with patients suffering from the infection. It highlighted the fact that the hands of healthcare workers and patients were the most common means of spread of infection. There could also be indirect spread of environmental contamination through equipment and instruments, such as commodes and bedpans.¹¹⁰ The people identified as most at risk from the infection were patients who were currently on antibiotics or who had had antibiotic therapy within the last eight weeks.¹¹¹ Wards where antibiotic use was high were identified as being a high risk environment.

The policy also provided that a care plan was to be put in place and that healthcare workers had to avoid exposure by wearing personal protective equipment. The importance of hand hygiene was emphasised, and in particular the fact that soap and water had to be used in conjunction with alcohol hand rub. Hands were to be decontaminated before and after each direct patient contact regardless of whether protective equipment was worn. The movement of patients between wards without prior consultation with the Infection Control Team was not advisable, except in cases of clinical emergencies. As was the case with the Loose Stools Policy, the *C. difficile* Policy warned

100 [TRA01250050-51](#); [GOV00380001](#)

101 [GGC00780001](#)

102 [TRA01050118](#)

103 [TRA00290113](#)

104 [WTS00680006](#); [TRA00810088](#); [TRA00800053-54](#)

105 [TRA01050120-121](#)

106 [GGC00780258](#); [GGC27590001](#)

107 [GGC00780259](#)

108 [GGC00780260](#)

109 [GGC00780252](#)

110 [GGC00780253](#)

111 [GGC00780253](#)

that an outbreak was likely if the infection control precautions stipulated in the policy were not followed.¹¹²

The guidance given on treatment was that if possible all current antibiotics should be discontinued and in the first instance metronidazole should be given. The policy also stipulated that loperamide (Imodium), an opiate anti-diarrhoeal agent, was not to be given to control diarrhoea.¹¹³

Outbreak Policies

Some of the provisions of the Outbreak Policies in place have already been discussed in Chapter 12. Of particular note are the definition of an outbreak as two or more linked cases of the same illness associated in person, place or time¹¹⁴ and the steps to be followed if an outbreak was suspected or confirmed, which included communication by the Infection Control Team with Management.¹¹⁵

Medical training and implementation of policies

None of the ward-based doctors who gave evidence had received any training in infection prevention and control prior to June 2008 other than as part of their undergraduate training,¹¹⁶ although some may have attended a presentation in January 2007 by Mrs Murray and Dr Barbara Weinhardt, Consultant Microbiologist, on CDI outbreaks at Stoke Mandeville Hospital and in Quebec.¹¹⁷ All ward-based doctors received training after June 2008.

Only one doctor had some understanding of what would constitute an outbreak.¹¹⁸ Some were aware of the existence of the Infection Control Manual,¹¹⁹ but with one exception¹²⁰ those doctors had not seen the Loose Stools Policy, the *C. difficile* Policy or the Outbreak

Policy.¹²¹ One doctor thought he might have been aware of the Infection Control Manual prior to June 2008, but on reflection his final position seemed to be that it was probably after June 2008.¹²² Two doctors appeared to be unaware of the existence of the Infection Control Manual.¹²³

Nursing staff training and implementation of policies

Nurses who had undertaken the CCP would have gained some insight into aspects of infection prevention and control. This is discussed in Chapter 12. Sister Lesley Fox, SCN on ward 6, had training in infection prevention and control elsewhere before she moved to work at the VOLH in 1997. This was part of her training in tissue viability because of the connection between continence and tissue damage.¹²⁴ Mrs Murray and Dr Weinhardt repeated the presentation on the Stoke Mandeville and Quebec hospitals for the benefit of the nursing staff in May 2007.¹²⁵ Of the 15 staff members who attended, nine were student nurses, three were staff nurses and one was a nursing assistant.¹²⁶ Those two presentations to doctors and nursing staff were the only education sessions on CDI provided by Mrs Murray in the period from January 2007 to June 2008.¹²⁷

The thrust of the evidence from nurses was that prior to June 2008 the nursing staff had received no formal training in CDI.¹²⁸ One nurse thought CDI was included in the CCP.¹²⁹ One nurse suggested in her witness statement that she had CDI training as part of her initial training¹³⁰ but clarified this in evidence as training more generally in infection prevention and control.¹³¹ A number of nurses pointed to the “bug of the month”

112 [GGC00780255](#)
 113 [GGC00780256](#)
 114 [GGC00780148](#)
 115 [GGC27390008](#); [GGC00780153](#)
 116 [TRA00730100-101](#); [TRA00710054-56](#); [TRA00830035](#); [TRA00820021](#); [TRA00770049-50](#); [TRA00760027-28](#); [WTS00840008-09](#)
 117 [TRA01010042-43](#)
 118 [WTS01910009](#)
 119 [TRA00730097-98](#); [TRA00830032](#); [TRA00820020](#)
 120 [TRA00830032-33](#)

121 [TRA00730098](#); [TRA00820020-21](#); [TRA00770045-47](#); [TRA00760034-36](#); [TRA00790108-109](#); [TRA00800054-56](#)
 122 [TRA00710050-54](#)
 123 [TRA00760034](#); [TRA00770044](#)
 124 [TRA00300041-43](#)
 125 [INQ03010001](#); [GGC17790002](#); [TRA01010041-44](#)
 126 [GGC17790002](#)
 127 [TRA01010043-44](#)
 128 [TRA00370005](#); [TRA00390019](#); [TRA00450085-86](#)
 129 [TRA00410027](#)
 130 [WTS00680006](#)
 131 [TRA00370117-118](#)

circular¹³² issued by the Infection Control Team as a source of information on infection control and on CDI in particular.¹³³ There was evidence that a “bug of the month” circular providing information specifically on CDI was issued to the nursing staff for the second time in April 2007.¹³⁴ Mandatory training in CDI was introduced in the VOLH after June 2008 for all staff.¹³⁵

The senior ward nurses who gave evidence said that they were aware of the existence of the Infection Control Manual and policies such as the Loose Stools Policy, the *C. difficile* Policy and the Outbreak Policy.¹³⁶ Most of those nurses knew what would constitute a CDI outbreak, although the Outbreak Policy

was never activated for *C. difficile* infection prior to May 2008.¹³⁷ The use of stool charts and care plans is discussed in Chapter 12.

Isolation

Despite the terms of the Loose Stools Policy, the general practice adopted at the VOLH across different wards (with some exceptions) was **not** to isolate patients with loose stools until the diagnosis of CDI was confirmed, either directly from the Laboratory or by the ICN. There was a general shortage of single rooms, and that was certainly the case in ward 3 where only one single room was available. Table 15.1 sets out the number of single rooms available in each ward.

Table 15.1 Number of beds and number of single rooms in each ward

Ward	Number of beds in each ward	Number of single rooms in each ward
3	20	1
5	20	1
6	21/22	3
F	16/17	3
14	24	4
15	24	4
Fruin	24	2
MAU	0	0

It does appear that in most cases patients were placed in a single room once a positive result was known. What is clear, however, is that symptomatic patients who could have been isolated were not isolated timeously in accordance with the terms of the Loose Stools Policy. Furthermore, in a significant number of cases the risk of cross infection caused by the practice of not isolating until a positive result was available was compounded by delays in isolation even after the results were

known. Delays in treatment after results were known are discussed in Chapter 14.

Delays in isolation after the result was known

Four patients had a further one day delay before being isolated after the *C. difficile* positive toxin result was known. There were six patients with three or more days’ delay in isolating after CDI was confirmed. Table 15.2 provides information on these patients.

132 [GGC17790003](#)

133 [TRA00460084-85](#); [TRA00370116-117](#); [TRA00370005](#)

134 [TRA00950130-131](#); [GGC17790003](#)

135 [TRA00910132](#)

136 [TRA00290113](#); [TRA00300110-112](#); [TRA00360050](#); [TRA00380108-109](#); [TRA00410011-12](#); [TRA00410097-98](#); [TRA00450056-57](#)

137 [TRA01010082](#); [TRA01010089](#); [TRA01010092](#); [TRA01010102](#)

Table 15.2 Isolation delays after positive result known

Patient name	Ward	Confirmed CDI	Date moved into isolation	No. of days delay
Alister Brand	F	12 February 2008	22 February 2008 (isolated after a further CDI result)	More than 5
Isobel Cameron	14	4 January 2008	8 January 2008	4
Margaret Dalton	6	17 December 2007	18 December 2007	1
Janet Fitzsimmons	14	24 April 2008	25 April 2008	1
Matthew Macfarlane	3	12 February 2008	15 February 2008	3
William McKenzie	5	14 January 2008 (CDI on admission)	15 January 2008	1
Jacqueline Patrick	5	7 May 2008	8 May 2008	1
Patient C	F	24 December 2007	27 December 2007	3
Elizabeth Rainey	15	4 January 2008	7 January 2008	3
Margaret Thompson	6	18 January 2008	21 January 2008	3
David Somerville	6, 14	11 February 2008	21 February 2008	10
David Somerville	15	7 May 2008	12 May 2008	5

In the case of Margaret Thompson there is a note on the Infection Control Card that the patient was to be moved into isolation when a side room became available.¹³⁸

Matthew Macfarlane was symptomatic in the company of other patients for a period of three days while in ward 3. The Infection Control Card does note “unable to isolate”.¹³⁹ On 14 February 2008 he was moved to the Medical Bed Day Unit before being returned to ward 3 later the same day, which posed a further risk of cross infection to other patients.¹⁴⁰

A significant example of poor isolation practice was the case of Alister Brand. CDI was formally confirmed by the Laboratory on 12 February 2008 after a five day delay.¹⁴¹ There is no note in the patient records of

when the positive result was communicated to the ward, and in fact there is a nursing note dated 12 February 2008 that at that time he was *C. difficile* toxin negative,¹⁴² although that is likely to be an error, since the clinical note for the same day says “still symptomatic of *C.diff*”.¹⁴³ This was Mr Brand’s second episode of CDI, as he had tested positive and been isolated in January 2008.¹⁴⁴ He was tested again on 22 February 2008¹⁴⁵ and was moved into isolation when the positive result was communicated that day.¹⁴⁶ It is noted in the Infection Control card that at that time he was in a six-bedded room.¹⁴⁷ It is not clear to what extent he continued to suffer from loose stools over that period.

138 SPF00760001; GGC29010005

139 SPF00630001

140 INQ01710007

141 GGC21070096; GGC21070021

142 GGC21070132

143 GGC21070021

144 SPF01210001; [WTS01900010](#)

145 GGC21070024; GGC21070094

146 GGC21070128

147 SPF01210001

The other significant example of a risk of cross-contamination is the case of David Somerville. Not only did he test positive on ward 3 on 11 February 2008 after a four day delay from his sample being collected,¹⁴⁸ but he was then moved to ward 6 the following day while still symptomatic, rather than to isolation.¹⁴⁹ This was despite a note in the patient records that he should be isolated when a room became available.¹⁵⁰ He was then moved again on 19 February 2008 to ward 14¹⁵¹ while he remained symptomatic, but was still not moved into isolation. He remained symptomatic on ward 14 until 21 February 2008.¹⁵² Matters may have been confused by a negative *C. difficile* result which came in the same day as the positive result on 11 February,¹⁵³ but the patient records do record the positive result¹⁵⁴ and metronidazole was administered.¹⁵⁵ He remained symptomatic throughout.

On a later occasion David Somerville also experienced another inexplicable delay of five days throughout which he was symptomatic. He tested positive on 7 May 2008,¹⁵⁶ experienced a one day delay in commencing vancomycin¹⁵⁷ and then was not isolated until 12 May 2008.¹⁵⁸

Isobel Cameron experienced a delay of six days overall in being isolated. There was a delay at every stage of her treatment, for as well as the four day delay in isolating after CDI was confirmed¹⁵⁹ there had been an earlier two day delay in the Laboratory reporting.¹⁶⁰ Review of the patient records shows that there was a further one day delay in commencing treatment, which did not start until 9 January 2008.¹⁶¹

Cohorting

“Cohorting” of patients suffering from CDI “classically”¹⁶² means the separation of those patients and their nursing staff from other patients because isolation facilities are not available. It is a measure of last resort because it is inefficient in preventing cross-contamination.

The Inquiry has been able to identify at least two occasions in the period from December 2007 to June 2008, once in ward 6 and once in ward F, when a number of patients were placed under a form of cohorting.¹⁶³ Sister Fox thought that that might have happened in ward 6 on more than one occasion.¹⁶⁴ There was no evidence of that from the documentation provided to the Inquiry, but it may be the case that cohorting of CDI patients occurred in ward 6 on another occasion prior to December 2007. There are references on the infection prevention and control Access database to CDI patients being cared for in “shared”¹⁶⁵ accommodation and “multi bed all +ve” accommodation,¹⁶⁶ so that it is likely that some form of cohorting was taking place in the VOLH prior to December 2007.¹⁶⁷

Ward 6

In ward 6 two CDI patients shared room 13, a two-bedded bay, between 21 and 29 December 2007. One of the patients was in room 13 from 17 December 2007¹⁶⁸ after testing positive for CDI that day.¹⁶⁹ The stool sample had been collected from the patient early on 15 December 2007.¹⁷⁰ This patient was moved out of room 13 on 22 December 2007 at her own request for a period of approximately 32 hours and placed into a four-bedded area,¹⁷¹ and while there she continued to have loose stools.¹⁷² This kind

148 GGC00520034; GGC28050009; GGC00520294

149 GGC00520417

150 GGC00520035

151 GGC00520294

152 GGC00520295

153 GGC28050010

154 GGC00520034

155 GGC00520034; GGC00520379

156 GGC00520318

157 GGC00520318

158 [GGC23180007](#)

159 SPF00450001

160 GGC00070191

161 GGC00070233

162 [TRA00690150-151](#)

163 [TRA00300067](#); [TRA00420041](#); [TRA00410123](#)

164 [TRA00310034](#); [TRA00310100](#)

165 INQ02970123

166 INQ02970124

167 [TRA01010088](#)

168 SPF01430001

169 GGC26380045

170 GGC26380058

171 GGC26380053-54

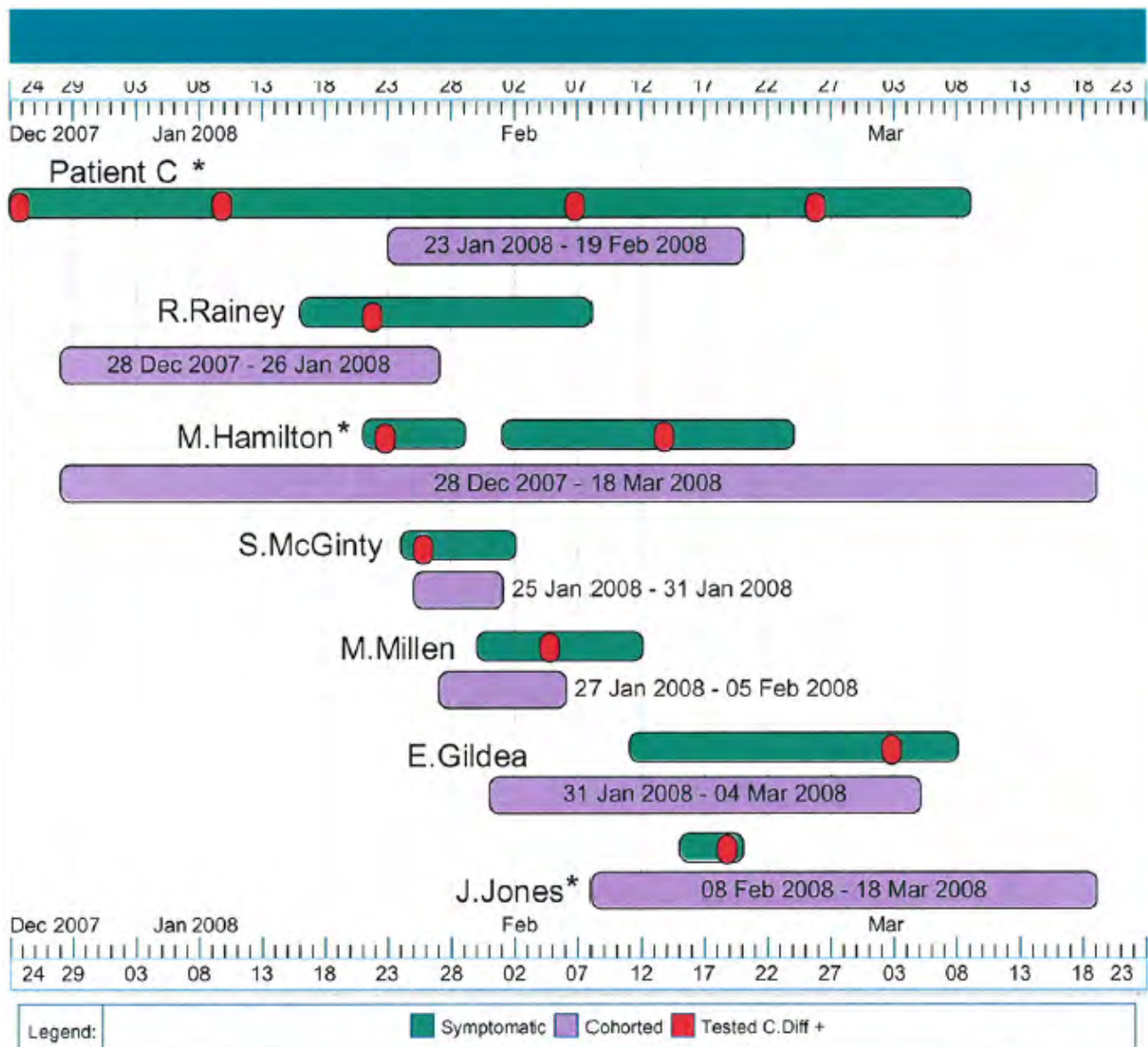
172 GGC26380054

of patient movement simply should not have happened, and served to increase the risk of spread of infection. It is not clear when the other patient was admitted to room 13, but it does appear from the Infection Control Card that she was there at least from 24 December 2007.¹⁷³

Ward F

The other clear instance of a form of cohorting occurred in January and February 2008 in ward F. Figure 15.2 displays the connections between patients in room 16 during January to March 2008 at times when patients were symptomatic or asymptomatic.

Figure 15.2 Patients cohorted in room 16 on ward F



*cohorted dates are best estimates derived from the patient records.

There are two coloured entries for each named patient on the chart.

The top entry shows when the patient was symptomatic for *C. difficile* (green) and the date the ward was aware of the CDI result (red).

The second line (purple) shows the period the patient was in room 16.

Over a period beginning on 21 January 2008¹⁷⁴ a total of seven patients were nursed together at different times in room 16. This was normally a three-bedded bay, but a contingency bed could be added to convert the room into a four-bedded bay. Four patients suffering from CDI were located there between 21 January and 25 January 2008.¹⁷⁵

Patient C first tested positive for CDI on 24 December 2007.¹⁷⁶ It is likely that she was in room 16 at that time. Although isolated elsewhere in ward F for a period, by 23 January 2008 she was certainly back in room 16.¹⁷⁷ She tested positive again for CDI on 9 January 2008¹⁷⁸ and again on 6 and 25 February.¹⁷⁹ She was the first patient to test positive for CDI in ward F in 2008, and because of a tendency to wander she was a difficult patient to place in isolation.¹⁸⁰ Patient C suffered from CDI for the whole period she was in room 16.

Another patient, Mary Millen, was admitted to ward F on 3 January 2008.¹⁸¹ She was asymptomatic with loose stools at the time. The patient records do not clearly specify her location, but it is likely she was moved into room 16 some time between 27 and 30 January as all four beds in the bay were occupied up until then. She was suffering from loose stools by 30 January 2008, when a sample was taken for *C. difficile* toxin analysis. Despite the suspicion of CDI and the fact that the test result was still awaited, on 31 January Mrs Millen was removed to the day space for a period of time because of her anxiety over another patient's behaviour.¹⁸² The Laboratory reported her sample as positive for CDI on 4 February 2008.¹⁸³ The Infection Control Card records that prior to isolation she had been in a shared bay with "previously positive patients".¹⁸⁴

By 31 January 2008 two other patients in room 16 had been moved into single rooms.¹⁸⁵ Quite inexplicably, Ellen Gildea, who was admitted to the VOLH on 29 January 2008 and who was not suffering from CDI, was moved into room 16 on 31 January 2008, at which point, as Figure 15.2 discloses, there were at least two patients in the room suffering from CDI.¹⁸⁶ Another patient in room 16 at that time, Mary Hamilton, had become asymptomatic by 29 January 2008,¹⁸⁷ but she became symptomatic again with loose stools, probably on 1 February 2008.¹⁸⁸

The placement of an asymptomatic patient in a bay where patients were suffering from CDI was extremely poor care for which the ICNs must bear responsibility. As the nurse in charge of ward F, Sister Laura Gargaro must also bear responsibility for this poor level of care. She was incorrect in her evidence in suggesting that the patients in room 16 were asymptomatic.¹⁸⁹ Furthermore, as Figure 15.2 discloses, Mrs Gildea was in room 16 for approximately four weeks along with symptomatic patients before she tested positive for CDI.¹⁹⁰ Having been moved to room 16 on 31 January, Mrs Gildea went on to develop loose stools on 11 February 2008. After stool samples collected on 12 February, 22 February and 25 February had tested negative for CDI, a positive sample was collected on 2 March 2008.¹⁹¹ She died on 7 March 2008,¹⁹² and CDI contributed to her death.¹⁹³

The admission of Mrs Jones

Mrs Jessie Jones was admitted to room 16 on ward F on 8 February 2008¹⁹⁴ when at least two patients were symptomatic with CDI. Mrs Murray was the ICN involved in that admission, since Mrs O'Neill was on leave.¹⁹⁵

174 SPF00710001; GGC00490013; GGC00490230
175 SPF00710001; GGC00490013-16; GGC00490231;
GGC28650006; SPF00660001; SPF01390002
176 GGC26340172
177 GGC26340178; SPF01390001-02
178 GGC26340175
179 GGC26340185; SPF01390002
180 SPF01390001-02
181 GGC20980132-133; GGC20980109
182 GGC20980142
183 GGC20980143
184 SPF01260001

185 GGC00490229; [TRA00020072](#); [TRA00430001-02](#)
186 [TRA00020072](#); [TRA00430161-162](#)
187 SPF00560001
188 SPF00560001
189 [TRA00420164-165](#)
190 GGC00230060
191 INQ01750008
192 SPF00160001
193 SPF00160001; EXP02500006
194 GGC21010117
195 [TRA00950152](#)

Mrs Murray said she had no recollection of the admission itself, but subsequently, when the circumstances of the admission were raised by Mrs Jones' family, Mrs Murray told Mrs Jones' daughter that she had been under pressure to admit her and "had nowhere else to put her".¹⁹⁶

In her evidence Mrs Murray accepted that Mrs Jones should not have been admitted to a bay where there were symptomatic patients.¹⁹⁷ Mrs Murray's sanctioning of the admission of Mrs Jones to a bay where there were symptomatic patients was a serious failure. Mrs Jones' daughter was correct in describing that decision as exposing her mother to a "life threatening situation."¹⁹⁸ Mrs Jones did in fact contract CDI,¹⁹⁹ but fortunately survived. This has been explored further in Chapter 12, where Sister Gargaro's role in this admission is more fully considered. Once again the admission of an asymptomatic patient to a bay where it was evident that CDI was present is indicative of poor care and a lack of real understanding of the seriousness of CDI.

Infection control – everyone's business

As discussed in Chapters 6 and 7, and with the establishment of the HAI Taskforce in 2003, there were numerous items of guidance produced by the Scottish Executive and later the Scottish Government on HAIs. For example, the NHS Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection²⁰⁰ was circulated to a number of groups including Chief Executives of Health Boards by letter dated 12 May 2004.²⁰¹ The key message to be promoted was that infection control was not the sole domain of infection control experts because "infection control is everyone's business".²⁰² This was a message that was repeated, and Mr Divers, the Chief Executive of NHS GGC in 2007 and 2008, said that it was directed at

"everyone"²⁰³ including nurses, doctors, domestic staff working on the wards and catering staff interacting with patients.²⁰⁴

It is apparent that this message had not reached the medical staff at the VOLH who gave evidence. In the main they were not aware of policies such as the Loose Stools Policy, the *C. difficile* Policy and the Outbreak Policy, although the senior ward nurses who gave evidence were aware of those policies. Some nurses had had some training in infection prevention and control, but nevertheless the Loose Stools Policy was generally not followed in a number of respects such as isolation, stool charts and care planning. Similarly, the *C. difficile* Policy was not followed on important matters such as care planning.

The cohorting that did take place, particularly in ward F, was a poor attempt at managing the number of patients who contracted CDI. The placing of a non-infected patient on at least two, and more likely three, known occasions into a bay where there was already at least one patient with CDI was unacceptable practice.

The response of the ICNs to the presence of a number of patients suffering from CDI in ward F who were closely associated in time and place is considered in Section 15.11 of this Chapter. The inability to realise that the patients who only developed CDI after being placed into room 16 were likely to have contracted CDI by cross-infection is difficult to comprehend.

As discussed later, senior nursing staff did raise the number of CDI patients in their individual wards with the Infection Control Nurses, but they were prepared to accept at face value the ICNs' explanation that all the cases could be explained by the antibiotic treatment being administered to patients.

196 [TRA00070060](#); [TRA00070082](#); [GGC14490001](#)

197 [TRA01010142](#)

198 [TRA00070060](#)

199 [GGC21010087](#)

200 [GOV00090001](#)

201 [GOV00980001](#)

202 [GOV00380005](#)

203 [TRA01250055](#)

204 [TRA01250055-56](#)

15.5 The Infection Control Manager

The appointment of Mr Walsh

Mr Thomas Walsh was the Infection Control Manager for NHSGGC from 25 June 2007.²⁰⁵ His predecessor, Dr Bill Anderson, left on 26 March 2007.²⁰⁶ Mr Walsh was told on 28 March 2007 that he had been appointed to the position but because he was required to provide 12 weeks' notice there was a delay of some three months before he could take up his new role.²⁰⁷

Mr Walsh's post immediately prior to becoming the Infection Control Manager was that of Planning Manager with Regional Services of NHSGGC, but from December 2002 to April 2006 he had held the post of Assistant Director of Nursing in NHS Argyll and Clyde, in which he had some responsibility for infection prevention and control.²⁰⁸ In that post his responsibilities also covered the VOLH.²⁰⁹ Mr Walsh was not qualified in infection control²¹⁰ but Professor Duerden considered his background "entirely appropriate" for the position of Infection Control Manager.²¹¹

The role of the Infection Control Manager

Guidance on the role of the Infection Control Manager was first provided by the then Scottish Executive Health Department (SEHD) in a letter dated 9 February 2001 to Boards and Trusts,²¹² which provided that Chief Executives of NHS Trusts had to ensure that:

"A senior manager (i.e. either a member of the Trust/Board or directly accountable to a member of the Trust/Board) is designated as having overall responsibility for risk assessment and management processes relating to ... infection control ..."

Subsequently, by letter dated 18 March 2005 from the SEHD to Chief Executives of NHS Boards, additional information was given on

the role of the Infection Control Manager.²¹³ It was expected that the Infection Control Manager would report directly to the Chief Executive and the Board,²¹⁴ and his or her responsibilities were to include the following:

- The co-ordination of prevention and control of infection.
- Delivery of the Board's Infection Control Programme²¹⁵ in conjunction with the Infection Control Committee and Infection Control Team.
- Provision of clear mechanisms for access to specialist infection control advice and support.
- Assessing the impact of all existing and new policies and plans on healthcare acquired infection, and making recommendations for change.
- Challenging non-compliance with local and national protocols and guidance relating to prevention and control of infection.
- The production of an annual report on the state of healthcare acquired infection.

Job description

Mr Walsh's job description repeated the description of the role set out in the SEHD letters of 9 February 2001 and 18 March 2005. It was his function to ensure that there were:

"clear and effective structures and processes designed for co-ordinated decisions that achieve system wide infection control decontamination, surveillance and cleaning services standards".²¹⁶

Part of his role was to ensure the:

"development of robust systems, policies, procedures...in line with current evidence base and national policy".²¹⁷

In the job description the post was described as "a management post with an emphasis on leadership and management".²¹⁸ It specified

205 [TRA01200003](#)

206 [TRA01200082](#)

207 [TRA01200082](#)

208 INQ04130001; [TRA01200002](#)

209 [TRA01200002-03](#)

210 [TRA01200085](#)

211 [TRA01050092](#)

212 [GOV00440006](#)

213 [GOV00440003](#)

214 [GOV00440004](#)

215 [GOV00440004](#)

216 [GGC01860001](#)

217 [GGC01860001](#)

218 [GGC01860001](#)

that the Infection Control Manager was to report directly to the Chief Executive and Medical Director of the Board. Mr Walsh himself said that he reported through the Medical Director, Dr Brian Cowan, who was his line manager, but that he would also report issues directly to Mr Divers, the Chief Executive.²¹⁹

The nature of the role

Terms such as “manager”, “leadership”, “management” and descriptions such as “overall responsibility for management processes” and “co-ordination of prevention and control of infection throughout the Board area” tend to suggest that the Infection Control Manager was to play a key operational and management role in the area of infection prevention and control. In reality, however, that was not the case, for Mr Walsh did not have any operational or line management responsibilities for infection prevention and control, and indeed that was the established practice when he took up the post in June 2007.²²⁰ Mr Walsh explained that the management reference in the job description related to “management of the processes rather than management of the human resources involved in this”.²²¹

In explaining the terms of the SEHD letter of 18 March 2005 that set out the role of the Infection Control Manager, Dr Kevin Woods, then Director General for Health for the Scottish Executive, accepted that the letter could be read in a way that suggested that the Infection Control Manager was not to have operational management responsibility.²²² Dr Syed Ahmed, Consultant in Public Health Medicine and Clinical Consultant in NHS GGC’s Public Health Protection Unit, explained that in Scotland there is a significant difference in size between Health Boards, with NHS GGC serving a population of about 1.2 million and managing around 20 hospitals.²²³ Because of this variation the SEHD did not prescribe a particular model job description for the Infection Control Manager. This explanation

did fit with Dr Woods’ evidence that the guidance for the role of Infection Control Manager reflected the diverse nature of Boards in Scotland and that the arrangements may have to be implemented in different ways.²²⁴ For an organisation the size of NHS GGC some latitude had to be given as to how the role of Infection Control Manager would work in practice.²²⁵

Dr Woods explained that what was

“non negotiable was that it needed to be somebody of standing, somebody with authority, somebody with access to highest level of the Board, and that there was clarity about how it was going to function in practice”.²²⁶

He went on to say that the Infection Control Manager had to have an overview across the whole of the Health Board and be able to “intervene at the highest levels”²²⁷ to ensure that appropriate action could be taken. Professor Paul Martin, former Chief Nursing Officer, drew an analogy in his evidence between the role of the Infection Control Manager as envisaged by the SEHD and the role that a quality assurance manager might play. The Infection Control Manager was someone who would be able to check that the systems and processes were working, but did not manage the system.²²⁸ This meant that the role would involve ensuring that there were clear infection control structures in place, and advising on those structures and on whether they were working appropriately and delivering what they were designed to deliver,²²⁹ but it was for line management to put the structures in place.

Mr Walsh’s position

In his evidence Mr Walsh agreed that he, together with the Nurse Consultant, could be thought of as a form of infection control policy unit.²³⁰ Nonetheless it was clear from other aspects of Mr Walsh’s own evidence that his responsibilities went beyond policy

219 [TRA01200079-80](#)
220 [TRA01200007](#)
221 [TRA01200007](#)
222 [TRA00970045-46](#)
223 [TRA01130145](#)

224 [TRA00970046](#)
225 [TRA00970047](#)
226 [TRA00970047](#)
227 [TRA00970048](#)
228 [TRA01080071-72](#)
229 [TRA01080073](#)
230 [TRA01200130](#)

and included strategic development of the annual infection control programme and education strategy.²³¹ The description of his role as a policy unit is more limited than that envisaged by Professor Martin, and Mr Divers was also of the view that the term “policy unit” was too narrow to describe the role of the Infection Control Manager.²³²

Mr Divers’ and Dr Cowan’s understanding of the role

According to Mr Divers, part of the Infection Control Manager’s responsibility was to ensure that guidance was implemented within the organisation.²³³ So far as Mr Divers was concerned the Infection Control Manager did have a management role, in the sense that he had to ensure the:

“introduction of the appropriate procedures and that those were acted on and were followed through, as opposed to a more hands-off role”.²³⁴

Dr Cowan also described the Infection Control Manager’s role to be a “very much policy”²³⁵ role, but he did elaborate on that to say that the Infection Control Manager had overall responsibility for the management processes, namely the committee structure, which could inform the Board as to what was happening with Infection Control. The Infection Control Manager had responsibility for overseeing those processes so that he could assure himself, and indeed Dr Cowan as his line manager, that those processes were working. The Infection Control Manager had to satisfy himself that the structure was intact and operating.²³⁶ That description was consistent with the one provided by Professor Martin.

An active role

After the CDI problem emerged in May 2008 Mr Walsh did appear to take an active role, chairing meetings at the RAH about cases of CDI on 21 and 28 May 2008²³⁷ and either

chairing the Outbreak Control Team meetings or attending as a member.²³⁸

Operational responsibility

What was clear from the evidence was that Mr Walsh did not have line management responsibility for infection prevention and control prior to June 2008.²³⁹ It is also the case that the manner in which the post of Infection Control Manager was structured in NHSGGC was based upon the SEHD letters of 9 February 2001 and 18 March 2005.²⁴⁰ After June 2008, and following upon the events at the VOLH, the role of the Infection Control Manager was changed in January 2009 to incorporate operational and line management responsibilities, and the job description now provides that the Infection Control Manager shall “Directly manage NHSGGC Infection Control Medical and Nursing Services”.²⁴¹ Mr Walsh described that as a significant change to the role.²⁴² He also said that, having had an opportunity of looking at the post of Infection Control Manager from both perspectives, there was a clearer line of accountability “up and down from board to ward”.²⁴³

The Inquiry experts’ approach

Both the infection control experts commissioned by the Inquiry, Mrs Christine Perry and Professor Duerden, were critical of the fact that the Infection Control Manager did not perform an operational role within the infection prevention and control structure prior to January 2009.

Mrs Perry saw the lack of operational responsibility as a gap. Her view was that if the Infection Control Manager was ultimately to be accountable to the Board for having the correct structures in place for the infection prevention and control service, then he had to have operational responsibility for the service.²⁴⁴ At the time of giving evidence Mrs Perry was the Director of Infection Prevention and Control at the NHS Trust by which she was employed, a position

231 [TRA01200005-06](#)

232 [TRA01250071](#)

233 [TRA01250074-75](#)

234 [TRA01250074](#)

235 [TRA01220084](#)

236 [TRA01220085-86](#)

237 [GOV00650009](#); [GOV00650012](#)

238 [GOV00650077](#); [GOV00650072](#)

239 [TRA01200007](#)

240 [GOV00440006](#); [GOV00380001](#)

241 [INQ04220001](#)

242 [TRA01200112](#)

243 [TRA01200105](#)

244 [TRA01040091-92](#)

broadly equivalent to that of an Infection Control Manager in Scotland. The guidance issued to NHS Trusts in England in May 2004 included among the responsibilities of Directors of Infection Prevention and Control that they would “be responsible for the Infection Control Team within the healthcare organisation”,²⁴⁵ and it was the absence of that degree of responsibility that Mrs Perry saw as a gap in the Infection Control Manager’s role. She saw the change introduced in January 2009 as producing a strong structure that could enable the delivery of good infection prevention and control across the Board area.²⁴⁶ Mrs Perry noted that the Infection Control Manager’s job description included among his responsibilities:

“ensuring there (were) clear and effective structures and processes designed for co-ordinated decisions that achieve system wide infection control ...”.²⁴⁷

Her view was that if the Infection Control Manager had been operationally responsible for the service, he would have been better placed to address the structural failures that did occur, namely the failure of committees to meet.²⁴⁸

The essence of Professor Duerden’s position was that he could not see how the Infection Control Manager could be non-operational and yet be responsible for the co-ordination of prevention and control of infection in a healthcare setting, as envisaged in the job description.²⁴⁹ Professor Duerden made particular reference to the NHS Scotland Code of Practice²⁵⁰ and the emphasis there on the Infection Control Manager having “overall responsibility for risk assessment and management processes”.²⁵¹ This is a description repeated in the letters of 9 February 2001 and 18 March 2005. Professor Duerden’s opinion was that the Infection Control Manager could not properly carry out his function as envisaged

by the Code of Practice if he did not have operational responsibility for the Infection Control Service.²⁵²

So far as Professor Duerden was concerned, if the Infection Control Manager did not have operational responsibility for the Infection Control Service, then that would be a

“serious gap in the system, and it would mean that there was not a coherent system ... from Board to ward or ward to Board, which should be a continuous line”.²⁵³

The Code of Practice and the guidance contained in the letter of 18 March 2005 envisaged that the Infection Control Manager would be a senior manager who would report directly to the Chief Executive and the Board,²⁵⁴ and as Professor Duerden explained, such reports should include matters such as the scale, numbers and rates of HAIs, trends, audits and the distribution and implementation of the Board’s policies.²⁵⁵ To carry out that level of reporting the Infection Control Manager would have to have operational responsibility for the service.

Mr Divers’ disagreement

Mr Divers disagreed with Professor Duerden’s view that there was a lack of coherence in the system with the Infection Control Manager having no operational responsibility. He explained his view that the necessary connection from Board to ward and ward to Board could be made in the following way:

“There is no reason why those connections could not be made, and I believe they were being made in Greater Glasgow as we moved through the arrangements with the merger with Clyde, that in having ... Bill Anderson/Sandra McNamee ... working very closely with the Infection Control Teams and the sector lead ICDs, we had a coherent system”.²⁵⁶

245 [INQ03630002](#)

246 [TRA01040093](#)

247 [GGC16000007](#)

248 [TRA01050171](#)

249 [TRA01050082](#)

250 [GOV00090001](#)

251 [GOV00090007](#)

252 [TRA01050084](#)

253 [TRA01050085](#)

254 [GOV00440004](#)

255 [TRA01050086](#)

256 [TRA01250077](#)

The reference to Bill Anderson is a reference to Mr Walsh's predecessor, and Mr Divers' point was that the Infection Control Manager and the Nurse Consultant would be working very closely with Infection Control Teams, including the ICDs. Mr Walsh, when asked about the working relationship with the Infection Control Team in the Clyde Sector, described it as a "reasonable working relationship"²⁵⁷ that was "delivered through the committee structures".²⁵⁸

The flaw in Mr Divers' argument is this. Mr Walsh and the Nurse Consultant, Ms Sandra McNamee, were members of the Acute Control of Infection Committee (ACIC) and the Board Infection Control Committee (BICC). So too was Dr Biggs, but as discussed later in this Chapter Dr Biggs did not attend the meetings of either of those committees in the period from January 2007 to June 2008. There was therefore no effective platform for the kind of working relationship envisaged by Mr Walsh. The Nurse Consultant did attend a meeting of the Clyde Acute Infection Control Support Group (the Support Group) on 13 February 2007. That may have been the first time she met Dr Biggs,²⁵⁹ and it would appear that the only other contact the Nurse Consultant had with Dr Biggs was when they both attended two Outbreak Control Team meetings, one at the RAH and the other at the IRH.²⁶⁰ Contrary to Mr Divers' belief, there was no effective close working relationship between the Infection Control Manager, the Nurse Consultant and the leader of the VOLH Infection Control Team to promote the coherent system he assumed was in place.

Lack of effective leadership

The Inquiry is satisfied that the role created by the Board for the Infection Control Manager, as understood by Mr Walsh, did not provide effective leadership of infection prevention and control. Despite the reference in the job description to the Infection Control Manager's post being a "management post with emphasis on leadership and management", there was no leadership role in the way the job was in fact carried out. The

Chief Executive was ultimately responsible for the system, but the Infection Control Manager, as the Chief Executive's most direct link to the system, should have had a clear leadership role in keeping an oversight over what was happening. That role should have included the Infection Control Manager reviewing data, including rates of infection.

None of that happened. Mr Walsh was not aware of the failure of the committee structure, nor was he aware of Dr Biggs' failure to carry out her responsibilities as ICD, issues that are discussed later in this Chapter. Had his role been a more proactive one it is likely that he would have become aware of those failures in the infection prevention and control system. The Inquiry therefore welcomes the Board's change of approach to the role of the Infection Control Manager in January 2009. It is a change that, as Mr Walsh recognised, provided for clearer accountability from Board to ward.²⁶¹

15.6 The Nurse Consultant

The appointment of Ms McNamee

Sandra McNamee was the Nurse Consultant for Infection Control for NHSGGC in the period from 1 January 2007 to June 2008, having taken up this post in November 2006.²⁶² Her qualifications include a diploma in Infection Control Nursing from Glasgow University,²⁶³ and since she first took up a post in infection prevention and control in 1994 she had gained a significant amount of experience in the field. General guidance had been issued on the role of Nurse Consultant by the SEHD in 2001, and although it did not have a particular focus on HAI²⁶⁴ it did envisage direct involvement with patients "for a significant proportion of the time".²⁶⁵

Job description

The job description for the post required the Nurse Consultant to provide "strong, strategic and clinical leadership across NHSGGC".²⁶⁶ It

257 [TRA01200050](#)

258 [TRA01200050](#)

259 [TRA01210030-31](#)

260 [TRA01210065-66](#)

261 [TRA01200105](#)

262 [TRA01210003](#)

263 [TRA01210002](#)

264 [GOV01250001](#); [TRA01090053](#)

265 [GOV01260002](#)

266 [GGC30330004](#)

went on to specify that the Nurse Consultant will ensure the development of:

“robust systems, policies, procedures, professional guidance, consistent standards and training strategies in line with current national policy”.²⁶⁷

So far as that aspect of her remit was concerned, Ms McNamee explained that one of her priorities was to establish the use of Statistical Process Control Charts (SPC Charts) across the Board area.²⁶⁸ She did not know what surveillance systems were in place in the VOLH prior to June 2008, which is particularly surprising since her job description provided that her responsibilities included the review and development of “audit and surveillance programmes to reduce risks”.²⁶⁹ So far as she was concerned, since there were outbreaks declared in the RAH and norovirus outbreaks declared in the VOLH, there appeared to be evidence that the existing surveillance systems were working, and she therefore did not have any reason to evaluate the systems at that stage.²⁷⁰

Ms McNamee’s job description envisaged that she would continue to perform a clinical role as a practising ICN. This was an element that was not to exceed two days a week,²⁷¹ but was to allow her to use her:

“highly specialised knowledge” to provide expert nursing practice in relation to direct and indirect patient care through direct involvement with patient care activities”.²⁷²

Ms McNamee said this did not happen in practice because when she took up the post there were a number of key priority areas that required attention, such as the introduction of the Infection Control Manual to the Clyde Sector. Prior to Ms McNamee taking up her post in November 2006 there had not been a Nurse Consultant in post, and although a Lead Nurse had been responsible for the co-ordination of the Infection Control

Manual this person had left some six months before Ms McNamee’s appointment. The result was that “there were things that had slipped that were national priorities”²⁷³ and that had to be put in place as soon as possible.

Line management

Ms McNamee’s line manager was Mr Walsh. Like him, she did not have line management or operational responsibility for the Infection Control Teams, although her job description did provide that:

“crucial to the success of the post will be the provision of professional leadership for all the Infection Control Nurses in NHS GGC”.²⁷⁴

Ms McNamee said that she achieved that level of professional leadership by meeting with ICNs at two subgroups of the BICC. She chaired the Infection Control Policy Subgroup, which was composed of the ICNs and in which relevant literature was reviewed and policies were drafted. She also chaired the Infection Control Education Subgroup, which was then involved in reviewing relevant literature and providing appropriate educational materials.²⁷⁵

As with Mr Walsh, Ms McNamee took over managerial and operational responsibility for the ICNs of NHS GGC from 2009²⁷⁶ when she became Assistant Director of Nursing (Infection Control),²⁷⁷ a newly created post but one in which she retained her nurse consultant responsibilities.²⁷⁸

VOLH visits

Ms McNamee thought she had visited the VOLH on two occasions between 1 January and 1 April 2007²⁷⁹ when she was engaged in ensuring the Infection Control Manual had been “fully rolled-out to Clyde”.²⁸⁰ Her purpose was to go through the policies with the ICNs to make sure that they were fit for

267 [GGC30330004](#)
268 [TRA01210005](#)
269 [GGC30330006](#)
270 [TRA01210006-07](#)
271 [GGC30330005](#)
272 [GGC30330007](#)

273 [TRA01210062-64](#)
274 [GGC30330005](#)
275 [TRA01210014](#)
276 [TRA01210025](#)
277 [TRA01210001](#)
278 [TRA01210026](#)
279 [TRA01210020](#)
280 [TRA01210019](#)

purpose for the Clyde area.²⁸¹ Only senior nurses were involved in that process, which meant that Mrs O'Neill was not included.²⁸²

Lack of knowledge

Ms McNamee was a member of the ACIC and the BICC. She was not aware that Dr Biggs had stopped attending meetings of these committees. In fact, so far as Ms McNamee was concerned Dr Biggs was fulfilling her role as the ICD for the hospitals for which she was responsible.²⁸³ This view was reinforced by the fact that she had met Dr Biggs at the RAH for meetings into an investigation of an outbreak of MRSA in the intensive care unit.²⁸⁴

Had the Nurse Consultant been more operationally responsible for the infection prevention and control structures, she would have been in a better position to identify deficiencies in those structures. This includes, for example, the failure of the committee structures at the Clyde Sector level discussed

later in this Chapter. The Inquiry welcomes the change of remit for the Assistant Director of Nursing. As with the change in the responsibilities of the Infection Control Manager it is a change that can only serve to strengthen the infection prevention and control system.

15.7 The infection control committee structure

Overview of committee structure

The intention in this Section is to identify the infection control committee structure in place in the period from January 2007 to June 2008 and to comment on how the different committees within that structure functioned. Figure 15.3 sets out the committee structure then in place. The Clyde Sector groups are those below the dotted horizontal line, and the black arrows indicate where minutes were intended to be passed on in accordance with each group's or committee's terms of reference.

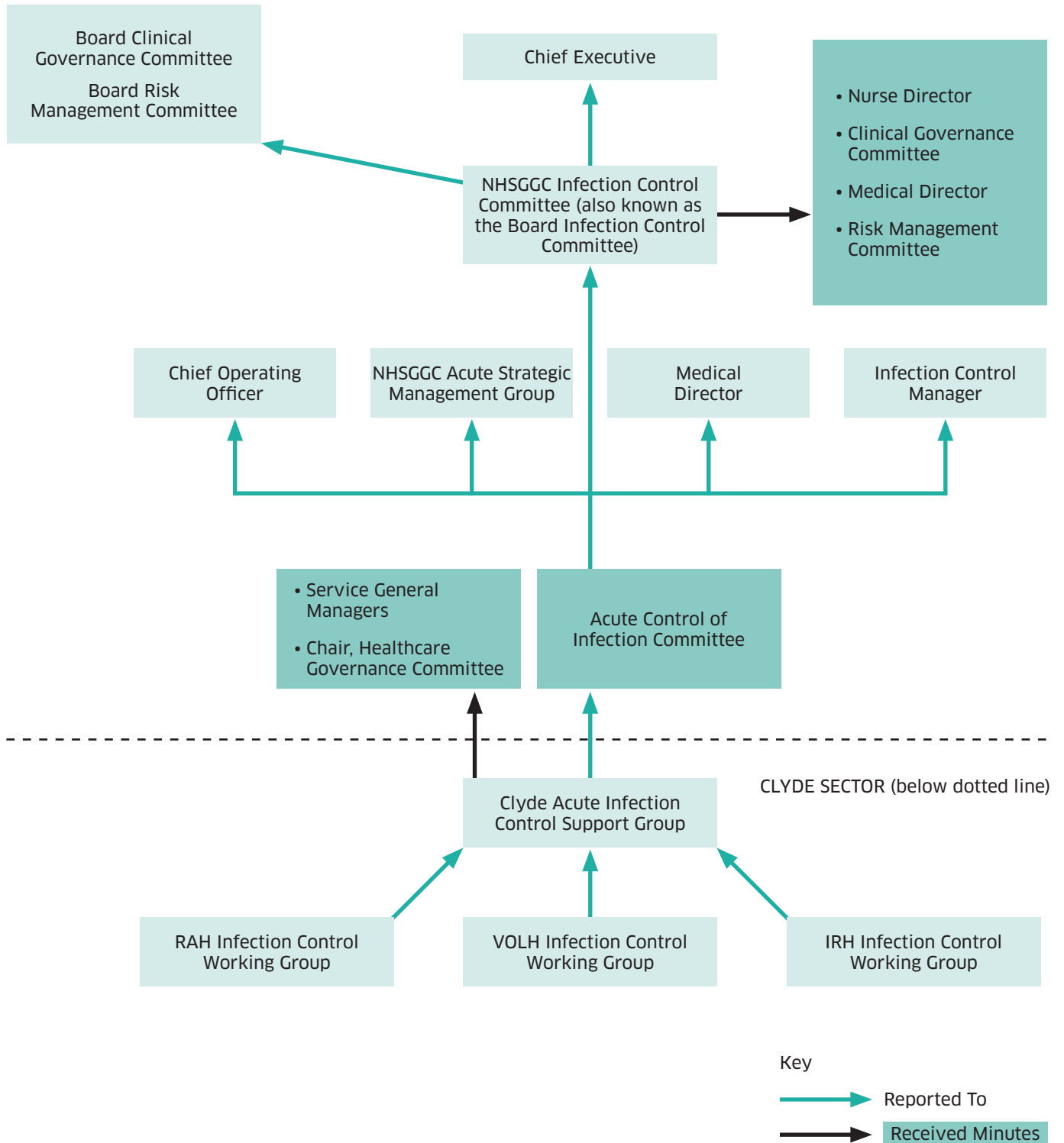
281 [TRA01210022](#)

282 [TRA01210021](#)

283 [TRA01210034-36](#)

284 [TRA01210037](#)

Figure 15.3 NHSGGC infection control reporting structures



Infection Control Link Nurses at the VOLH

The VOLH had an Infection Control Link Nurse system in place. The rationale underlying the system was well intentioned, and it represented an attempt to increase awareness of infection prevention and control issues at ward level in the VOLH, although the meetings of the Infection Control Link Nurses were not strictly within the infection control committee structure and there was no reporting line to a committee higher up the chain.

In the VOLH the intention was that the Infection Control Link Nurses would meet every two months.²⁸⁵ The meetings were chaired by Mrs O'Neill, and Link Nurses were supposed to attend as representatives of each ward. Mrs O'Neill would update those nurses on infection prevention and control issues, and they were then to report back to their respective wards.²⁸⁶ The group ceased to meet on 5 February 2008, and while Mrs O'Neill could not remember why²⁸⁷ she did recall that attendance was one of the problems.²⁸⁸

Overall, the attendance was extremely poor. An examination of the minutes of that group from 7 February 2007 to its final meeting on 5 February 2008²⁸⁹ discloses that there were at least two Link Nurses who never attended any of the meetings. Another two Link Nurses only attended on one occasion.

One Link Nurse gave oral evidence to the Inquiry. She qualified as a nurse in 2006, but could not recall receiving any training in infection prevention and control,²⁹⁰ and she only became the Link Nurse for her ward because the Link Nurse in place was leaving and she was asked to step into the position.²⁹¹ She only attended one meeting.

In the minute of the meeting of 4 April 2007 the following entry has been made:

285 [TRA00500115](#)
286 [TRA00950120](#)
287 [TRA00950121](#)
288 [TRA00950121-123](#)
289 [GGC17790010](#); [GGC17790004](#); [GGC17790007](#);
[GGC17790012](#); [GGC17790015](#); [GGC28080001](#)
290 [TRA00500096](#)
291 [TRA00500113](#)

“just to make staff aware of the increase in patients who are positive for C.diff. Could staff pay particular attention to:

- keeping stool charts so that staff are aware of when symptoms develop and cease”.²⁹²

It is clear from the evidence given to the Inquiry that this advice was often not followed. This is elaborated on in Chapter 12.

In the minute of the meeting of 5 February 2008 it was recorded that the meeting had to end prematurely as staff needed to go back to their areas of work. It was also minuted that the next meeting was to take place on 8 April 2008 but, as already noted, that did not happen.²⁹³

According to Mrs O'Neill one of the problems over attendance was that it was difficult for staff to get time off from their ward duties to attend. Whatever the cause, however, the key point is that the system was not working. Such poor attendance when the group did meet meant that the reporting back to the wards was inadequate.

There was no evidence before the Inquiry that this group made any effective contribution to infection prevention and control in the VOLH during the period from 1 January 2007 to 1 June 2008. The concept of having a local group at that level with the purpose of disseminating information on infection prevention and control to individual wards was a good one but it failed in practice.

VOLH Infection Control Working Group

The background to the establishment of the VOLH Infection Control Working Group (the Working Group) was the disbandment of the Argyll and Clyde Infection Control subgroups and their replacement by the Support Group. The Support Group wanted to have local working groups with a remit that included assisting the Infection Control Team in supporting NHSGGC's infection control programme and reporting to the Support Group.²⁹⁴ The terms of reference

292 [GGC17790005](#)
293 [GGC28080002](#)
294 [GGC11710001](#)

of the Support Group, drafted by Dr Biggs, stipulated that the Support Group was to “receive reports from the three acute hospital control teams”,²⁹⁵ but at the meeting of the Support Group held on 13 February 2007 it was minuted that it had been agreed at the previous meeting of 12 December 2006 that the papers and minutes from the three working groups would simply be available for the meeting. Any issues arising would be addressed by the Senior ICNs.²⁹⁶

Although terms of reference for the Working Group are mentioned in the minutes of the meeting held on 27 June 2007²⁹⁷ and of the meeting held on 26 September 2007,²⁹⁸ the Board was not able to supply the Inquiry with those terms of reference. The Working Group was due to meet on a quarterly basis, and the meetings that took place were chaired by Mrs Murray.

The first meeting of the Working Group was held on 5 April 2007, when Mrs Murray explained that it was important to have a local working group that could report to the next level in the structure, namely the Support Group and “thus to the Health Board”.²⁹⁹ The minute of that meeting discloses that those in attendance included Mrs Susan Wilson, Lead Nurse for Emergency Care and Medical Specialities, Mrs Elizabeth Rawle, Lead Nurse for the Rehabilitation and Assessment Directorate and Ms Judy Taylor, Senior Nurse Professional Practice. It was noted that apologies had been received from a number of people, including Dr Douglas McCrudden, Consultant Physician.

Meetings of the Working Group were poorly attended. Dr McCrudden was not able to attend any of the meetings. The Working Group last met on 28 September 2007, for although an agenda for a proposed meeting on 19 December 2007 was drawn up that did not take place. There were no further meetings after September 2007.

In the minute of the meeting held on 5 April 2007 it was noted that the numbers of *C. difficile* toxin positive patients were up on previous years; “a 40% increase on last year”.³⁰⁰ It was also minuted that Mrs Murray said that there appeared to be a significant increase in CDI since the start of enhanced surveillance. According to the minutes, Mrs Murray went on to say that because of this increase patients with *C. difficile* diarrhoea were to be nursed in isolation and that priority should be given to isolating patients who were *C. difficile* toxin positive over MRSA patients.

Mrs Murray said in evidence that the meeting of the Working Group proposed for December 2007 did not take place because so many apologies for non-attendance were received.³⁰¹ The next meeting would have been in March 2008, but no date for a further meeting was fixed.

Following her appointment as Consultant Microbiologist with designated responsibilities for Infection Control at the RAH and VOLH, Dr Bagrade proposed that the VOLH and RAH Infection Prevention and Control Working Groups be combined, having become aware that the Working Group at the VOLH had “experienced some difficulties in establishing the group”.³⁰² That combined group was duly constituted and held its first meeting on 14 May 2008.³⁰³

Clyde Acute Infection Control Support Group

The remit of the Support Group was set out as an appendix to the document “Proposed Infection Control Structure in NHS Greater Glasgow and Clyde”,³⁰⁴ and included a provision that the Support Group was to report to the ACIC any identified infection control incidents or outbreaks.³⁰⁵ In addition, Dr Biggs drafted what were styled “terms of reference” for the Support Group that reflected her intentions for the scope of its work. Those terms of reference provided that the Support Group was:

295 [GGC29140001](#)
296 [GGC29240001](#)
297 [GGC14760001](#)
298 [GGC14770001](#)
299 [GGC14750001](#)

300 [GGC14750004](#)
301 [TRA01010148](#)
302 [GGC13390015](#)
303 [GGC13390002](#)
304 [GGC29210001](#)
305 [GGC29210009-10](#)

“to disseminate good practice in the prevention and control (of) infection in the Acute Sector for the population of Clyde division”.³⁰⁶

It was to report to the ACIC, as set out in its remit.³⁰⁷ The terms of reference also envisaged that the Support Group would receive reports on outbreaks. It was to meet quarterly.³⁰⁸ Dr Biggs was named as the Chair, and was specifically designated in the document as “Infection Control Doctor”.³⁰⁹

Support Group meeting on 9 May 2007

A meeting of the Support Group was held on 9 May 2007, chaired by Dr Biggs. Mrs Murray, who was a member both before and after she became interim Lead Nurse, was not present, but Ms Rankin was present as the Head ICN. Mr Walsh was also present and is described in the minutes as “Infection Control Manager”,³¹⁰ although he was not yet in post. Ms McNamee had been present at the meeting of the Support Group on 13 February³¹¹ but was not present at the meeting of 9 May 2007. Ms Martin was also a member of the Support Group and was present on 9 May 2007. At the meeting Dr Biggs tabled a report for the VOLH for the period February to April 2007 in the absence of Mrs Murray,³¹² in which the following comments were made:

“numbers of *C. difficile* had increased in March and April causing some concern. The ICT are continuing to monitor this”.³¹³

The report concluded by noting that:

“April: There was an increase in the numbers of patients testing positive for *C. difficile* (see previous figures) particularly on one ward”.³¹⁴

This is discussed later, but it was apparent from the evidence given to the Inquiry that

the information disclosed in this report at this meeting did not prompt any action or investigation.

Support Group meeting on 10 July 2007

The next Support Group meeting on 10 July 2007 was chaired by Dr Biggs. Ms Martin and Mrs Murray were present, but the minutes record apologies from Ms Rankin and Mr Walsh. They also record that Dr Biggs felt that the ICD should not be the person to chair the Support Group as the ICD “has no actual link to feed the reports to”.³¹⁵ What was meant by that comment is not entirely clear, but it is certainly not correct that the Support Group had no reporting link, because the terms of reference drafted by Dr Biggs clearly provided that it was “to link into the Acute Control of Infection Committee”,³¹⁶ a committee of which Dr Biggs herself was a member.

It was also noted at the meeting of 10 July 2007 that Mrs Murray had nothing to report to the Support Group.³¹⁷ She tabled the surveillance report advising that there were “no major concerns”.³¹⁸ That surveillance report covered the period April to June 2007³¹⁹ and disclosed a significant increase in numbers of *C. difficile* toxin positive cases in comparison to the previous quarter (January to March 2007).

Failures to meet

The next meeting was due on 9 October 2007,³²⁰ but the Support Group did not meet again after 10 July 2007. Mrs Murray could provide no real explanation of why the Support Group stopped meeting except to surmise that Dr Biggs did not want to chair it.³²¹ She thought that Ms Martin was considering ways in which it could be resurrected.³²² When questioned by the Internal Investigation on this particular topic Dr Biggs is noted to have suggested that “nobody was coming to meetings ... managers

306 [GGC29140001](#)

307 [GGC29140001](#)

308 [GGC29140002](#)

309 [GGC29140002](#)

310 [GGC13260006](#)

311 [GGC29240001](#)

312 [GGC13260008](#)

313 [GGC13260013](#)

314 [GGC13260020](#)

315 [GGC20940002](#)

316 [GGC29140001](#)

317 [GGC20940002](#)

318 [GGC20940004](#)

319 [GGC20060001](#)

320 [GGC20940006](#)

321 [TRA01010085](#)

322 [TRA01010085](#)

saying too busy to come to IRH”.³²³ That was an obvious overstatement although certainly the meetings of 9 May 2007 and 10 July 2007 were quite poorly attended. Dr Biggs also claimed at that interview that Ms Martin would address the failure of the Support Group to meet but “nothing happened”.³²⁴

Ms Martin said in evidence that she was aware that the October meeting of the Support Group did not take place. She said initially in her evidence that because she was on secondment, what she could do about the issue was very limited as it was not her responsibility at that stage.³²⁵ Subsequently, when asked if she did anything about it she replied by saying that she was “limited” in what she could do, but that she:

“did flag it up with ... I’m sure I flagged it up with Robin Reid (Associate Medical Director, Diagnostics Directorate) but I definitely spoke to Isabel Ferguson (General Manager for Laboratory Medicine NHSGCC) and Tom Walsh about it”.³²⁶

Mr Walsh had no recollection of Ms Martin speaking to him about this matter. As far as he was concerned he only became aware that the Support Group was not meeting after May 2008.³²⁷ Dr Reid had no recollection of such a conversation. If he had been told that the Support Group was not meeting his response would have been to ask Ms Martin what she was doing about reinstating it.³²⁸ The issue of knowledge of the Support Group’s failure is discussed in Section 15.9.

Attendance by Mr Walsh and Ms McNamee

As noted previously, Mr Walsh attended the meeting of the Support Group held on 9 May 2007, although Ms McNamee did not. Neither Mr Walsh nor Ms McNamee attended the last meeting of the Support Group held on 10 July 2007. The minutes record Mr Walsh’s apologies for non-attendance, but Mr Walsh explained in evidence that in fact he had told Dr Biggs that it was not appropriate for him and the Nurse Consultant to attend

sector group meetings such as the meeting of the Support Group, as they did not belong to any other sector group.³²⁹ His attendance on 9 May 2007 was simply part of an orientation process prior to taking up post. Although Dr Biggs in drafting the terms of reference for the Support Group had included in its membership the Infection Control Manager and Consultant in Public Health,³³⁰ these were people who did not sit in on the sector group meetings.³³¹ The Inquiry accepts that Mr Walsh was not a member of the Support Group. The Nurse Consultant was not on the membership list in the terms of reference, and although she was present on 13 February 2007 Ms McNamee did not become a member of the Support Group.

Impact of committee failures

With the failure of the Support Group in July 2007 and the subsequent failure of the Working Group in September 2007, as Dr Ahmed, Consultant in Public Health Medicine and Clinical Consultant in the Public Health Protection Unit, said, there was a significant gap in the chain from the VOLH to the Board level.³³² So far as Dr Ahmed was concerned, there was a:

“significant risk to the whole organisation that information from the site may not be reaching to the top level of the organisation”.³³³

The reason nothing was done to remedy the situation that developed is addressed later in this Chapter.

The Acute Control of Infection Committee

The reporting line for the Support Group was to the ACIC. The ACIC’s primary objective was that of reducing the risks of HAIs to patients, relatives and healthcare workers in a number of ways, which included advising Mr Calderwood on infection control risks and significant unresolved issues.³³⁴ Its terms of reference included advising and supporting site Infection Control Teams and considering

323 [GOV00890101](#)
 324 [GOV00890101](#)
 325 [TRA01160019](#)
 326 [TRA01160068](#)
 327 [TRA01200039](#)
 328 [TRA01180041-42](#)

329 [TRA01200034-36](#)
 330 [GGC29140002](#)
 331 [TRA01200034-35](#); [TRA01130087](#)
 332 [TRA01130087](#)
 333 [TRA01130088](#)
 334 [GGC29210009](#)

reports on infections and infection-related problems from the site Infection Control Support Groups. These could come either from the Lead Nurse for Infection Control or the ICD. The attention of the Chief Operating Officer was to be drawn to any serious potential or actual risks in relation to infection control.³³⁵ It was also the function of the ACIC to develop and agree actions in response to specific outbreak situations.³³⁶

According to its terms of reference the ACIC was supposed to meet on a quarterly basis, but Dr Reid explained that this was changed because the importance of the committee's work demanded a shorter interval between meetings, and for that reason the ACIC met every second month.³³⁷ The terms of reference provided that it was to report to the Chief Operating Officer, the BICC, the Medical Director and the Infection Control Manager.³³⁸ Dr Reid agreed that the ACIC did report to the BICC but explained that the main line of reporting was to the Acute Strategic Management Group chaired by the Chief Operating Officer.³³⁹ The Infection Control Manager was in fact a member of the ACIC and reported to the Medical Director,³⁴⁰ who in turn reported to the Chief Executive.³⁴¹ It seems, therefore, that the reporting lines envisaged by the terms of reference were in place, albeit in a roundabout fashion.

Membership and attendance

The ACIC was chaired by Dr Robin Reid, and included in the membership of that committee were the Infection Control Doctors for each of the four sectors which made up NHSGCC, including Dr Biggs. Mr Walsh was a member of the ACIC, as Infection Control Manager, as were Ms McNamee and Ms Rankin. Mrs Murray became a member of the ACIC after she became the interim Lead Nurse for Infection Control for the Clyde Sector, and the first meeting that she attended was on 24 July 2007.³⁴²

Dr Biggs' attendance at ACIC

Dr Biggs did not attend any of the meetings of the ACIC in the period from January 2007 to June 2008. The minutes of the meeting of 23 January 2007 record apologies on behalf of Dr Biggs,³⁴³ but there is no such note in any of the other minutes covering the period up to June 2008. She did attend one meeting of the ACIC in the second half of 2006, but before that she had not been a member of the group.³⁴⁴ This means that from the time Dr Biggs became a member of the ACIC in 2006 up to June 2008 she only ever attended one meeting.

Dr Biggs' continued absence from the ACIC meetings was a matter that Dr Ahmed found "very concerning".³⁴⁵ In his evidence he said that he would have expected Dr Reid, as chairman, to investigate the reason for her absence over that period.³⁴⁶ Dr Reid explained, however, that any concerns he had were mitigated by the presence of other members of the Clyde team on the ACIC. He considered that their presence ensured that the flow in information was not being compromised by the absence of Dr Biggs.³⁴⁷ Furthermore, Dr Reid and others had a meeting with Dr Biggs at the IRH in September 2007 at which Dr Biggs indicated that her lack of mobility compromised her ability to attend meetings.³⁴⁸ According to Dr Reid, because Dr Biggs' line manager, Ms Martin, was present at the meeting and appeared to accept that explanation, he felt that it was a reasonable decision on the part of Dr Biggs³⁴⁹ not to attend the ACIC meetings. While Dr Reid's explanation is understandable, nevertheless regular attendance at meetings by the ICD was part of that job, and Dr Bgrade first attended the ACIC on 29 January 2008.³⁵⁰

As Dr Ahmed explained, it was particularly crucial at the level of the ACIC that the Sector ICD attended the committee meetings.³⁵¹

335 [GGC29210009-10](#)

336 [GGC29210010](#)

337 [TRA01180006](#)

338 [GGC29210009](#)

339 [TRA01180004](#)

340 [TRA01220083](#)

341 [TRA01220088](#)

342 [GGC02330001](#)

343 [GGC02320001](#)

344 [TRA01180006](#)

345 [TRA01130071](#)

346 [TRA01130071](#)

347 [TRA01180017](#)

348 [TRA01180017](#)

349 [TRA01180017](#)

350 [GGC02350001](#)

351 [TRA01130072-73](#)

This was not so important at the level of the BICC because a number of other people from Acute Services did attend and therefore Dr Ahmed could still communicate or pass down information.

The Board Infection Control Committee

Like the ACIC, the BICC, also known as the NHSGGC Control of Infection Committee, included among its objectives the reduction of the risks of infection to members of the public and patients.³⁵² Those objectives were to be achieved in a number of ways including advising the Chief Executive on all matters relating to infectious diseases throughout NHSGGC.

The BICC was also to liaise with other appropriate committees in NHSGGC and monitor their performance. It carried out a number of review functions including the reviewing of infection control policies. The BICC reported to the Chief Executive and to the Board Clinical Governance Committee, and the proposed infection control structure³⁵³ envisaged that the BICC would also report to the Risk Management Committee, but according to Dr Ahmed the reporting lines were only to the Chief Executive and the Board Clinical Governance Committee.³⁵⁴ The BICC was to meet quarterly.³⁵⁵

Membership

The BICC was chaired by Dr Ahmed, who at the time was a Consultant in Public Health Medicine in NHSGGC and also the Clinical Director of the Public Health Protection Unit.³⁵⁶ Dr Ahmed explained in evidence that the BICC had a broad remit, with HAI being only part of that remit. Its membership included representatives from Public Health and also representatives from Acute Services and Partnership Services. Dr Reid was a member as were Mr Walsh, Ms McNamee, Ms Rankin and Dr Biggs.

Dr Biggs' attendance at BICC

Dr Biggs first attended a BICC meeting on 20 March 2006 shortly before the dissolution of NHS Argyll and Clyde.³⁵⁷ She attended another two meetings in 2006,³⁵⁸ but none after that. Dr Bagnard first attended on 17 March 2008,³⁵⁹ when Dr Biggs' apologies for non-attendance are recorded. There is no record of apologies on Dr Biggs' behalf for non-attendance at any other meeting of the BICC. In short, Dr Biggs did not attend any meetings of the BICC from 1 January 2007 to 1 June 2008. Dr Ahmed said that her absence was a matter he did not pursue,³⁶⁰ and he could not remember whether her absence was noticed. He expected her to attend because that meeting was a forum for her to raise any issues at a very senior level.³⁶¹

NHSGGC Acute Strategic Management Group

According to its terms of reference the main purpose of the Acute Strategic Management Group (Acute SMG) was the development of overall strategy and policy for the Acute Services Division within the overall strategies and policies set by NHSGGC.³⁶² The Acute SMG was chaired by Mr Calderwood, and its membership included Mrs den Herder, Ms Harkness, Dr Cowan and Dr Reid. The terms of reference envisaged that the Acute SMG would set its own cycle of meetings but in the main would meet on a monthly basis. According to the ACIC Chair, Dr Reid, the ACIC reported to the Acute SMG, although this is not mentioned in the Acute SMG's terms of reference.³⁶³

In the period from 1 January 2007 to 27 September 2007 seven meetings of the Acute SMG took place without any reference in the minutes to infection prevention and control.³⁶⁴ At the meeting of 27 September 2007 it was noted in the minutes that Dr Reid introduced the Infection Control Report, which summarised the issues discussed in the

352 [GGC29210007](#)
 353 [GGC29210007](#)
 354 [TRA01130013](#)
 355 [GGC29210008](#)
 356 [TRA01130001](#)

357 [SPF01150002](#)
 358 [TRA01130022](#)
 359 [GGC02250001](#)
 360 [TRA01130028-29](#)
 361 [TRA01130023](#)
 362 [QIS01280001](#)
 363 [TRA01180004](#)
 364 [GGC01390001](#); [GGC01340001](#); [GGC01350001](#);
[GGC01410001](#); [GGC01380001](#); [GGC01150001](#);
[GGC01370001](#)

past year by the ACIC.³⁶⁵ It was also minuted that:

“work towards providing a unified control of infection service across the single system was nearing completion”.³⁶⁶

Dr Reid was also noted as stating that one particular issue was the need to gather:

“consistent data across the whole of the organisation and then provide it in a meaningful manner”.³⁶⁷

In his evidence Dr Reid said that the process had developed to a point at which a more complete data set was in fact available by early 2008.³⁶⁸ By that time infection control teams had started to produce much more information, and SPC Charts, discussed later in this Chapter, were in place for a number of areas of the Health Board. SPC Charts were not in place for the VOLH prior to May 2008, an issue that is considered in Section 15.7.

There was no mention of infection prevention and control in the minutes of the five meetings of the Acute SMG that took place between September 2007 and April 2008.³⁶⁹ At the meeting of the Acute SMG held on 24 April 2008 the minutes disclose that the Infection Control Quarterly Report was introduced by Dr Reid,³⁷⁰ who reported that significant work had been undertaken to harmonise the infection control teams across the Board area, although there remained work still to be done. He also said that SPC Charts were being circulated to wards. There was some reference made to the HAI Task Force’s new Delivery Plan for 2008-11, and it was agreed that detailed progress of the targets contained in the plan would be monitored by the ACIC and that Dr Reid would report on progress in his routine reports to the Acute SMG.³⁷¹

15.8 Reporting within the infection control committee structure

Summary of the reporting structure

As set out earlier, in ascending order: the Support Group reported to the ACIC; the ACIC in turn reported to BICC; the BICC was the link to the Chief Executive and the Board Clinical Governance Committee. This Section is not concerned with the issues of clinical governance identified in Chapter 10, but with reporting within the infection control structure itself.

Exception reporting

From 1 January 2007 to June 2008 the reporting of issues relating to infection prevention and control was carried out within an established system of exception reporting. This meant that at the levels of the BICC and the ACIC an issue would only be reported to them if there was a concern that it was outwith normal parameters.³⁷² An outbreak of CDI would qualify for exception reporting.³⁷³ In addition, however, Dr Ahmed as the Chair of the BICC expected to have been told long before any meeting of that committee if there was an outbreak of CDI in any of the Health Board’s hospitals.³⁷⁴

The exception reporting system was designed to control the flow of information through the hierarchy of committees so that issues that could be resolved at a more local level did not need to be considered at a higher level.³⁷⁵ With an organisation as large as NHSGCC it was important that senior management was not inundated with matters that could be managed adequately at levels further down the chain.³⁷⁶ The focus of the Inquiry has been on the VOLH and on the Clyde Sector, but it is necessary to bear in mind that the VOLH is just one hospital in an organisation covering some 20 hospitals³⁷⁷ of which ten were acute hospitals. Some of these are a significant size, and at the time Clyde Sector was only one of five sectors in NHSGCC.

The system of exception reporting depends upon individuals recognising and reporting

365 [GGC01430005](#)

366 [GGC01430005](#)

367 [GGC01430005](#)

368 [TRA01180012](#)

369 [GGC01400001](#); [GGC01360001](#); [GGC01980001](#);
[GGC02410001](#); [GGC02400001](#)

370 [GGC02380005](#)

371 [GGC02380005](#)

372 [TRA01130032-33](#); [TRA01200087](#)

373 [TRA01130034-35](#)

374 [TRA01130034](#)

375 [TRA01180073-75](#)

376 [TRA01200132](#)

377 [TRA01130145](#)

exceptional events. Under this system, therefore, if staff at a lower level do not recognise or report an exceptional event, senior management do not become aware of it unless there are other systems to inform them of the event and of the earlier failure to report. It becomes critical, therefore, that at senior level there is assurance that the system is working and that patients are not being exposed to unnecessary risk.

The exception reporting system failed in relation to the CDI problem that existed in the VOLH throughout most of 2007 and in 2008 until its discovery in May 2008. As discussed later in this Chapter, there should have been a system in place for reporting the rates of CDI through the committee structure that could provide senior management and ultimately the Chief Executive with the necessary assurance that HAI was being managed successfully.

Sector level reporting – the Support Group

Dr Ahmed's expectation was that the CDI rates in hospitals within the jurisdiction of each of the sector committees would be reported to the relevant sector committee.³⁷⁸ At the level of the sector committees the membership included the ICDs and Lead ICNs. At least on the face of it, therefore, these committees possessed appropriate levels of expertise in infection prevention and control.

As discussed in Section 15.7, the Support Group for the Clyde Sector defined its terms of reference to include receiving reports from three hospital Infection Control Working Groups, including the VOLH Infection Control Working Group. In any event, the Support Group was to receive reports from the Infection Control Teams at the IRH, the RAH and the VOLH. Mention has already been made of the fact that at the meeting of the Support Group of 9 May 2007 Dr Biggs tabled the VOLH Infection Prevention and Control Report in the absence of the Lead Infection Control Nurse, Mrs Murray.³⁷⁹ That report is an 11 page document which provides important and detailed information about the prevalence of CDI rates at the VOLH. The heading of the report indicates that it was

for the period "February – April 2007",³⁸⁰ but particular attention is drawn in it to the figures for the month of April, in the course of which there were ten patients suffering from CDI in the hospital. Despite that, and in contrast to the report for the IRH, where the minutes disclose that certain aspects of the contents of that report were discussed,³⁸¹ there is no record of any discussion of the contents of the VOLH report at the Support Group meeting.

The Acute Control of Infection Committee meetings

In the period from 1 January 2007 to 1 June 2008 eight meetings of the ACIC took place. A meeting originally planned for 27 May 2008 did not take place until 3 June 2008. A meeting was also planned for 27 March 2007³⁸² but does not seem to have taken place.³⁸³ The ACIC minutes disclose that infection control reports were provided on an exception reporting basis on behalf of infection control sector groups.

The first meeting of the ACIC after the Support Group meeting of 9 May 2007 was on 15 May 2007. As previously discussed, Dr Biggs, although a member of the ACIC, did not attend any of the meetings in 2007. ICDs for other sectors were in attendance at that meeting,³⁸⁴ as were Ms Martin, Ms McNamee and Ms Rankin, all of whom had been in attendance at the Support Group meeting of 9 May 2007. The minutes record that the exception report of the Clyde Sector indicated that:

"There had been a few outbreaks of suspected norovirus at the Royal Alexandra Hospital and an outbreak of MRSA and C-Diff in a Care of the Elderly Ward".³⁸⁵

The reference to an outbreak of CDI here is to the RAH.³⁸⁶

The Chair, Dr Reid, would have expected the ACIC to be provided with an indication of the

378 [TRA01130150](#)
379 [GGC13260008](#)

380 [GGC13260011](#)
381 [GGC13260008](#)
382 [GGC02320006](#)
383 [GGC29230001](#)
384 [GGC02310001](#)
385 [GGC02310005](#)
386 [TRA01180009](#)

number of patients involved, the severity of the outbreak and a description of the actions taken, but these details are not minuted.³⁸⁷ It is, however, apparent from the minutes of the meeting of the Support Group on 9 May 2007 that an outbreak report was being prepared in relation to those outbreaks of MRSA and CDI raised in the exception report for the RAH,³⁸⁸ so that there appears to have been a response to those outbreaks.

The ACIC meeting of 24 July 2007 was the first Mrs Murray attended on becoming the interim Lead Nurse for Infection Control on 1 July 2007.³⁸⁹ The minutes record that in the Clyde Sector “the C.diff trend was downwards”.³⁹⁰ Nonetheless, in June 2007 there were four CDI patients closely associated in time in ward 3 of the VOLH. Moreover, about the time of the ACIC meeting of 24 July 2007 three patients were positive for *C. difficile* toxin in ward 14 of the VOLH. These numbers are examined later in this Chapter in Section 15.11.

The ACIC meeting of 24 July 2007 had been preceded by what was the final meeting of the Support Group on 10 July 2007³⁹¹ at which Mrs Murray had “reported that there were no major concerns”,³⁹² despite tabling a surveillance report which disclosed that in the period April 2007 to June 2007 there were 24 patients suffering from CDI in the VOLH. Of that number 21 were classified in the report as hospital acquired infection, with the remaining three said to have been community acquired. None of this information reached the ACIC. The simple fact is that important information available to Support Group meetings of 9 May and 10 July 2007 on figures and rates of CDI was never placed before the ACIC, even although the ACIC received reports from the Clyde Sector. The Support Group’s terms of reference, as drafted by Dr Biggs, envisaged that its minutes would be submitted to the ACIC,³⁹³ but according to Dr Reid that did

not happen.³⁹⁴ A number of reports were submitted by Mrs Murray to the ACIC, on 24 July, 12 October, 27 November 2007 and 29 January 2008,³⁹⁵ but not one of these alerted the ACIC to the CDI problem which existed in the VOLH.

Dr Reid confirmed that there was no discussion at the ACIC about the prevalence of CDI in the VOLH in the period from January 2007 to May 2008. No discussion was prompted by the system of exception reporting.³⁹⁶ Dr Reid’s evidence was that when he first became aware of the situation at the VOLH between January 2007 and May 2008 he “was completely taken by surprise”.³⁹⁷ He would have expected to be told of the situation at the time.³⁹⁸ Dr Reid said he should, for example, have been made aware of the report presented to the Support Group meeting of 9 May 2007 which makes reference to increases in the numbers of the *C. difficile* toxin positive patients. If he had been made aware, he would have asked what significance was attributed to the increases and what actions the operational team had put in place.³⁹⁹

Dr Reid went on to say that, had the information been made available, he would have wanted the Infection Control Team to monitor the position “in real time”.⁴⁰⁰ He could see in retrospect that there had been a serious problem, and had it been apparent at the time it would “unequivocally have been escalated to the Board committee”.⁴⁰¹ It would have been referred to the operational team without waiting for any further meetings.⁴⁰²

Reporting to the Board Infection Control Committee

There were a number of potential routes by which the information available to the Support Group on 9 May and 10 July 2007 could have been made known to the BICC at its meetings on 18 June and 17 September

387 [TRA01180009-11](#)
388 [GGC13260008](#)
389 [TRA01010004](#)
390 [GGC02330004](#)
391 [GGC20940001](#)
392 [GGC20940004](#)
393 [GGC29140002](#)

394 [TRA01180039](#)
395 [TRA01180043](#)
396 [TRA01180045](#)
397 [TRA01180049](#)
398 [TRA01180049](#)
399 [TRA01180052](#)
400 [TRA01180053](#)
401 [TRA01180053](#)
402 [TRA01180053](#)

2007. The information could have been reported by the ACIC, had that committee become aware of it. Dr Biggs would in theory have been in a position to raise the issue, but even if she had identified the problem, and there is no indication that she did, she did not attend any meetings of the BICC in 2007.

Ms Rankin was another potential source since she was a member of both the Support Group and the BICC, and presented the ACIC reports to the BICC. Ms Rankin did not cause any additional investigations to take place because, as explained later in this Chapter, it was Dr Biggs who tendered the VOLH report on 9 May 2007 and Ms Rankin assumed that Dr Biggs would have carried out an investigation since she was the ICD. No doubt Mrs Murray's assertion at the meeting of 10 July 2007 that there were "no major concerns"⁴⁰³ would also have provided her with some comfort about the situation in the VOLH.

In short, the BICC was not made aware of the persisting problem with CDI at the VOLH during this period. The trail that might have led to the discovery of the prevalence of CDI at the VOLH ran cold at the level of the Support Group.

The Inquiry expert's critique

Professor Duerden was critical of the fact that reports on the number of cases and rates of CDI for a sector such as the Clyde Sector were not provided to the ACIC as standing items on its agenda.⁴⁰⁴ His position was that the surveillance data from each sector should have been made available to the ACIC as a matter of course.⁴⁰⁵ If the data disclosed any outbreaks then so far as Professor Duerden was concerned that information needed to "go to the top",⁴⁰⁶ by which he meant the BICC. In any event, it is clear that if data disclosed that there was or had been an outbreak the Chief Executive would be informed. Making the surveillance data available to the ACIC would have provided the opportunity for some re-assessment, particularly in relation to the VOLH, of

whether there had been any outbreaks and whether there had been an appropriate response.⁴⁰⁷ He explained that although there would have to be a degree of summarising as the information passed through the hierarchy of committees, that process should not obscure what was happening within hospitals. Senior management had to be assured by the data that infection prevention and control was being properly managed.

Dr Ahmed said "not everything" that happens at hospital level can be discussed in detail at the other end of the committee structure.⁴⁰⁸ His view was that the sector level was the appropriate level at which the detailed data should be assessed, and that thereafter it should only be reported on an exception basis.⁴⁰⁹ At the sector level, with people such as ICDs and Head Nurse of the Infection Control Service being members of the committee, there was a level of expertise available to consider properly the material presented on the numbers of cases and rates. His view was that if the structure worked in the way it was intended to work there was a control system in place that was designed to pick up problems.

Dr Cowan said that in a Board as large as NHSGGC there had to be "robust systems"⁴¹⁰ of reporting in place. He also saw the "key"⁴¹¹ to such a system at the time to be the sector Support Groups.

The Inquiry agrees that the Clyde Sector Support Group had a key role to play in examining the numbers and rates of cases of CDI in hospitals in its jurisdiction. Furthermore, it is undoubtedly the case that if the infection control structure at that level had worked in the way it was intended to work the problem with CDI at the VOLH would have been discovered and responded to. At the very least the ACIC should have been told of the prevalence of CDI at the VOLH at its meetings on 15 May and 24 July 2007. The Inquiry accepts that as a committee the ACIC was ignorant of the

403 [GGC20940004](#)
404 [TRA01050109-110](#)
405 [TRA01050110](#)
406 [TRA01050111](#)

407 [TRA01050133](#)
408 [TRA01130143](#)
409 [TRA01130143](#)
410 [TRA01220123](#)
411 [TRA01220123](#)

position due to individual failures and to the system of exception reporting adopted at that level in the committee structure.

The CSBS Standards provided that the results of surveillance should be “routinely reported”⁴¹² to the Infection Control Committees of the Board. That would certainly include reporting the results to committees such as the ACIC and the BICC, and indeed Dr Reid had recognised the need for his committee to see HAI statistics. This need was beginning to be satisfied from March 2008 by the production of data in the form of the SPC Charts and reports.⁴¹³

In fact those data were already available at the VOLH, at least for the VOLH, because of the existence of the Infection Control database, as the report prepared for the Support Group meeting of 9 May 2007 discloses.⁴¹⁴ It is apparent from the material contained in that report that information on the total number of cases, the number of cases in individual wards, and the assessment of trends could be presented in an intelligible way.

Infection prevention and control is a “core part”⁴¹⁵ of patient safety. It is essential that senior management is aware of the rates and trends of a HAI such as CDI. Indeed this was accepted by NHSGGC at the time. The principle of Board to ward, and ward to Board, means that there must be an unbroken line of reporting, accountability and assurance.

The failure to have a system in place which ensured that rates and trends of CDI in hospitals such as the VOLH were available at least to meetings of the ACIC, and subsequently reported to the Board, was a system failure that contributed to the CDI problem persisting up to June 2008. This is a failure for which the Board has to bear ultimate responsibility.

15.9 The failure of the committee structure

Committee structure gap

In principle there was a hierarchy of committees for reporting infection control issues from the VOLH to the Board, but there were malfunctions at the level of the Support Group and the Working Group which resulted in a significant gap⁴¹⁶ in the chain of information from the VOLH to Board level in the latter part of 2007. The intention in this Section is to examine who was responsible for or aware of the failure of those committees.

The failure of the VOLH Infection Control Working Group

As the Chair of the Working Group, Mrs Murray was directly responsible for its failure to meet after 28 September 2007. If the meeting fixed for 19 December 2007 could not take place because of lack of numbers, a meeting of the group should have been fixed for another date. That did not happen. This issue was addressed by Dr Bagraade after she became ICD for the VOLH in early February 2008.

The failure of the Clyde Acute Infection Control Support Group

As the Chair of the Support Group, Dr Biggs was directly responsible for its failure to meet after 10 July 2007. Even though she was dissatisfied with her particular role, Dr Biggs should have ensured that the Support Group continued to meet until alternative arrangements were made.

Ms Martin maintained that she was on full-time secondment from August 2007 to April 2008, and this is considered in detail later in this Chapter, but the Inquiry is satisfied that Ms Martin continued to retain her responsibilities for infection prevention and control in the Clyde Sector during that period. Ms Martin’s evidence that because she was on secondment she was “limited in what (she) could do”⁴¹⁷ is not accepted. She knew the Support Group had ceased to meet.⁴¹⁸ Indeed

412 [GOV00160045](#)

413 [GGC01890001-02](#); [TRA01180076-79](#)

414 [GGC13260017](#)

415 [GOV00380002](#)

416 [TRA01130087](#)

417 [TRA01160019](#)

418 [TRA01160019](#)

Dr Biggs made it clear to her by e-mail dated 5 September 2007 that she would not “attend or chair any meetings”⁴¹⁹ in connection with infection control until she had her role clarified. Ms Martin had direct responsibility to tackle the problem created by Dr Biggs’ failure to convene the Support Group. Her failure to do so was a serious failure.

Dr Ahmed was not aware of the failure of the Support Group. As chair of the BICC he should have been made aware of the Support Group’s malfunction,⁴²⁰ and if Dr Biggs had attended BICC meetings she would have had the opportunity to raise the issue. Ms Rankin attended a meeting of the BICC on 17 December 2007 and did not mention the problem.⁴²¹

Another possible source of information for Dr Ahmed was Dr Reid, the Chair of the ACIC, but the Inquiry is satisfied that Dr Reid did not become aware of the situation with the Support Group prior to June 2008. Ms Martin was incorrect in suggesting that she had “flagged”⁴²² the problem to him. Dr Reid’s view was that if Ms Martin had raised the problem with him, his response would have been “what are you doing about it to reinstate the committee?”⁴²³ That was perfectly understandable because, so far as he was concerned, Ms Martin was the manager responsible for infection prevention and control for the Clyde Sector.

Ms Martin also said she had spoken to Mr Walsh about the Support Group’s failure. Mr Walsh said he only became aware of the position after May 2008,⁴²⁴ and that if he had been told by Ms Martin that the Support Group had ceased to function that was not something he “would either forget or neglect”.⁴²⁵ He would regard such a failure as an important matter⁴²⁶ and would have done something about it.⁴²⁷

The Inquiry considers that Mr Walsh would have raised the failure of the Support Group with Ms den Herder or Mr Calderwood if he had known about it and if it had not been resolved, and is satisfied that Mr Walsh did not know before May 2008 that the Support Group had ceased to meet. Nonetheless, although Mr Walsh did not have operational responsibility for infection prevention and control at that time, he did have an oversight role to ensure that the committee structure was intact and functioning.⁴²⁸ He should have been made aware of the Support Group’s failure to meet.

Ms Martin suggested she raised the issue with Ms Isabel Ferguson, General Manager for Greater Glasgow Laboratory Medicine and Infection Control, but there would be no reason for her to do so, since the Clyde infection prevention and control management system was being operated separately from the rest of Greater Glasgow. Ms Ferguson was not even aware that Dr Biggs chaired the Support Group,⁴²⁹ and did not become aware of the suggestion that Ms Martin might have taken up a secondment position in August 2007 until she read the transcript of the evidence given by Ms Martin to the Inquiry.⁴³⁰ Furthermore, the problem was ultimately one for Mrs den Herder to deal with. Ms Ferguson was working on the basis that Dr Biggs was fulfilling her role as the ICD for the VOLH.⁴³¹ She had no reason to think otherwise.

Ms Rankin was aware that the Support Group had ceased to meet.⁴³² In her evidence she said she raised this at a meeting of the ACIC, of which she was a member, in November 2007. She went on to say in evidence that:

“there was some need to bring consistency and composition and meeting arrangements around the sector Infection Control Committees”.⁴³³

That response was almost identical to what had been recorded in the minutes of the

419 [SPF01130003](#)

420 [TRA01130090](#)

421 [GGC02270001](#)

422 [TRA01160068](#)

423 [TRA01180042](#)

424 [TRA01200039](#)

425 [TRA01200066](#)

426 [TRA01200066](#)

427 [TRA01200067](#)

428 [GGC30350001-02](#)

429 [TRA01210095](#)

430 [TRA01210091](#)

431 [TRA01210101](#)

432 [TRA01000025](#)

433 [TRA01000026](#)

ACIC held on 27 November 2007.⁴³⁴ What is clear, as Ms Rankin said in her evidence, is that what she mentioned at that meeting “wasn’t just particularly in relation to the Clyde Sector”.⁴³⁵ Ms Rankin had a further opportunity to raise this issue with the ACIC at its meeting of 29 January 2008 and did not do so. By then the Support Group had also failed to hold its January quarterly meeting. As already mentioned, Ms Rankin did not raise this issue at the BICC meeting of 17 December 2007. When recalled to give evidence she accepted that the failure of the Support Group was something not raised by her because her

“focus was on single-system working and integration, but I can’t give a rationale as to why this didn’t concern me, why I didn’t raise it”.⁴³⁶

Mrs Catherine MacGillivray, Head of Nursing for Clyde Acute, was a member of the Support Group and knew that it had ceased to meet.⁴³⁷ For that reason she had monthly meetings with Mrs Murray from autumn 2007 in order to be aware of “issues that would have been of importance”.⁴³⁸ These meetings usually took place in the VOLH.⁴³⁹ Mrs MacGillivray had no recollection of CDI being discussed at these meetings,⁴⁴⁰ but said that, with the knowledge she now had, she should have been told about the incidence of CDI in the VOLH.⁴⁴¹

Mrs MacGillivray could not remember if she discussed the failure of the Support Group with Mrs den Herder. Mrs MacGillivray would certainly have had the opportunity to do so as she was a member of the Clyde Acute Management Team and Mrs den Herder chaired⁴⁴² their monthly meetings.⁴⁴³ There was no reason why she would not tell Mrs den Herder, particularly as she was meeting Mrs Murray on a regular basis because of the Support Group’s failure. Mrs MacGillivray’s

view was that Mrs den Herder “must have known”⁴⁴⁴ that the Support Group had ceased to meet.

Mrs den Herder maintains in her letter dated 13 September 2012 that she did not know the Support Group had ceased to meet.⁴⁴⁵ That was also her position when she gave evidence to the Internal Investigation.⁴⁴⁶ As Mrs MacGillivray pointed out, however, Mrs den Herder did receive the minutes of the Support Group,⁴⁴⁷ and it should therefore have become apparent to her that the Support Group had stopped functioning.

As a member of the Support Group, Mrs Murray was aware that it had stopped meeting. Mrs Murray was also present at the ACIC meeting of 27 November 2007,⁴⁴⁸ and under the heading “Committee Reports” Mrs Murray is noted as having delivered the exception report for the Clyde Sector. There is no indication there that the Support Group had failed to hold its October meeting, nor did Mrs Murray mention the failure of the Support Group to hold its quarterly January 2008 meeting in the report she made to the ACIC meeting of 29 January 2008. Mrs Murray said that she did not do anything to see if the Support Group could be reinstated. She thought that Ms Martin was considering ways in which it could be resurrected.⁴⁴⁹

It therefore appears that those who could have informed the ACIC directly of the failure of the Support Group, Ms Rankin and Mrs Murray, did not do so. The ACIC was accordingly unaware that the Support Group had ceased to function. By autumn 2007 Ms Martin had stopped attending meetings of the ACIC on the unfounded basis that she no longer had managerial responsibility for infection prevention and control. Furthermore, members of the BICC were also unaware of the position, with the exception of Ms Rankin, who although a member did not mention the failure to the committee.

434 [GGC02340006](#)

435 [TRA01000026](#)

436 [TRA01260025](#)

437 [TRA00900090](#); [TRA00900096](#)

438 [TRA00900090](#)

439 [TRA00900093](#)

440 [TRA00900094](#)

441 [TRA00900096](#)

442 [GGC04550001](#)

443 [TRA00900145](#); [TRA00900147](#)

444 [TRA00900103](#)

445 [INQ04960006](#)

446 [GOV00890121](#)

447 [TRA00900103](#)

448 [GGC02340001](#)

449 [TRA01010085](#)

The failures by Ms Martin, Ms Rankin and Mrs Murray to raise this issue were serious failures. Mrs den Herder too should at least have realised that the Support Group was not meeting.

15.10 Surveillance systems

Clinical Standards Board for Scotland

It was evident from the CSBS Standards⁴⁵⁰ and other guidance produced by the SEHD that the prevention and control of HAIs was to be a “high-profile priority issue”⁴⁵¹ for NHSScotland. The duty on Chief Executives was that of designating the prevention and control of infection as a “core part”⁴⁵² of clinical governance and patient safety.

The CSBS Standards required Boards to have in place surveillance systems so that they could respond rapidly to outbreaks and minimise the risk of infections.⁴⁵³ The “Proposed Infection Control Structure in NHSGGC”⁴⁵⁴ produced in December 2005 and revised in March and June 2006⁴⁵⁵ referred to the CSBS Standards and acknowledged the Chief Executive’s accountability for “successful prevention and control of infection”.⁴⁵⁶ It set out that the Chief Executive had designated the prevention and control of infection as a “core part”⁴⁵⁷ of the Board’s clinical governance and patient safety. The SEHD’s letter of 10 July 2006⁴⁵⁸ included instructions to Boards on the mandatory reporting of *C. difficile* toxin positive cases from 1 September 2006, and

the vital importance of an “integrated and validated system of surveillance”⁴⁵⁹ was re-emphasised.

Effective surveillance is a necessary prerequisite of a properly functioning infection prevention and control system. As Professor Duerden suggested, “If you can’t measure it you can’t manage it”.⁴⁶⁰ In setting out the criteria relevant to surveillance of infection the CSBS Standards provided as follows:

“Results of surveillance with interpretation and recommendations are routinely reported to the ICC, clinicians, nurses, managers at all levels”.⁴⁶¹

Here the reference to the ICC is a reference to an Infection Control Committee with an equivalent status to that of the BICC.⁴⁶²

The T-card system

The ICNs at the VOLH operated a T-card monitoring system. This system used a wall mounted rack where coloured cards were placed to provide a real-time picture for each ward of patients suffering from different HAIs. The cards for *C. difficile* toxin positive cases were yellow. When a patient tested positive for *C. difficile* toxin the patient’s details were written on a card, and further information such as the patient’s location, treatment and dates of positive results was generally added. Figure 15.4 is an example of a T-card for a patient who has tested positive for *C. difficile* toxin.

450 [GOV00160001](#)

451 [GOV00090031](#)

452 [GOV00380002](#)

453 [GOV00160044](#)

454 [GGC29210001](#)

455 [GGC29210005](#)

456 [GGC29210001](#)

457 [GGC29210001](#)

458 [GOV00430001](#)

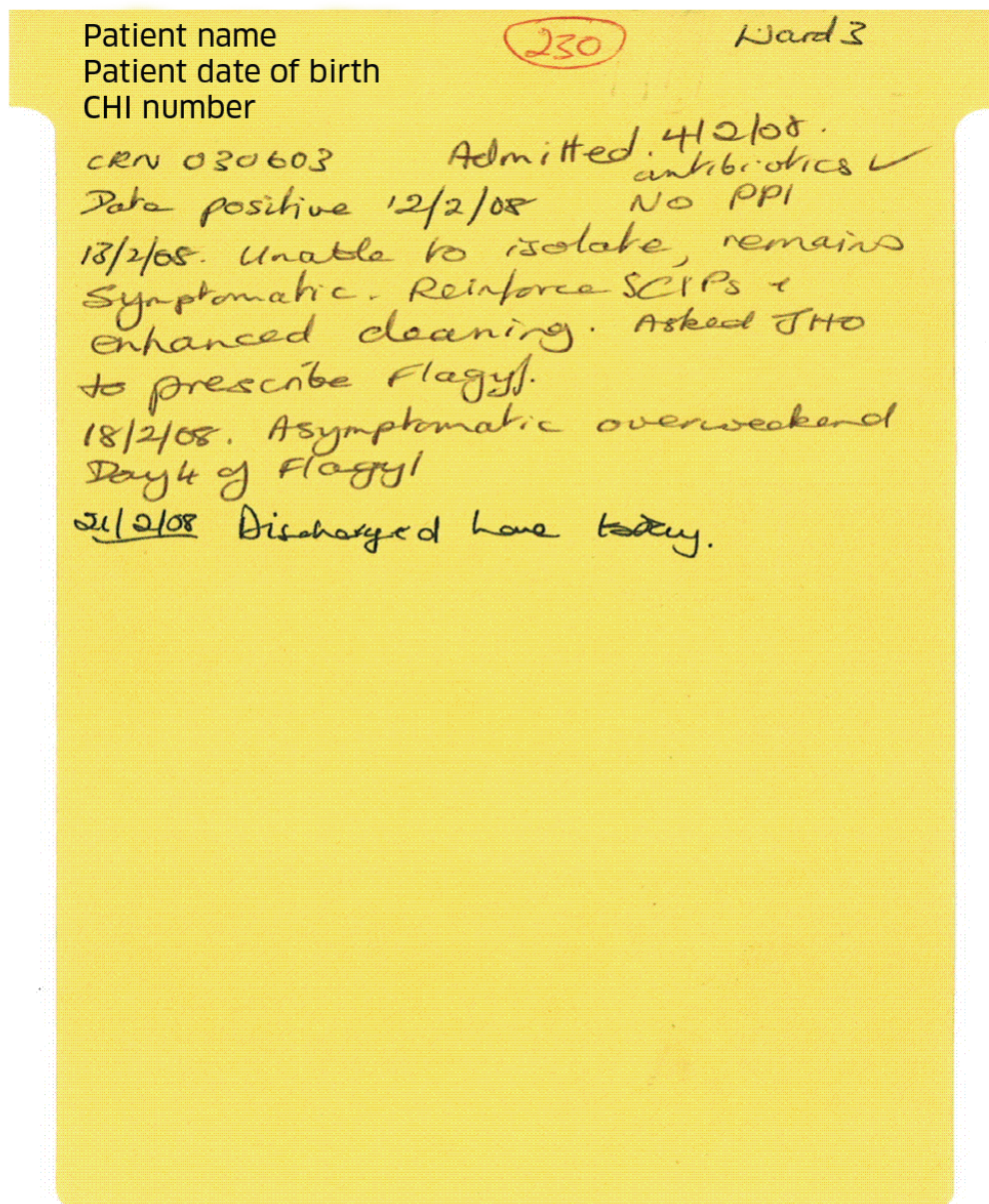
459 [GOV00430003](#)

460 [TRA01050121](#)

461 [GOV00160045](#)

462 [GOV00160030-31](#)

Figure 15.4 A T-card



Mrs Perry said that she would have expected sufficient detail of the contact the ICNs had made with the clinical team to be recorded on the T-card. This would include any telephone call or ward visit. The card should also detail the patient's condition and what advice had been given to the ward by the ICN.

Having reviewed the T-cards available, Mrs Perry concluded that the ICNs failed to maintain records of *C. difficile* positive

patients to an appropriate standard.⁴⁶³ There were instances where information about the antibiotic treatment being given for CDI was not recorded. There were cases where it was apparent there was a delay in recording the reporting of a positive result for *C. difficile* toxin. On occasions this delay was in excess of three days. Gaps between entries (in one instance a gap of 20 days)⁴⁶⁴ revealed failures to record what reviews of patients, if any,

463 [TRA01040069](#)
 464 [TRA00950076](#)

were being conducted by the ICNs. Reviews appeared infrequent even though there were patients who may have suffered relapses of the infection.⁴⁶⁵

The *C. difficile* Policy set out that a risk assessment of “a patient and environment”⁴⁶⁶ was to be undertaken by the Infection Control Team. Mrs Murray’s job description included responsibility for carrying out risk assessments for patients with CDI,⁴⁶⁷ and the job description for Mrs O’Neill included the following responsibility:

“Use risk assessment frameworks in order to assess situations and implement the most appropriate corrective action where required”.⁴⁶⁸

Mrs O’Neill said risk assessments were carried out that involved discussions with ward staff about the availability of isolation,⁴⁶⁹ but that no record was made of such risk assessments.⁴⁷⁰ Mrs Murray said that risk assessment would include looking at other risk factors such as a patient’s age, underlying medical conditions and antibiotic usage. She agreed that a record should have been kept but that that was not done.⁴⁷¹

Mrs O’Neill said that the failure to record ward visits or patient reviews did not mean that such visits or reviews had not taken place.⁴⁷² Her position was that the gaps were a sign of poor record keeping.⁴⁷³ Mrs Murray said that the documenting of a patient’s condition and progress was not as good as it should have been.⁴⁷⁴ When Ms Higgins took over as interim Lead Nurse for Control of Infection in April 2008 she considered that the information provided on the T-cards was “very sparse”.⁴⁷⁵ It was not what she expected to find, and she expressed her concerns to Mrs O’Neill at the time about the

lack of information provided.⁴⁷⁶ It is perfectly clear to the Inquiry that the record keeping by Mrs O’Neill and Mrs Murray was totally inadequate.

The T-cards as a surveillance system

Professor Duerden described the T-card system as a “rudimentary form of surveillance”.⁴⁷⁷ This was not to decry the importance of it as a system that could provide contemporary information on the number of *C. difficile* toxin positive cases. The system could provide the information to the ICNs that they had a number of cases at the same time in the same ward. It could also show information hospital-wide and reveal whether there was a similar problem in more than one ward.⁴⁷⁸ If there were two or three CDI cases in a particular ward at the same time there would be two or three yellow cards in a line to display that information. According to Professor Duerden, two, three or four yellow cards on the board at the same time for the same ward should have triggered a response from the ICNs.⁴⁷⁹ Dr Ahmed said that the T-card system was “more than adequate”⁴⁸⁰ to identify an outbreak, and Ms Higgins described the system as a “good visual aid”.⁴⁸¹ That was undoubtedly the case.

The Infection Control database

There has already been some reference to the Infection Control database (the database) in this Chapter as well as in Chapter 5. This was an Access database system used by the ICNs to record information on patients who tested positive for *C. difficile* toxin, including the patient’s name, where the patient was located in the hospital, the date of admission to the hospital, the date of the onset of symptoms and the date the patient tested positive for *C. difficile* toxin. There was also a record made of whether or not the CDI was hospital or community acquired. Figure 15.5 is an example of a patient card which has been extracted from the database.

465 [TRA01040066-67](#)
 466 [GGC00780255](#)
 467 [GGC00780254](#)
 468 [INQ00380008](#)
 469 [TRA00950014](#)
 470 [TRA00950014](#)
 471 [TRA01010048](#)
 472 [TRA00950076](#)
 473 [TRA00950076](#)
 474 [TRA01010055](#)
 475 [TRA00990017](#)

476 [TRA00990017-18](#)
 477 [TRA01050122-123](#)
 478 [TRA01050123](#)
 479 [TRA01050127-128](#)
 480 [TRA01130141](#)
 481 [TRA00990023](#)

Figure 15.5 A patient card

Patient Details			
ID:	<input type="text"/>	CHI Number:	<input type="text"/>
Unit Number:	<input type="text"/>	Surname:	<input type="text"/>
First Name:	<input type="text"/>	Date of birth:	<input type="text"/>
Admission			
Hospital:	<input type="text" value="VOL"/>	Ward:	<input type="text" value="15"/>
Situated:	<input type="text" value="single room"/>		
Adm date:	<input type="text" value="23/11/2007"/>	Hospital related or community acquired:	<input type="text" value="Hospital"/>
State hospital:	<input type="text" value="VOL"/>	Ward:	<input type="text" value="15"/>
Onset symptoms:	<input type="text" value="04/12/2007"/>		
Date positive:	<input type="text" value="05/12/2007"/>	Relapse/Reinfection/New:	<input type="text"/>
Risk Factors			
Any risk factors:	<input type="text" value="Yes"/>	Age	<input checked="" type="checkbox"/>
ITU	<input type="checkbox"/>	Bowel history	<input type="checkbox"/>
N.G. OR P.E.G.	<input type="checkbox"/>	Bowel Surgery/procedure	<input type="checkbox"/>
Immunosuppressed	<input type="checkbox"/>	Enemas	<input type="checkbox"/>
Recent antibiotics	<input checked="" type="checkbox"/>	Constipation	<input type="checkbox"/>
Medical Condition	<input type="checkbox"/>	Laxatives	<input type="checkbox"/>
		Previous gastroenteritis	<input type="checkbox"/>
		Patients in Same Bedded Area	<input type="checkbox"/>
		Patients in Other Bedded Area	<input type="checkbox"/>
		Proton Pump Inhibitor	<input type="checkbox"/>
Outcome			
Antibiotic treatment:	<input type="text" value="yes metronidazole"/>		
Outcome:	<input type="text"/>	Deceased:	<input type="checkbox"/>
Date of death:	<input type="text"/>		

Mr Nixon's role from 2006 to December 2007 has been referred to in Section 15.2, and was described as one of "general administration"⁴⁸² in which he was based at the VOLH for three days a week. He could obtain information from the database that could be used by the ICNs, and in particular produced spreadsheets and quarterly reports providing data on patients with HAIs such as *C. difficile*. Mrs Murray was Mr Nixon's line manager.⁴⁸³ Mr Nixon did not input data to the database himself. All information was entered onto the database by Mrs Murray or Mrs O'Neill.⁴⁸⁴

Mr Nixon understood that the purpose of the quarterly reports was to identify historical trends,⁴⁸⁵ and was aware that the quarterly reports were taken to quarterly meetings.⁴⁸⁶ In addition to producing quarterly reports containing data on infection prevention and

control, Mr Nixon said that he produced graphs to show the nature of the trends. The material attached to the minute of a meeting of the Clyde Infection Control Support Group on 9 May 2007, for example, was produced by Mr Nixon for Mrs Murray.⁴⁸⁷ He would not seek to interpret trends, but simply produced data that were available on the database.⁴⁸⁸ Mr Nixon said he could have also used the material in the database to produce reports on a much more regular basis showing the number of patients who had tested positive for CDI in each ward.⁴⁸⁹ An alert system that would warn if a particular number of patients tested positive was not in place,⁴⁹⁰ but such a system could have been in place and Mr Nixon would have been able to do that if asked.⁴⁹¹

Knowledge of the database system

In addition to the local members of the

482 [TRA00920005-07](#)

483 [TRA00920009](#)

484 [TRA00920010](#)

485 [TRA00920012](#)

486 [TRA00920012](#)

487 [TRA00920012-13](#)

488 [TRA00920013](#)

489 [TRA00920016](#)

490 [TRA00920018](#)

491 [TRA00920018-19](#)

Infection Control Team, a number of others were also aware of the existence of the database. Dr Bagrade knew the database existed but thought wrongly that it was not in active use.⁴⁹² She was unaware that the ICNs continued to input data into the database.⁴⁹³ Mrs Murray had been told by Ms Rankin not to input data into the database because of the planned introduction of the SPC Charts system, but Mrs Murray continued to do so because she saw no “harm” in doing so.⁴⁹⁴

Ms Rankin was also aware of the existence of the database and knew that along with the T-cards it formed the local surveillance system.⁴⁹⁵ She could not understand why the ICNs continued to enter data into the database after Mr Nixon left in December 2007 as they could “get nothing back from”⁴⁹⁶ it, and indeed this appears to have been the position after Mr Nixon’s departure.

Ms Martin was aware of the existence of the database. In particular she knew that when Mr Nixon was in post he could provide statistical information on the wards at the VOLH.

Dr de Villiers was aware of the T-card system but did not appear particularly certain whether or not there was a database system in place.⁴⁹⁷ Dr Alison Claxton, Consultant Microbiologist at the RAH, had no knowledge of the database,⁴⁹⁸ and neither did Mr Kinloch.⁴⁹⁹

In her second police statement Dr Biggs said she was aware that the VOLH had a “form of surveillance” but that she was “not sure which method they were working”.⁵⁰⁰ This issue was not raised with Dr Biggs in the course of her interview with the Internal Investigation panel.⁵⁰¹ Dr Biggs’ apparent ignorance of the surveillance arrangements is illustrative of the lack of interest she had in infection prevention and control at the VOLH.

Neither Mr Walsh nor Ms McNamee was aware of the database. Although they could have been made aware of its existence during the investigation carried out by the Outbreak Control Team, it appears they were not told.⁵⁰² In fact, the Outbreak Control Team Report does not mention the database system.

Ms Higgins’ perspective

After she took on the post of interim Lead Nurse in April 2008, Ms Higgins did discover the existence of the database as part of her fact finding exercise to see whether there was anything she should be concerned about.⁵⁰³ She was surprised to find that the Infection Control Team at the VOLH appeared to have “a database full of information” but that there were no reports available that she could look at to see if there were any issues of concern.⁵⁰⁴

Ms Higgins was surprised that Mrs McIntyre was unable to produce simple reports from the database because she did not have the expertise to do so at the time.⁵⁰⁵ Her view was that SPC Charts could have been produced from the database prior to May 2008.⁵⁰⁶ What Ms Higgins meant by that was that charts providing information on historical trends could have been constructed from the information contained on the database, and those charts would have contained similar information to that provided on SPC Charts.⁵⁰⁷

Ms Higgins was able to construct a chart from the information on the database in May 2008 that revealed that there was a problem with CDI in ward 6.⁵⁰⁸ That chart is not available to the Inquiry, but Ms Higgins also produced a chart for the period to June 2008,⁵⁰⁹ which is reproduced in Figure 15.6 and represents the position in ward 6 up to June 2008. The points on that chart representing the position in ward 6 in February and April 2008 would have been the same on the original chart produced by Mrs Higgins.

492 [TRA01020095-96](#)

493 [TRA01140024](#)

494 [TRA01010061](#)

495 [TRA00990170](#)

496 [TRA01260033](#)

497 [TRA00840092-95](#)

498 [TRA01220071](#)

499 [WTS02170012](#)

500 [SPF01470003](#)

501 [GOV00890099-101](#)

502 [TRA01200097](#); [TRA012000102-103](#); [TRA01210054-55](#)

503 [TRA00990018-19](#)

504 [TRA00990019](#)

505 [TRA00990019](#)

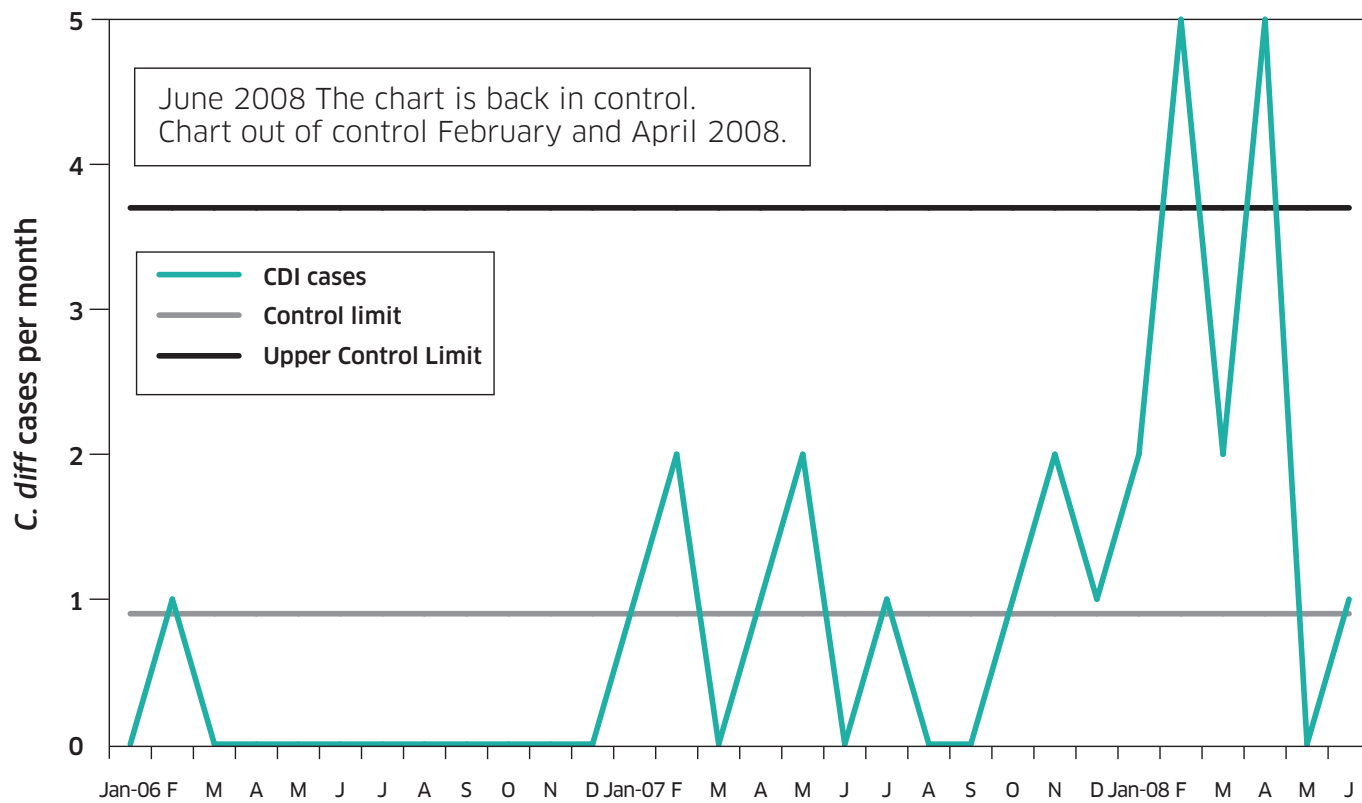
506 [TRA00990093-95](#)

507 [TRA00990094-96](#)

508 [TRA00990072-73](#)

509 [TRA00990072-73](#); [GGC16630014](#)

Figure 15.6 New cases of CDI from 2006 to 2008 on ward 6



It is important to note that an SPC Chart is retrospective. It cannot be used to detect an outbreak in real time.

Adequacy of the T-card and the database

The systems available at the VOLH were perfectly adequate for the ICNs to discover the existence of potential outbreaks of CDI.⁵¹⁰ There was a combination of systems which ought to have alerted them to the existence of CDI patients in the VOLH who appeared to be linked closely in time and in place, and which should have initiated outbreak procedures.

15.11 Failure to identify outbreaks

Local failures

The failures at local level to appreciate the existence of a persisting CDI problem at the VOLH were serious and had a profound effect on patient care. In Chapter 5 points in time have been identified at which it was apparent in different wards that there were patients suffering from CDI who were linked in time and place. According to Dr Ahmed:

“Two cases of *C. difficile* linked in time and place is an outbreak, regardless whether you are waiting for the typing”.⁵¹¹

Opportunity after opportunity was missed to carry out a proper investigation. There clearly were outbreaks. And if an outbreak had been declared the appropriate reporting steps and procedures envisaged by the Outbreak Policies could have been taken.

510 [TRA01050124](#); [TRA01060017-18](#); [TRA01040053-54](#)

511 [TRA01130061](#)

The policy of infection control being everyone's business was not practised in the VOLH. The medical staff seemed oblivious to the persisting CDI problem. The attention paid to *C. difficile* toxin positive cases by nursing staff was influenced by the ICNs. The attitude adopted by the ICNs, and Mrs Murray in particular, is one that the Inquiry has difficulty in understanding. Professor Duerden described Mrs Murray's failure to respond to the *C. difficile* toxin positive cases as an "error of judgement".⁵¹² Mr Divers quite rightly could not understand how despite:

"the evidence in front of their eyes (they) somehow managed to conclude that there wasn't an outbreak".⁵¹³

In addition to the local failures discussed in this Section, there was a missed opportunity by others to recognise that there was a CDI problem at the VOLH.

An early missed opportunity

As mentioned earlier in this Chapter, information on the increased rates of CDI in the VOLH in April 2007, "particularly on one ward"⁵¹⁴ was available to the Support Group at its meeting of 9 May 2007 when Dr Biggs presented the report in the absence of Mrs Murray. Two extracts from that report are set out in Table 15.3⁵¹⁵ and Figure 15.7.⁵¹⁶

Table 15.3 discloses that in April 2007 there were 22 positive results for CDI in the VOLH, nearly half the total amount of infections recorded. Another source of evidence indicates that four of those CDI patients tested positive in ward 14 in the week beginning 13 April 2007.⁵¹⁷

Table 15.3 NHSGGC Infection Control report - number of infections at the VOLH

Lab Findings	Week ending				Grand Total
	06/04/07	13/04/07	20/04/07	27/04/07	
<i>Chlamydia trachomatis</i>	-	-	1	2	3
<i>Clostridium difficile</i> Toxin AB	6	6	8	2	22
<i>E.coli</i>	-	-	-	1	1
Group A Streptococcus	-	1	-	1	2
Group C Streptococcus	-	-	1	-	1
Group G Streptococcus	-	-	-	2	2
<i>Haemophilus influenzae</i>	-	-	-	1	1
MRSA	3	3	-	5	11
<i>Staphylococcus aureus</i>	1	-	-	1	2
Total	10	10	10	15	45

512 [TRA01050128](#)

513 [TRA01250078](#)

514 [GGC13260020](#)

515 [GGC13260019](#)

516 [GGC13260018](#)

517 [INQ02580001](#)

Figure 15.7 NHSGGC Infection Control report – *C. difficile* trend at the VOLH

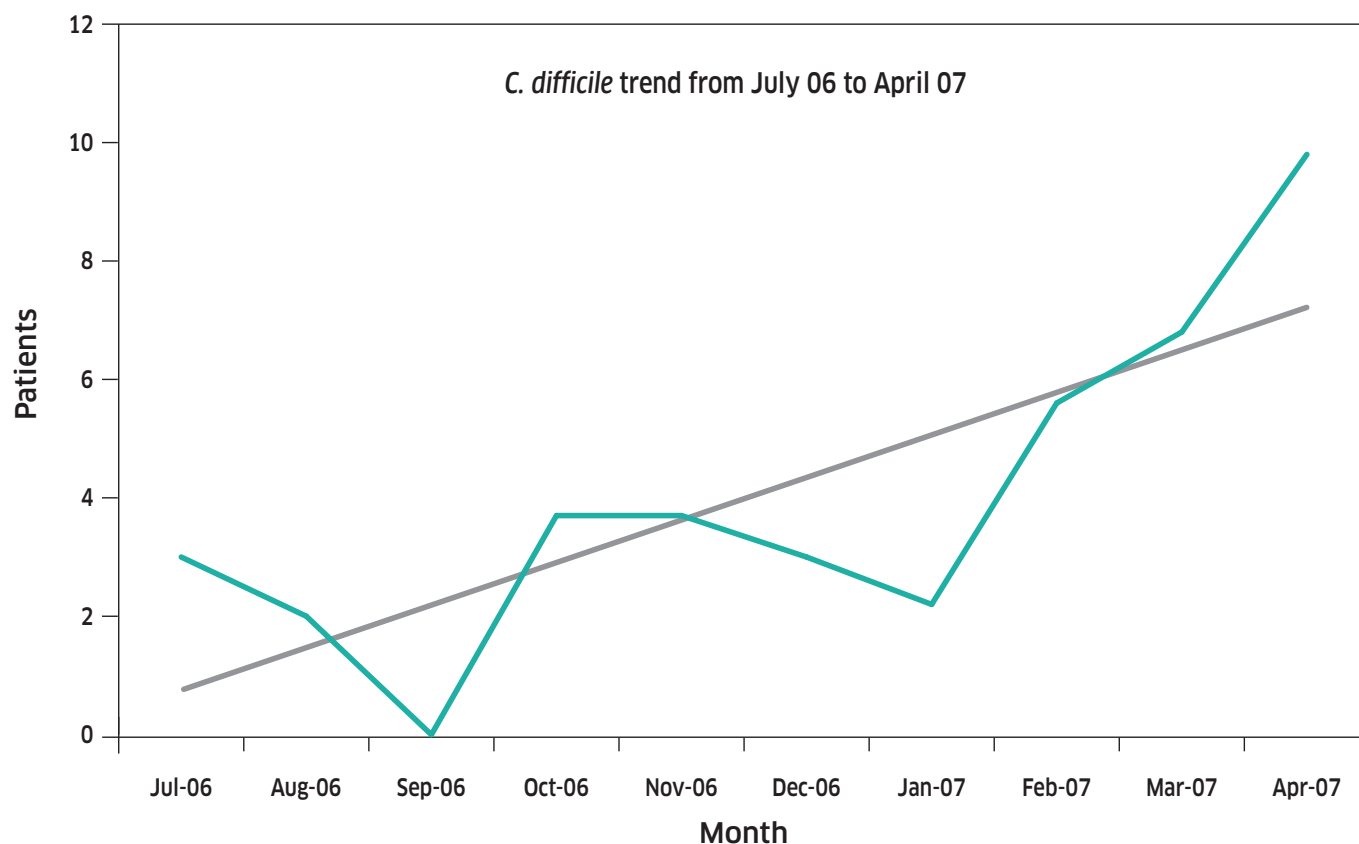


Figure 15.7 shows the rising trend of CDI in the VOLH. This material was produced by Mr Nixon from information on the database,⁵¹⁸ and again this information was contained in the report presented by Dr Biggs at the Support Group meeting of 9 May 2007. That meeting was attended by Ms Martin, Ms Rankin, Mr Walsh, Mrs MacGillivray and of course the Chair, Dr Biggs.⁵¹⁹

Mr Divers was of the view that because Mr Walsh had not yet taken up his post of Infection Control Manager he did not have a direct responsibility to react to the CDI rates reported.⁵²⁰ That seems a valid point. Mr Walsh did seem to recall some discussion in relation to the VOLH report on increases in *C. difficile* toxin positive rates, but his expectation was that the issue would be investigated by the local Infection Control Team.⁵²¹

Mr Divers said that Ms Martin, Ms Rankin and Mrs MacGillivray had greater responsibility than Mr Walsh to act upon the concerns raised by the *C. difficile* toxin positive rates reported.⁵²² Dr Ahmed was of the view that there should have been a discussion and efforts made to find an explanation for the increase in *C. difficile* toxin positive cases.⁵²³ If there was no proper explanation and it was thought that there might be an outbreak he would expect “them to escalate further up”.⁵²⁴ As Dr Ahmed explained, the reason the Support Group was established was to monitor what was going on in that sector, if necessary by investigation and taking appropriate action.⁵²⁵

Had the Support Group responded to the VOLH report presented at the meeting on 9 May 2007, an investigation would have

518 [TRA00920012-14](#)
 519 [GGC13260006](#)
 520 [TRA01250113-115](#)
 521 [TRA01200122-123](#)

522 [TRA01250113](#)
 523 [TRA01130049-50](#)
 524 [TRA01130050](#)
 525 [TRA01130052](#)

disclosed the existence of potential outbreaks and the failure to report in terms of the Outbreak Policy.

Chapter 5 sets out the information the Inquiry has extracted from a number of sources on patients who tested positive for *C. difficile* toxin in the VOLH. This includes April 2007, the period covered by the report to the Support Group on 9 May 2007. Table 5.4 in Chapter 5 identifies four patients who tested positive for *C. difficile* toxin in ward 14 between 13 and 17 April 2007. Table 5.8 sets out CDI patients on ward 6 from February to April 2007. It identifies three patients who tested positive for *C. difficile* toxin between 5 and 13 April 2007. Earlier in March 2007 three patients tested positive for *C. difficile* toxin in ward F within a period of about three days. This is set out in Table 5.6. These are all instances of two or more CDI patients who were closely connected in place and time, and should have initiated outbreak procedures.

Ms Rankin said in evidence that “with hindsight”⁵²⁶ she should have enquired about the information provided to the Support Group meeting. Despite her responsibility for infection control, Ms Rankin did not consider any further investigation because from her perspective it was Dr Biggs, as the ICD and the person who had tendered the VOLH report, who had a direct responsibility for infection control at the VOLH. As Ms Rankin explained in evidence, the CDI rates at the VOLH were not raised as a particular concern with her, either by Mrs Murray or Dr Biggs.⁵²⁷ Moreover, Ms Rankin proceeded on the basis that there would have been an investigation into each case to see if there was a link.⁵²⁸ It was unfortunate that Ms Rankin did not respond in a more proactive way at that time, but it is at least understandable why she did not cause further enquiries to be made in such circumstances.

Mr Divers also mentioned Mrs MacGillivray and Ms Martin as having some responsibility to respond to concerns raised by the CDI rates reported. Mrs MacGillivray had held the post of Head of Nursing for the Clyde

Acute Directorate since 2006,⁵²⁹ and her line manager was Mrs den Herder. She had no recollection of the response to the CDI rates at the meeting of 9 May 2007⁵³⁰ but she would have expected the situation to be monitored. It would be unreasonable to be critical of Mrs MacGillivray for failing to respond more actively to the VOLH report. Ms Martin could be said to have had more direct responsibility than Mrs MacGillivray as Dr Biggs’ line manager, but as the Report had been tendered by Dr Biggs in her capacity as the ICD the Inquiry is not inclined to criticise Ms Martin for failing to take a more proactive stance in response to the contents of the report.

Dr Biggs should have conducted an investigation into the CDI information she presented in the report to the Support Group meeting on 9 May 2007. That would have disclosed the real likelihood of outbreaks at the VOLH that the local Infection Control Nurses had not properly investigated. Her failure to respond to the information available to her at that time was a significant one and professionally unacceptable.

Reasons for local failures

In Chapter 5 a number of occasions have been identified in the period from 1 January 2007 to 1 June 2008 when it was likely that there were CDI outbreaks in different wards at the VOLH. The intention now is to consider some aspects of practice in the VOLH and examine why the local ICNs did not respond appropriately by invoking the provisions of the NHSGGC Outbreak Policy.

Knowledge of outbreaks - nursing staff

The evidence from the senior nurses on the presence of CDI on the wards was somewhat mixed. Sister Lesley Fox, SCN for ward 6, said that it did not occur to her at any time that there could have been an outbreak in ward 6 because the cases could be explained.⁵³¹ Her evidence was that she had been told by Mrs O’Neill that the explanation lay in the fact that the patients had been given antibiotics.⁵³² Ms Isobel Law, the VOLH Bed

526 [TRA01260027](#)

527 [TRA01000014](#)

528 [TRA01000018](#)

529 [TRA00900074](#)

530 [TRA00900113-114](#)

531 [TRA00310094](#)

532 [TRA00340110-111](#)

Manager, raised the number of cases with Mrs Murray in 2007 and was reassured that there was not a problem with cross infection.⁵³³ Over the period from December 2007 to June 2008 Sister Anne Madden, SCN for ward 15, said that she did not think that she had given the presence of CDI in ward 15 a great deal of consideration.⁵³⁴

Mrs Margaret Kelso, a staff nurse in ward F, was concerned in January or February 2008 about the number of patients suffering from CDI, and was prompted to consult the infection control manual to check the definition of an outbreak. She thought the ward should be closed, and spoke to Sister Laura Gargaro, SCN for ward F, about her concerns. She assumed that the matter would be addressed at the bed meetings. Her evidence was that there was general concern among members of the nursing staff, and that there was also a feeling that patients were being moved into the ward when there were patients in the ward suffering from CDI.⁵³⁵

Sister Gargaro said that she did recognise, particularly in January 2008, that there was a level of CDI cases on ward F which exceeded the gastro-intestinal definition of an outbreak.⁵³⁶ She discussed the position with Mrs O'Neill when there were already three symptomatic patients in the ward and a fourth patient became symptomatic. Mrs O'Neill offered advice on cohorting patients. Sister Gargaro said in evidence that she asked Mrs O'Neill "should we not be closing?"⁵³⁷ but according to Sister Gargaro Mrs O'Neill's response was that the cases could be explained.⁵³⁸ Again the explanation given was that the patients had been on antibiotics "particularly ones that are C.diffogenic".⁵³⁹ Mrs O'Neill's final position in evidence was that she did not provide this explanation,⁵⁴⁰ but the antibiotic explanation was one advanced by Mrs Murray in evidence, and that does lend some credence to Sister Gargaro's evidence on this issue.

Knowledge of outbreaks – medical staff

The infection prevention and control policies covered in Section 15.4 apply to all healthcare workers. The Outbreak Policy states that "This policy applies to all staff employed by NHS Greater Glasgow and Clyde".⁵⁴¹ It goes on to specify that healthcare workers must follow the policy and must also report to the Infection Control Team when they suspect there may be an outbreak.⁵⁴² As noted in Section 15.4, only one doctor had some understanding of what would constitute an outbreak. None of the doctors who gave evidence considered there to be a particular problem with CDI at the time, and since they lacked knowledge of what constituted an outbreak it is hardly surprising that none of them gave much consideration to the prevalence of CDI.

Knowledge of outbreaks – Infection Control Nurses

The Inquiry has great difficulty in understanding why the ICNs did not appreciate the nature and extent of the CDI problem at the VOLH. From June 2007 Mrs O'Neill was the main presence at the VOLH, a factor that has already been commented upon in Section 15.2, but the CDI problem had developed before June 2007 at a time when Mrs Murray was the Senior ICN.

Mrs O'Neill's evidence – loose stools

Mrs O'Neill's evidence was that there was no regular practice prior to June 2008 of the ICNs being informed of patients who developed loose stools or who had samples taken for analysis.⁵⁴³ This contradicted the evidence of some nurses that the ICN would be informed of every case.⁵⁴⁴ The Inquiry sees no reason not to accept Mrs O'Neill's evidence on this issue. She did explain that the practice changed after June 2008.

533 [TRA00890024](#)
534 [TRA00390005-06](#)
535 [WTS02190004-07](#)
536 [TRA00410100](#)
537 [TRA00410102](#)
538 [TRA00410102-104](#)
539 [TRA00410104-105](#)
540 [TRA00950178-179](#)

541 [GGC00780145](#)
542 [GGC00780147](#)
543 [TRA00950050-51](#)
544 [TRA00950056](#)

Mrs O'Neill's position on outbreak definition

Mrs O'Neill was aware of an increase in *C. difficile* toxin positive patients in the period up to April 2007, but she did not consider at the time that there was a particular problem.⁵⁴⁵ Mrs O'Neill was aware that two or more linked cases of CDI could constitute an outbreak.⁵⁴⁶

Mrs O'Neill's position on CDI on the wards

The position in ward 14 as set out in Table 15.4 suggests that in April 2007 four patients were positive for *C. difficile* toxin in that ward and closely linked in time. This was considered by Mrs O'Neill in oral evidence.⁵⁴⁷

Table 15.4 *C. difficile* toxin positive cases in ward 14 in April 2007

	Admission to VOLH	Admission to ward 14	Patient records		Lab report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 1	19/03/07 to ward 3	28/03/07	unknown	13/04/07	13/04/07	17/04/07
Patient 2	12/01/07 from RAH to ward 5	15/01/07	unknown	13/04/07	13/04/07	17/04/07
Patient 3	10/04/07 from Western Infirmary to ward 14	10/04/07	unknown	16/04/07	14/04/07	17/04/07
Patient 4	21/03/07 to ward 6	13/04/07	16/04/07	17/04/07	16/04/07	19/04/07

Mrs O'Neill said that in this situation there would be a row of yellow T-cards representing the positive patients visible on the infection control board.⁵⁴⁸ She said that this picture could represent an outbreak, but was not able to explain why that possibility was not recognised at the time.⁵⁴⁹ She was

not aware of there being a reluctance to declare an outbreak.⁵⁵⁰

The position in ward F in March 2007 as set out in Table 15.5 was also explored in evidence with Mrs O'Neill.

545 [TRA00950124](#)546 [TRA00950033](#)548 [TRA00950124-125](#)549 [TRA00950124](#)547 [TRA00950123](#)550 [TRA00950125-126](#)

Table 15.5 Patients who tested *C. difficile* toxin positive on ward F in March 2007

	Admission to VOLH	Admission to ward F	Patient records		Lab report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 7	20/02/07 to ward 3	02/03/07	unknown	18/03/07	18/03/07	21/03/07
Patient 8	09/02/07 to ward 6	20/02/07	26/03/07	27/03/07	26/03/07	28/03/07
Patient 9	19/01/07 from RAH to ward 6	26/01/07	29/03/07	29/03/07	29/03/07	02/04/07
Patient 10	unknown	21/02/07	29/03/07	29/03/07	29/03/07	02/04/07

Again she accepted that there would be four yellow T-cards in a row for ward F on the infection control board.⁵⁵¹ When asked why this presentation on the board did not provoke a response, Mrs O'Neill said she did raise her concerns about the general increase in CDI with Mrs Murray.⁵⁵² It was this concern that prompted the re-issue of the "Bug of the Month" circular.⁵⁵³ What Mrs O'Neill could not explain was why an outbreak of CDI was not considered at the time.⁵⁵⁴ This presentation for ward F was at a time when there was a similar presentation for ward 14.⁵⁵⁵

Mrs O'Neill's discussion with Mrs Murray

Mrs O'Neill acknowledged that it was a failure on her part not to appreciate at the time that there might have been an outbreak of CDI. Her evidence was that she had raised the issue with Mrs Murray, her line manager, and that "it was for her to deal with that".⁵⁵⁶ Mrs O'Neill expected Mrs Murray to contact the Infection Control Doctor but she did not suggest that to her.⁵⁵⁷ Even though it seems that Mrs O'Neill did think that there may have been an outbreak, she did not use the

term "outbreak"⁵⁵⁸ in her discussion with Mrs Murray.

When asked to consider the prevalence of *C. difficile* toxin positive patients in December 2007, Mrs O'Neill could offer no explanation of why an outbreak was not considered, despite it being apparent that there were infected patients closely connected in time and place.⁵⁵⁹

Mrs O'Neill again raised her "concerns" with Mrs Murray in January 2008,⁵⁶⁰ at a time when there were a number of *C. difficile* toxin positive patients in ward F and there would have been four yellow T-cards in a row allocated to that ward.⁵⁶¹ Mrs Murray told Mrs O'Neill that she would contact Dr Biggs. According to Mrs O'Neill she "just raised (her) concerns again that we had an increased number of C.diff in the hospital",⁵⁶² and said that she "probably pointed to the board",⁵⁶³ by which she meant the infection control board that displayed the yellow T-cards. Mrs O'Neill's understanding was that Mrs Murray was going to inform Dr Biggs of the increase in numbers of *C. difficile* toxin positive

551 [TRA00950130](#)

552 [TRA00950130-131](#)

553 [TRA00950130](#)

554 [TRA00950130](#)

555 [TRA00950130](#)

556 [TRA00950133](#)

557 [TRA00950133](#)

558 [TRA00950130-131](#)

559 [TRA00950142-144](#)

560 [TRA00950148-149](#)

561 [TRA00950149](#)

562 [TRA00950149](#)

563 [TRA00950150](#)

patients.⁵⁶⁴ Although Mrs O'Neill did consider that there was an outbreak of CDI, again, somewhat surprisingly, the term "outbreak" was not used in her discussions with Mrs Murray.⁵⁶⁵ She expected the situation to be investigated by the "senior members of the team".⁵⁶⁶ She was expecting an "answer"⁵⁶⁷ but none was forthcoming.⁵⁶⁸ Mrs O'Neill did not raise the issue again, but could not explain why she did not do so.⁵⁶⁹ The following exchange occurred in the course of her evidence:

"Q. Do you, yourself, see, at that time, you had a duty to make the point that there was an outbreak here?"

A. No, because I felt I had dealt with it by informing my senior".⁵⁷⁰

In a similar way, Mrs O'Neill was shown a timeline covering in particular the period January to February 2008.⁵⁷¹ This had been prepared by Mrs Murray in response to a complaint that a patient had been admitted to a bay in ward F when there may have been a patient or patients suffering from CDI present. Mrs O'Neill did consider that this was evidence of an outbreak, but she did not raise that with Mrs Murray because she felt she "had raised it with her before".⁵⁷² Nor did she raise the possibility of an outbreak with anyone else.⁵⁷³

Mrs O'Neill's relationship with Dr Bagnade

When Dr Bagnade visited the VOLH as the new ICD in February 2008 Mrs O'Neill did not mention her concerns about the numbers of CDI patients because she assumed "Mrs Murray would have that discussion with her".⁵⁷⁴ After Mrs Murray retired in March 2008 there were further instances of patients suffering from CDI closely associated in time and place, particularly in ward 6, and Mrs O'Neill agreed that it would have been

incumbent on her to consider whether there was an outbreak. She said initially that she did not know why she did not declare an outbreak at that time,⁵⁷⁵ but then went on to say that the situation was the same as previously and she assumed that the ICD "was aware of that situation and nothing happened, and I felt this was the same situation".⁵⁷⁶

Mrs O'Neill's relationship with ward sisters

Mrs O'Neill had no recollection of discussions with ward sisters in which she suggested that CDI patient numbers could be explained by antibiotics.⁵⁷⁷ Indeed her position was ultimately that she did not provide such an explanation.⁵⁷⁸ Nevertheless, Mrs Murray's concentration on the effect of antibiotics on patients whom she regarded as carriers does lend support to the ward sisters' recollections.

Mrs O'Neill's position

The Inquiry has given serious consideration to whether Mrs O'Neill should be criticised for failing to recognise the likelihood of outbreaks of CDI. No doubt a competent infection control nurse would have realised the real nature of the CDI problem and acted so as to ensure that the problem was recognised and addressed. Mrs O'Neill, however, was in a rather unusual position. She had no qualification in infection prevention and control and there was no prospect of her obtaining such a qualification. There are mitigating circumstances to be found in the lack of ICD leadership and lack of adequate supervision. The Inquiry accepts too that at least she did raise the issue of CDI numbers with Mrs Murray. The Inquiry also recognises Mrs Murray's inability to recognise cross infection, as discussed below. In the circumstances the Inquiry does not criticise Mrs O'Neill.

Awareness of CDI cases in ward 6

A number of people had been made aware that there were patients who tested positive for *C. difficile* toxin in ward 6 in December

564 [TRA00950150](#)
 565 [TRA00950150](#)
 566 [TRA00950150-151](#)
 567 [TRA00950151](#)
 568 [TRA00950151](#)
 569 [TRA00950151](#)
 570 [TRA00950152](#)
 571 [SPF00990002-03](#)
 572 [TRA00960047-48](#)
 573 [TRA00960048](#)
 574 [TRA00950156](#)

575 [TRA00950167](#)
 576 [TRA00950170](#)
 577 [TRA00950177-178](#)
 578 [TRA00950178-180](#)

2007. By email dated 17 December 2007 Mrs Murray notified Mrs McNamee, Ms Martin and Ms Rankin that there were then three CDI patients on ward 6. In her evidence to the Inquiry Ms Rankin could not recall if she responded to that email, but her normal

practice would have been to investigate and call Mrs Murray to discuss individual cases.⁵⁷⁹ Table 15.6 sets out those three patients along with their CDI testing data as established by the Inquiry.

Table 15.6 CDI patients on ward 6 in December 2007

	Admission to VOLH	Admission to ward 6	Patient records		Lab report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Mary Burns	05/12/07 from RAH	05/12/07	05/12/07	06/12/07	05/12/07	07/12/07
Margaret Dalton	18/11/07 to ward 4 (Moved to HDU 19/11/07)	03/12/07	17/12/07	17/12/07	17/12/07	19/12/07
Patient B	07/12/07 to ward 6	07/12/07	15/12/07	17/12/07	15/12/07	17/12/07

In preparation for giving her evidence at the Inquiry’s public hearing⁵⁸⁰ Ms Rankin had reviewed the three cases; Mary Burns, Margaret Dalton and Patient B. From the information she took from both the Infection Control Cards and the database, she did not consider the patients to be linked in time and place.⁵⁸¹ Her explanation was that one patient had tested positive prior to admission and another had tested positive the day after admission, so that neither result could be attributed to ward 6. In coming to that conclusion she applied the 48 hour conventional test discussed in Chapter 3 to define a hospital acquired infection.

An analysis of the records discloses, however, that Margaret Dalton and Patient B had been admitted to ward 6 more than 48 hours before they became symptomatic for *C. difficile*. The correct admission date has been omitted from the Infection Control

Card for Margaret Dalton, and incorrectly entered in the Infection Control database as 17 December 2007.⁵⁸² The correct admission date to the VOLH was 18 November 2007, with movement to ward 6 on 3 December 2007. On the basis of that information the criteria for an outbreak were indeed met. Ms Rankin did accept that in any event, having regard to the “increased burden”⁵⁸³ of CDI on the ward, some epidemiological investigation should have been carried out to see where patients had been previously in order to ascertain the source of the infection.⁵⁸⁴

Ms McNamee could not remember seeing the email of 17 December 2007. Her evidence was that she would have expected Ms Rankin to deal with it and that she would only have become involved if an Outbreak Control

580 [TRA01000029](#)
581 [TRA01000029-30](#)

579 [TRA01000029](#)
582 [INQ02970062](#)
583 [TRA01000032](#)
584 [TRA01000032-33](#)

Team was to be convened.⁵⁸⁵ Ms Martin had no recollection of receiving the email of 17 December 2007, although she did say it was the kind of email she would receive as General Manager.⁵⁸⁶

Mrs Murray's rationale

Mrs Murray knew that in terms of the Outbreak Policy an outbreak could include two or more linked cases of the same illness associated in place and time.⁵⁸⁷ She knew that if she did think there might be an outbreak certain procedures had to be followed.⁵⁸⁸ In the period from 1 January 2007 through to her retirement in March 2008, Mrs Murray was also aware that there were *C. difficile* toxin positive patients in different wards at the VOLH. In evidence she was asked to consider a number of occasions when, as discussed in Chapter 5, it was evident that there were patients suffering from CDI in different wards in the VOLH closely connected in time. Her position was that at the time she concluded that even if there were a number of CDI patients in the same ward at about the same time they were not linked.⁵⁸⁹

Mrs Murray's position on CDI on certain wards

The position in ward 14 in April 2007 set out earlier in Table 15.4 was put to Mrs Murray. As already mentioned, the Table shows four

patients tested positive for *C. difficile* toxin in that ward closely linked in time. In the database the CDI was described as "hospital related" for each of these four patients.⁵⁹⁰

Mrs Murray said that she thought that she was aware at that time of this number of patients testing positive for *C. difficile* toxin in ward 14.⁵⁹¹ Her evidence was that she excluded cross-infection because there were other risk factors that could lead to patients developing *C. difficile* diarrhoea. She summarised her position in the following way:

"That was our assumption at the time, yes, that there wasn't cross infection; that people were doing what they should have been doing and there were perhaps other reasons for the patients developing C.diff".⁵⁹²

That such an assumption should be made in the face of the evidence is difficult to understand. What is more, Mrs Murray had no recollection of discussing these particular patients with Dr Biggs at this particular time.⁵⁹³

Under reference to the timeline⁵⁹⁴ prepared by the Inquiry, Mrs Murray was also asked about the position in ward 3 in June 2007. Table 15.7 sets out the position in ward 3 at that time.

585 [TRA01210040](#)
586 [TRA01160089-90](#)
587 [TRA01010039-40](#)
588 [TRA01010040](#)
589 [TRA01010092](#)

590 [INQ02970123](#); [INQ02970022](#); [INQ02970124](#);
[INQ02970024](#)
591 [TRA01010091](#)
592 [TRA01010095](#)
593 [TRA01010096-97](#)
594 [INQ02910001](#)

Table 15.7 CDI patients on ward 3 in June 2007

	Admission to VOLH	Admission to ward 3	Patient records		Lab report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 14	01/06/07 to ward 3 (Previously discharged 15/05/07)	01/06/07	unknown	unknown	02/06/07	06/06/07
Patient 15	17/05/07 to ward 4	19/05/07	unknown	08/06/07	07/06/07	12/06/07
Patient 16	21/05/07 to ward 3	21/05/07	unknown	14/06/07	13/06/07	15/06/07
Patient 17	11/06/07 to ward 3 (Previously discharged 08/06/07)	11/06/07	unknown	unknown	12/06/07	15/06/07

Mrs Murray accepted that there were probably three patients testing positive for *C. difficile* toxin at about the same time but “for the same reasons” did not think that there was a link.⁵⁹⁵

Similarly, Mrs Murray was asked to consider the position in ward 6.⁵⁹⁶ Table 15.8 sets out the position from February to April 2007.

Table 15.8 Patients who tested *C. difficile* toxin positive on ward 6 from February to April 2007

	Admission to VOLH	Admission to ward 6	Patient records		Lab report sheets	
			Date specimen collected	Ward aware	Date specimen collected	Report date
Patient 18	08/02/07 to ward 6 (Previously discharged 01/02/07)	08/02/07	unknown	15/02/07	14/02/07	17/02/07
Patient 19	05/02/07 from RAH to ward 6	05/02/07	unknown	16/02/07	15/02/07	19/02/07
Patient 20	07/02/07 from RAH to ward 6	07/02/07	unknown	unknown	21/02/07	27/02/07
Patient 21	26/02/07 from RAH to ward 6	26/02/07	unknown	01/03/07	28/02/07	05/03/07
Patient 22	17/02/07 to ward 4	21/02/07	unknown	unknown	28/02/07	02/03/07 (Transferred to RAH 01/03/07)
Patient 18	08/02/07 to ward 6 (Previously discharged 01/02/07)	08/02/07	12/03/07	13/03/07	12/03/07	16/03/07
Patient 18	08/02/07 to ward 6. (Moved to ward 15 13/03/07)	28/03/07	29/03/07	unknown	29/03/07	03/04/07
Patient 23	03/04/07 from RAH to ward 6	03/04/07	04/04/07	05/04/07	04/04/07	09/04/07
Patient 24	08/04/07 to ward 6	08/04/07	unknown	10/04/07	08/04/07	11/04/07
Patient 25	21/03/07 to HDU	24/03/07	13/04/07	13/04/07	13/04/07	17/04/07

Mrs Murray conceded that there were probably more than two patients positive in that ward at the same time, and said that she would have considered an outbreak at this point.⁵⁹⁷ Mrs Murray's evidence on that period, and indeed on other periods, was that she would always consider the possibility of an outbreak but that the possibility of outbreaks was discounted. Although throughout 2007 and into 2008 there were what appeared to be clusters of CDI patients in different wards, at no stage did she conclude that there was an outbreak.⁵⁹⁸ Again, this approach is simply incomprehensible.

Mrs Murray's contact with Dr Biggs

Mrs McIntyre did recall an occasion when she mentioned to Mrs Murray that there were "an awful lot of yellow cards coming in to be filed".⁵⁹⁹ This conversation took place around January or February 2008.⁶⁰⁰ According to Mrs McIntyre, Mrs Murray responded by saying that there was a "little problem"⁶⁰¹ and that she had contacted the ICD. Mrs McIntyre did not know who the ICD was,⁶⁰² and had never seen Dr Biggs at the VOLH.

Mention has already been made of Mrs O'Neill's expressions of concern to Mrs Murray about increases in *C. difficile* toxin positive cases in January 2008,⁶⁰³ and of Mrs Murray's response that she would contact Dr Biggs.⁶⁰⁴ This may have been at around the same time Mrs McIntyre raised the number of yellow cards discussed in the previous paragraph, when the focus was on ward F. The evidence of Mrs O'Neill and Mrs McIntyre on this broadly reflects Mrs Murray's evidence that she did contact Dr Biggs about the number of cases in ward F.⁶⁰⁵ The context, however, according to Mrs Murray, was not that of suspecting an outbreak but rather of concern over antibiotic prescribing. In the course of that conversation Mrs Murray told Dr Biggs that there were a number of *C. difficile* toxin positive patients in the same ward, and she

may have told Dr Biggs there were four cases.⁶⁰⁶ Mrs Murray explained that Dr Biggs' response was "Well, what do you want me to do about it?"⁶⁰⁷ It is to be noted that Dr Biggs told the Internal Investigation carried out by NHSGGC after the emergence of the *C. difficile* problem that she had not been aware of *C. difficile* issues at the VOLH. She did say that she had some contact with Mrs Murray in March 2007 and told that there was a "slight increase".⁶⁰⁸ That appears to have been a different occasion to the one described by Mrs Murray in early 2008. The Inquiry accepts that Mrs Murray did contact Dr Biggs in early 2008 and that Dr Biggs responded in the manner described by Mrs Murray.

Dr Biggs' response was one that sums up her attitude to her responsibilities as ICD for the VOLH. An ICD acting appropriately would have investigated the situation. Mrs Murray had no recollection of contacting Dr Biggs about the numbers of *C. difficile* toxin positive patients on any other occasion.

Mrs Murray's email of 7 February 2008

On 7 February 2008 Mrs Murray sent an email⁶⁰⁹ to Mrs Ann Lang, Ms Rankin's secretary, with information on the number of *C. difficile* toxin positive patients at the VOLH in the period January 2006 to December 2007,⁶¹⁰ revealing a significant increase in the numbers in 2007 as compared to 2006. The information was being submitted for the purpose of collecting data for the SPC Charts, and Ms Rankin's secretary was not expected to make any clinical assessment of the data.⁶¹¹ Ms Rankin said that she did not see that information at the time, and that if she had been told about this she would have been concerned and would have contacted the Infection Control Team to clarify the position.⁶¹² That is not the point; what is significant about this evidence is that Mrs Murray was supplying this information to Ms Rankin's secretary on the basis that all the cases were cases of hospital associated CDI.

597 [TRA01010107](#)

598 [TRA01010116-117](#)

599 [TRA00920041](#)

600 [TRA00920043](#)

601 [TRA00920042](#)

602 [TRA00920042](#)

603 [TRA00950149](#)

604 [TRA00950150](#)

605 [TRA01010112-113](#); [TRA01010118-119](#)

606 [TRA01010119](#)

607 [TRA01010118](#)

608 [GOV00890100](#)

609 [GGC17250001](#)

610 [GGC17250016](#)

611 [TRA01000084-85](#)

612 [TRA01000085](#)

An illogical position

Mrs Murray's approach to the evidence of the CDI in the VOLH in the period from 1 January 2007 to March 2008 simply does not make sense. That is particularly so when the great majority of the cases were described in the database as hospital related. Nor can it be said that Mrs Murray was not aware of the risks of cross infection. As previously discussed, in April 2007 Mrs Murray and Mrs O'Neill re-issued the "Bug of the Month"⁶¹³ newsletter, prompted by an awareness of an increasing incidence of CDI, not only in the VOLH but also nationally, about which they themselves wanted to raise awareness in the VOLH.⁶¹⁴ Under the heading "TRANSMISSION" the following advice is given:

"Although some people can be healthy carriers of *C. difficile*, in most cases it develops after cross infection from another patient, either through direct patient contact, via healthcare staff, or via a contaminated environment".⁶¹⁵

Although the primary focus of the newsletter on transmission was on cross-infection, when faced with evidence of clusters of CDI, Mrs Murray unfortunately adopted a mindset that excluded cross infection.

Mrs Murray's position also flies in the face of her participation in the delivery of presentations on CDI, drawing upon the outbreaks of CDI at hospitals in Montreal and Quebec in Canada and Buckinghamshire in England,⁶¹⁶ to highlight infection control issues.⁶¹⁷ The first presentation was in January 2007, and subsequently in May 2007 Mrs Murray delivered the same presentation.⁶¹⁸ In light of that level of knowledge and expertise, her repeated rejection of the possibility that cross infection may have been responsible for the clusters of CDI that occurred on the VOLH from 1 January 2007 until her retirement in March 2008 is incomprehensible.

A memorandum dated 15 March 2007 was circulated by Mrs O'Neill to all Senior Charge Nurses.⁶¹⁹ The terms of this memorandum had been discussed with Mrs Murray,⁶²⁰ and the second paragraph was in the following terms:

"Where possible, patients who have developed diarrhoeal symptoms should be nursed in isolation as soon as they become symptomatic, to reduce the risk to other patients in the ward and to prevent an outbreak situation".

Clearly the concern here was the risk of cross infection. Yet although this was a risk that was apparently recognised, in practice Mrs Murray considered that, despite the number of clusters of CDI in different wards in the VOLH, there had been no ingestion of spores in the hospital and all these cases were patients who were already carriers of *C. difficile*.

Mrs Murray's conclusion that there was no cross infection is even more difficult to understand in light of a complaint made by the family of one patient who contracted CDI. Mrs Murray had a telephone conversation with that family member on 24 January 2008 and noted the nature of the complaint on the patient's Infection Control Card (T-card).⁶²¹ The thrust of the complaint was that the patient had had contact with a patient suffering from CDI who was wandering in the ward.⁶²² Mrs Murray's inability to see that cross infection was the likely cause of the patient contracting CDI once more simply does not make any sense, particularly as there were a number of other patients suffering from CDI in that ward.

Ms Law had discussions in 2007 with Mrs Murray about the fact that there seemed to be an increase in the number of *C. difficile* toxin positive patients.⁶²³ According to Mrs Law, Mrs Murray told her that all the cases could be explained and there was no evidence of cross infection.⁶²⁴ This response

613 [GGC17790003](#)

614 [TRA00950130](#)

615 [GGC17790003](#)

616 [INQ03010001](#)

617 [TRA01010042](#)

618 [TRA01010042](#)

619 [GGC17360002](#)

620 [TRA01010123](#)

621 [TRA01010124-125](#); SPF00710001

622 [TRA01010125-126](#)

623 [TRA00890024-25](#)

624 [TRA00890024](#)

was consistent with the line taken by Mrs Murray in her evidence.

In Chapter 12 the evidence surrounding the admission of a patient in February 2008 to ward F to a bay where there were symptomatic patients has already been considered. A family member, having carried out some research, put to Mrs Murray that there was an outbreak of CDI,⁶²⁵ and Mrs Murray responded by saying she would close the ward.⁶²⁶ There is no evidence that she did that.

Mrs Murray repeatedly failed to recognise that the most likely explanation for the presence of two or more patients suffering from CDI in the same ward and closely linked in time was cross infection. These were serious failures. Her failures meant that the outbreak procedures that would have alerted other levels of management were never invoked. Mrs Murray's failures contributed in a significant way to the persisting CDI problem in the VOLH. Her failures contributed to undetected outbreaks of CDI. She failed in a significant way in her duty of care to patients in the VOLH.

15.12 Role of the Microbiologists

Positions held

Dr Stephanie Dancer was the resident Consultant Microbiologist at the VOLH from January 1996 to February 2002,⁶²⁷ and was also the ICD. She resigned in February 2002 but continued to work at the VOLH as a locum until June 2002. Although her post at the VOLH had been advertised on a number of occasions over the years, Dr Dancer was not replaced.⁶²⁸ It was not an attractive post, particularly as the uncertainty over the future of the VOLH increased. Moreover, a single post with no colleagues can be unattractive to potential applicants.⁶²⁹

From 1 January 2007 to 1 January 2008 Dr Barbara Weinhardt was the Consultant Microbiologist at the RAH. In January 2008

Dr Linda Bagrade and Dr Alison Claxton also took up posts as Consultant Microbiologists at the RAH. Between 1 January 2007 and June 2008 Dr François de Villiers and Dr Biggs were Consultant Microbiologists based at the IRH. The role of Dr Biggs as Infection Control Doctor has already been discussed and is discussed further below.

The stopgap arrangements

Dr Geoffrey Douglas was a Consultant Anaesthetist until his retirement in April 2008. From November 2005 to April 2006 he was also the Clinical Director of Laboratory Specialities for Argyll and Clyde, and had clinical line management responsibility for Dr Biggs and Dr de Villiers.⁶³⁰ By 2005 there was a real concern about the number of vacant microbiology posts, with two out of the five posts being vacant,⁶³¹ and as a “stop gap”⁶³² position he arranged for Dr de Villiers to attend the VOLH for one session a week to provide microbiology input. A session was normally considered to be four hours,⁶³³ and travelling time was considered part of the session.⁶³⁴

Dr de Villiers

Dr de Villiers confirmed that from 1 January 2007 to January 2008 he did have a clinical responsibility for the VOLH. Although the plan had been that he would attend the VOLH on a weekly basis, in reality that was not possible, for his availability at the VOLH was dependent on Dr Biggs being present at the IRH. If Dr Biggs was on leave, at a meeting, or off work for some other reason, then he would not go to the VOLH.⁶³⁵ When he was on leave himself the VOLH would not be covered.⁶³⁶ Leave was normally a period of six weeks per year.⁶³⁷ Nor was there cover when Dr de Villiers or Dr Biggs was on study leave, a further period of some four weeks per year.⁶³⁸ Finally, because travelling time was included in his session, his attendance at the VOLH would normally be just a little

625 [TRA00070061](#)

626 [TRA00070062](#)

627 [TRA00850003](#)

628 [TRA00850105](#)

629 [TRA00850105](#)

630 [TRA01250022](#)

631 [TRA01250022-23](#)

632 [TRA01250028](#)

633 [TRA01250027](#)

634 [TRA01250027](#)

635 [TRA00840006-07](#); [TRA00840010](#)

636 [TRA00840008](#)

637 [TRA00840010](#)

638 [TRA01250004](#)

over two hours.⁶³⁹ It follows that there was not a great deal of direct microbiology cover in the VOLH, and as Dr de Villiers explained, he was really only maintaining some microbiology “visibility” at the VOLH.⁶⁴⁰ When he did attend he had an office based in the Laboratory and he would normally visit the High Dependency Unit. He would only visit a ward if he was called to do so for a particular reason.

As discussed in Section 15.2, Dr de Villiers did not have any responsibility for infection prevention and control as ICD at the VOLH.

Dr Weinhardt

After Dr Dancer’s departure Dr Biggs had taken on responsibility for the VOLH Laboratory, but she asked to be relieved of that responsibility because of her workload,⁶⁴¹ and in April 2006 Dr Douglas asked Dr Weinhardt to take on the responsibility as the head of department for the VOLH Laboratory.⁶⁴² At the time Dr Weinhardt was reluctant to take on that responsibility because a fellow Consultant Microbiologist had left the RAH in December 2005 and had not been replaced by April 2006,⁶⁴³ but she agreed to take on the responsibility because her understanding at the time was that all the microbiology services were going to be centralised at the RAH and that two new colleagues would be “swiftly” appointed.⁶⁴⁴

Dr Weinhardt had anticipated that the vacancies would be filled within a number of months, but that did not happen as Dr Bagnade and Dr Claxton did not take up their posts until January 2008. Because of her workload there were times when Dr Weinhardt felt under stress.⁶⁴⁵ She endeavoured to visit the Laboratory on a weekly basis for about two hours, but that obviously did not happen when she was on annual leave. Nor was she able to visit when she was otherwise too busy at the RAH. Dr

Weinhardt did not consider the position to be at all satisfactory, although on a day-to-day basis with locum support she did believe the clinical service was safe.⁶⁴⁶

Dr Douglas said he was at the time extremely concerned about Dr Weinhardt’s position as she was the only microbiologist left at the RAH, which was the largest and busiest hospital of the three main hospitals in Argyll and Clyde.⁶⁴⁷ From April 2006 Dr Douglas was absent from work for a considerable time due to illness,⁶⁴⁸ and his line management responsibility ceased at that point.⁶⁴⁹

Except at weekends and bank holidays, Dr Weinhardt did not have any clinical responsibility for the VOLH until February 2008.⁶⁵⁰ Her evidence was that she only had any responsibility for infection control issues at the VOLH on an out-of-hours basis and at weekends.⁶⁵¹

Authorisation of *C. difficile* toxin positive results

Although *C. difficile* toxin positive results required to be authorised by a Consultant Microbiologist, on occasion that did not happen. The reports prepared at the VOLH recording that a test for *C. difficile* toxin was positive could be accessed by computer at the IRH and the RAH, and prior to February 2008 the authorisation of those positive results was carried out at the IRH, primarily by Dr de Villiers and Dr Biggs. After January 2008 this exercise was carried out from the RAH by Dr Weinhardt, Dr Bagnade and Dr Claxton. The authorisation of such results was carried out on the computer screen, and the Consultant Microbiologists did not receive a hard copy of the report.⁶⁵²

There were discrete lists of reports to be authorised for each hospital laboratory, which meant that the person authorising the report could see a separate list for the VOLH.⁶⁵³ There was not, however, a separate

639 [TRA00840013](#)

640 [TRA00840011](#)

641 [TRA00850106](#)

642 [TRA00850100](#)

643 [TRA00850104](#)

644 [TRA00850104](#)

645 [TRA00850107](#)

646 [TRA00850120](#)

647 [TRA01250029-30](#)

648 [TRA01250025](#)

649 [TRA01250026](#)

650 [TRA00850103](#)

651 [TRA00850098](#)

652 [TRA00840026](#)

653 [TRA00840026-27](#)

list for *C. difficile* toxin positive results, which could be in a list mixed with other results such as blood culture results. Nor was there a separate list for hospital patients: the list contained all results for the VOLH Laboratory, which also served the community, and along with the results for the hospital there would also be results for patients of General Practitioners (GPs).⁶⁵⁴ These comprised around 60% of the work done in the VOLH.⁶⁵⁵ There could be as many as 80 reports to be authorised in one day,⁶⁵⁶ and authorisation of reports was carried out at different times in the course of the day rather than as a complete batch at a particular time.⁶⁵⁷

The number of positive results authorised by Dr Weinhardt

It would appear from the data recovered from the VOLH computer system that there were times from December 2007 to June 2008 when positive results for *C. difficile* toxin closely associated in time were authorised by the same Consultant Microbiologist. Table 15.9 has been prepared by the Inquiry based on the data obtained from the VOLH Laboratory computer system.

654 [TRA00840027-28](#)

655 [TRA00840030](#)

656 [TRA01020117](#)

657 [TRA01020117-118](#)

Table 15.9 *C. difficile* toxin positive results authorised by Microbiologists

Microbiologist	Ward	Report date	Patient
Dr de Villiers	14	05/12/07	Isobel Cameron
	15	06/12/07	Mary Broadley
	HDU	14/12/07	Alexander McDonald
	6	17/12/07	Patient B
	6	19/12/07	Margaret Dalton
	15	20/12/07	Mary Broadley
	14	20/12/07	Isabella Lettis
	6	24/12/07	Agnes Burgess
	6	24/12/07	Julia Monhan
	F	26/12/07	Patient C
Dr Weinhardt	F	25/02/08	Alister Brand
	6	25/02/08	Martha McGregor
	6	25/02/08	Elizabeth Valentine
	14	28/02/08	Anne Gray
	F	28/02/08	Patient C
	6	28/02/08	Moira McWilliams
Dr Bgrade	F	06/02/08	Mary Millen
	14	06/02/08	James Thomson
	3	08/02/08	David Somerville
	F	11/02/08	Patient C
	F	12/02/08	Alister Brand
	15	18/02/08	Margaret Gaughan
Dr Claxton	F	20/02/08	Jessie Jones
	F	20/02/08	Jessie Jones
	6	20/02/08	Annie Shaw
	3	21/02/08	William Hunter

It is evident from Table 15.9 that Dr Weinhardt authorised six positive results for *C. difficile* toxin in the period 25 February 2008 to 28 February 2008. It did occur to Dr Weinhardt at the time that there were a number of *C. difficile* toxin positive results emanating from the VOLH, and she said that she had a conversation with Dr Bagnade at about that time in connection with the increased rates of CDI. Dr Weinhardt's evidence was that Dr Bagnade had indicated to her that there could be a problem at the VOLH, which Dr Weinhardt understood related to the increase in CDI cases. Later, and Dr Weinhardt thought this was in April 2008, Dr Bagnade confirmed to her that there was a genuine problem with CDI at the VOLH.⁶⁵⁸

The increase identified by Dr de Villiers

Table 15.9 discloses that in the month of December 2007 Dr de Villiers authorised ten positive reports for *C. difficile* toxin. He said in evidence that this may have been one of the reasons that he had an impression that there was an increased incidence of CDI,⁶⁵⁹ although the main reason for the impression seems to have been an increase in calls for clinical advice,⁶⁶⁰ which he thought happened in January 2008.⁶⁶¹ At the time Dr de Villiers believed that the increase was in the IRH, and raised the issue with an ICN in the IRH, asking her to investigate. Dr Biggs was present when he made this request.⁶⁶² The ICN reported back to him the same day that there was no increase in the IRH.⁶⁶³ Again Dr Biggs was present, and at that stage Dr de Villiers suggested to Dr Biggs that she should have a look at the other hospitals for which she was the ICD.⁶⁶⁴

Dr de Villiers could not remember if Dr Biggs reported back to him⁶⁶⁵ and he did not pursue the matter any further.⁶⁶⁶ There is no evidence that Dr Biggs carried out any such investigation into the prevalence of CDI at the VOLH. In December 2007 there were patients

suffering from CDI, particularly in ward 6. In January 2008 there were patients suffering from CDI in a number of wards in the VOLH with five patients suffering from the infection in ward F alone. An investigation at that time would have disclosed the likelihood of an outbreak.

Authorisation by Dr Bagnade

Table 15.9 shows Dr Bagnade also authorised a number of *C. difficile* toxin positive results in February 2008. Her evidence was that, because of the way in which the authorisation system worked, that alone would not have suggested to her that there was a problem. A significant number of different types of results would be authorised in the course of a working day, and, as mentioned earlier, many results were for specimens submitted by GPs.

Dr Bagnade said that she did not have a conversation with Dr Weinhardt about a problem in the VOLH with CDI. She thought that she may have discussed the situation in relation to wash-hand basins at the VOLH with Dr Weinhardt.⁶⁶⁷

Authorisation by Dr Claxton

Dr Claxton was also involved in authorising *C. difficile* toxin positive results.⁶⁶⁸ Table 15.9 discloses that Dr Claxton authorised four positive reports for three patients on 20 and 21 February 2008. Although her evidence on this was not entirely clear, Dr Claxton did not have a specific recollection of what she did at the time.⁶⁶⁹ Her evidence was that in such circumstances she would expect the Infection Control Team to investigate.

Dr Bagnade's knowledge of CDI rates at the VOLH

Like Dr Weinhardt, Dr Claxton also gave evidence that Dr Bagnade had said there might be a problem at the VOLH in relation to CDI. She thought this was some time in March 2008. That date was the "nearest"⁶⁷⁰ she could estimate, and Dr Weinhardt was

658 [TRA00850130-33](#)

659 [TRA00840074-76](#)

660 [TRA00840074](#)

661 [TRA00840075](#)

662 [TRA00840075](#)

663 [TRA00840076](#)

664 [TRA00840076](#)

665 [TRA00840077-79](#)

666 [TRA00840079](#)

667 [TRA01020120](#)

668 [TRA01220056](#)

669 [TRA01220062-63](#)

670 [TRA01220068](#)

present at the time.⁶⁷¹ Dr Claxton did not know if Dr Bagnade was talking about CDI numbers or some other aspect of CDI.⁶⁷² Dr Claxton's recollection of the event was poor, and having regard to her uncertainty over the date any conversation that did take place could very well have been after the problem emerged.

The Inquiry is not able to come to a conclusion on this divergence in the evidence. It is certainly the case that when the CDI problem emerged in May 2008 Dr Bagnade did respond promptly.

Other Consultant Microbiologists' knowledge of CDI rates at the VOLH

Although there seems to have been an awareness of an increased incidence of CDI at the VOLH, particularly by Dr Weinhardt and Dr de Villiers, that awareness did not result in any action at the time. The Inquiry accepts that Dr de Villiers did raise this issue with Dr Biggs in January 2008 and that Dr Biggs did not respond to his concerns.

Consultant Microbiologist staffing from January 2007 to January 2008

The staffing arrangements for Consultant Microbiologists were totally unsatisfactory in the period from January 2007 to January 2008 and had been for some time before that period. Dr Douglas's temporary reorganisation of the microbiology service in around April 2006 was well intentioned, but it was a temporary solution that remained unresolved for a significant period of time.

Dr Weinhardt's concerns over the microbiology service, and the stress that she was under, caused her to press for the vacant posts to be filled, and on 22 September 2006 she wrote to a member of the Board setting out the nature of the problem and asking for the two vacant posts to be re-advertised.⁶⁷³ The posts had not been advertised since January 2006,⁶⁷⁴ and because there had previously been difficulties in filling the vacant post at the VOLH Dr Weinhardt

pressed for the three Consultant Microbiologists to be based at the RAH.⁶⁷⁵

Dr Weinhardt secured a meeting with Mrs den Herder in December 2006 and authority was given for the vacant RAH post to be advertised,⁶⁷⁶ but it appears that neither of the two posts was advertised until summer 2007. Shortly before that Mrs den Herder discussed her intentions with Dr Cowan, seeking his view on her proposal to advertise one of the posts as a Microbiologist with ICD responsibilities.⁶⁷⁷ The posts were not filled until the appointment of Dr Bagnade and Dr Claxton in January 2008.

The division of responsibility

Professor Duerden explained that a system where different microbiologists were intended to undertake separate duties for the VOLH was:

“unlikely to provide a robust, secure and reliable situation for the Laboratory, the hospital clinicians or the infection control staff”.⁶⁷⁸

Dr de Villiers' intended role was in reality even more limited than that envisaged by Dr Douglas. Dr Weinhardt was under pressure because of the staffing problems and her role as head of the Laboratory service was a limited one. Critically, Dr Biggs' performance as Infection Control Doctor was inadequate. The Inquiry agrees with Professor Duerden that a co-ordinated, integrated service was not being provided to the VOLH.⁶⁷⁹ The inadequate nature of Dr Biggs' role is further explored in Section 15.13, and her failure as ICD was clearly highly relevant to the nature of the microbiology service provided at the VOLH. The difficulties in recruiting staff were also an important factor.

671 [TRA01220068](#)

672 [TRA01220070](#)

673 [TRA00860015-16](#); [INQ03500001](#)

674 [TRA00860022-23](#)

675 [TRA00850105-106](#)

676 [TRA00860019](#)

677 [TRA01220110-111](#)

678 [TRA01050066](#)

679 [TRA01050067](#)

15.13 The Infection Control Doctor

Dr Biggs

Unfortunately, as explained in Chapter 2, Dr Biggs was unable on health grounds to provide a written statement or give oral evidence to the Inquiry. Two police statements made by Dr Biggs in the course of the earlier police investigation were available to the Inquiry, dated 16 March 2009⁶⁸⁰ and 7 May 2009 respectively.⁶⁸¹ In addition, Dr Biggs had been interviewed by the Internal Investigation panel on 18 June 2008, and notes of that interview were available to the Inquiry.⁶⁸² The Internal Investigation is considered further in Chapter 17.

As already mentioned, Dr Biggs was the designated ICD for the Clyde Sector, which included the VOLH. Her responsibility as ICD for the VOLH certainly spanned the period from 1 January 2007 to early February 2008, when Dr Bagnall took over that particular responsibility. Although as discussed in this Section Dr Biggs claimed that her role was a “firefighting”⁶⁸³ one the Inquiry finds that there was no excuse for her not being fully aware that she was the designated ICD for the VOLH. She did not in fact carry out her responsibilities as ICD.

Professional line management

Dr Douglas was Dr Biggs’ professional line manager until he went on leave due to illness in April 2006.

It has to be stressed that a professional line manager has an important role to play in providing advice and support, but there is some confusion over who took on the role of Dr Biggs’ professional line manager after Dr Douglas’s departure. There was no Clinical Director replacing Dr Douglas, and the next person in the professional line management chain was Dr Elizabeth Jordan, the Associate Medical Director. She should have taken over professional line management for Dr Biggs to fill the gap left by Dr Douglas, and at her interview with the Internal Investigation Dr Biggs is noted to have said that in the

absence of a Clinical Director she would contact Dr Jordan.⁶⁸⁴ According to the police statement she provided on 16 September 2009, however, Dr Biggs said that Dr Jordan was only her line manager up to May 2007 and that Dr Jordan had “resigned”.⁶⁸⁵ Dr Jordan did not in fact leave her post until 12 August 2007,⁶⁸⁶ so Dr Biggs may have been confused about the date, and in the email exchanges discussed below between Dr Biggs and Mr Walsh in June 2007 Dr Biggs was directed by Mr Walsh to contact Ms Martin and Dr Jordan, a response that suggests that Dr Jordan was Dr Biggs’ professional line manager at that time.

As set out in Chapter 2, Dr Jordan, who is in Australia, has declined to co-operate with the Inquiry, but there is no evidence before the Inquiry that she provided any real support to Dr Biggs. After Dr Jordan left, her position as Associate Medical Director was taken over in September 2007 by Dr John Dickson,⁶⁸⁷ although it appears he did not step into the role of professional line manager for Dr Biggs.⁶⁸⁸ Dr Douglas did return to work in September 2007, but he did not resume his professional line management responsibilities.⁶⁸⁹

Inadequate professional line management

So far as the Inquiry can ascertain the professional line management for Dr Biggs was inadequate, and this is a factor that must be taken into account when considering Dr Biggs’ position. It is not at all clear why Dr Biggs was not given greater professional support. This may be an issue on which Dr Jordan could have provided the Inquiry with some assistance. It is apparent, as discussed later, that Dr Biggs was unhappy with her role, and a higher level of professional support should have been available to her.

Dr Biggs’ job description

Dr Biggs did not receive a job description providing details of her role until it was sent to her by her line manager Ms Martin on

680 [SPF01460001](#)

681 [SPF01470001](#)

682 [GOV00890099-101](#)

683 [GOV00890100](#)

684 [GOV00890101](#)

685 [SPF01460003](#)

686 [GGC33120001](#)

687 [WTS00820001](#)

688 [WTS02290001-02](#)

689 [WTS02350004](#)

19 September 2007.⁶⁹⁰ This was in response to a series of emails from Dr Biggs to Ms Martin from at least 20 August 2007⁶⁹¹ seeking “absolute clarification”⁶⁹² on her role as ICD. Ms Martin said that until then she was not aware that Dr Biggs did not have a job description, because she took over as her line manager in April 2006 when Dr Biggs was already in her post as ICD. Ms Martin should have clarified the position much earlier with Dr Biggs, but Dr Biggs could have been in no doubt what her duties were and she did not question the terms of the job description⁶⁹³ sent to her in September 2007.⁶⁹⁴

Ms Martin's position

Ms Martin was clear that Dr Biggs was the ICD for the VOLH and “the leader of the Infection Control Team”,⁶⁹⁵ but she also maintained that Dr Biggs could delegate her VOLH ICD responsibilities to Dr de Villiers, and knew that Dr de Villiers was due to attend the VOLH one day a week.⁶⁹⁶ Ms Martin suggested that this arrangement had been set up in 2006 by Dr Douglas because of the problems Dr Biggs had with her mobility and also because of the shortage of consultant microbiologists.⁶⁹⁷

The Inquiry does not accept Ms Martin's evidence that the arrangement she described had been put into place. Ms Martin's position is not supported by Dr Douglas and it is contradicted by Dr de Villiers. Dr Douglas met Dr Biggs and Dr de Villiers together in the latter part of 2005. Thereafter, Dr Douglas had separate meetings with Dr Biggs (7 December 2005) and Dr de Villiers (14 February 2006).⁶⁹⁸ However, Dr Douglas did not set up an arrangement whereby Dr de Villiers had responsibilities as ICD for the VOLH beyond what was expected of any microbiologist on a day-to-day basis.⁶⁹⁹ So far as Dr Douglas was concerned it was Dr Biggs who was to perform the duty of ICD for

the VOLH.⁷⁰⁰ Dr de Villiers also contradicted Ms Martin's understanding of his role.⁷⁰¹ In fact, for a significant percentage of the year, for reasons already mentioned, Dr de Villiers did not go to the VOLH.⁷⁰² Ms Martin said she understood that Dr de Villiers attended the VOLH on a weekly basis other than when he was on annual leave.⁷⁰³

Nor indeed can any support for Ms Martin's evidence be gleaned from statements made by Dr Biggs. There is no suggestion in the police statements provided by Dr Biggs, or from the notes taken in the interview to the Internal Investigation panel, that she delegated her ICD responsibilities for the VOLH to Dr de Villiers. According to the police statement dated 7 May 2009 Dr Biggs said that Dr de Villiers would cover as ICD when she was on annual leave,⁷⁰⁴ but there is no suggestion that Dr de Villiers had the role ascribed to him by Ms Martin. Furthermore, as discussed later in this Chapter, in the emails written by Dr Biggs in 2007 about what she perceived to be her role as ICD for the VOLH there is no suggestion that Dr de Villiers was to cover for her in that role on his visits to the VOLH.

When she was recalled to give further evidence, the evidence of Dr de Villiers and Dr Douglas was put to Ms Martin.⁷⁰⁵ She provided some equivocal responses to questions but seemed to accept she could have misunderstood the position.⁷⁰⁶ At one point she gave the following explanation:

“I honestly did think that Dr de Villiers was covering infection control issues on behalf of Dr Biggs while he was at Vale of Leven”.⁷⁰⁷

The Inquiry can sympathise with the view that if a microbiology colleague attends a hospital in the capacity of Consultant Microbiologist it would be reasonable to assume there would be a degree of cross-

690 [SPF00970002](#)

691 [GGC08690001](#); [GGC08700001](#); [GGC08710001](#)

692 [GGC08690001](#)

693 [GGC32170001](#)

694 [TRA01160033-34](#); [SPF00970002](#)

695 [TRA01160011](#)

696 [TRA01160013](#)

697 [TRA01160013-14](#)

698 [WTS02350001](#)

699 [TRA01250024](#); [WTS02350003](#)

700 [TRA01250030](#)

701 [TRA01250001-05](#)

702 [TRA01250004-05](#)

703 [TRA01160061](#)

704 [SPF01470006](#)

705 [TRA01260072](#)

706 [TRA01260073](#)

707 [TRA01260073](#)

cover on infection prevention and control matters. That was not, however, the position. Ms Martin said that if she had appreciated the true position, and understood that Dr de Villiers was not covering for Dr Biggs, she would have been concerned and would have made other arrangements.⁷⁰⁸

The fact that Ms Martin may have thought that Dr de Villiers was covering for Dr Biggs as ICD at the VOLH on his visits there itself highlights the dysfunctional nature of the arrangements for infection prevention and control at the VOLH. There was no coherent strategy for ICD cover there.

Dr Biggs' concerns

In a series of emails in 2007 Dr Biggs raised a number of issues in relation to her position as ICD. The issue of her job description has already been covered, but by email dated 1 June 2007 from Dr Biggs to Mr Walsh, who was about to take up post as Infection Control Manager, and copied to a number of other people including Ms Martin, Dr Biggs began by saying that she was finding her position as ICD for Clyde was “becoming untenable”.⁷⁰⁹ She ends the email by intimating that she would need to “carefully decide whether I can continue in this role”.⁷¹⁰

By email dated 5 June 2007 Mr Walsh responded that Dr Biggs would need to raise the issues relating to her role as ICD with Dr Jordan and Ms Martin.⁷¹¹ The response directing Dr Biggs to Ms Martin, her line manager, was a reasonable one on the part of Mr Walsh at that time. The reference to Dr Jordan was made because Mr Walsh understood that, as Dr Jordan was Associate Medical Director, she was Dr Biggs' professional manager⁷¹² in the absence of Dr Douglas.

By email dated 16 August 2007 Dr Biggs complained to Ms Martin of “great stress” and concluded the email in the following way:

“I can take no responsibility for outbreaks or any infection control issues as I have no say in any matter of management of infection control services. I feel my position is becoming untenable”.⁷¹³

Ms Martin responded to that email the same day, but did not address the infection control issues raised by Dr Biggs. This is a point made by Dr Biggs in a subsequent email that day.⁷¹⁴

Ms Martin said in evidence that although she was responding to Dr Biggs it was not her responsibility to do so as she was on full-time secondment.⁷¹⁵ She said that even though it was not her responsibility she would “never ignore Dr Biggs”.⁷¹⁶ So far as Ms Martin was concerned Dr Biggs was “being dramatic and just expressing herself very strongly”.⁷¹⁷

On 20 August 2007 Dr Biggs sent another email to Ms Martin stipulating that she needed “absolute clarification of my role as Infection Control Doctor...”.⁷¹⁸ On 27 August 2007 she sent a further email to Ms Martin headed “high priority”,⁷¹⁹ in which she indicated that she had still had “no response to my email about roles responsibilities and professional line management”.⁷²⁰ Ms Martin was able in evidence to give some background to what was troubling Dr Biggs at this stage. She explained that Dr Biggs was “disgruntled”⁷²¹ about the fact that by this time the other sectors in NHSGGC had been provided with a particular structure for the role of ICD, whereas a similar structure had not been put in place for the Clyde Sector. Ms Martin did respond to Dr Biggs by email dated 31 August 2007 reassuring her that there was to be a paper issued “shortly from Glasgow which will answer your questions in relation to Acute”.⁷²²

708 [TRA01260073-74](#)
709 [GGC08650001](#)
710 [GGC08650001](#)
711 [GGC08660001](#)
712 [TRA01200028](#)

713 [SPF01130002](#)
714 [SPF01130002](#)
715 [TRA01160045-46](#)
716 [TRA01160042](#)
717 [TRA01160042](#)
718 [GGC08690001](#)
719 [GGC08700001](#)
720 [GGC08700001](#)
721 [TRA01160047-49](#)
722 [SPF00900002](#)

Dr Biggs' response to Ms Martin is contained in an email dated 5 September 2007 in which she said that she would not "attend or chair any meetings as far as infection control is concerned until I have the role clarified".⁷²³ Ms Martin agreed that Dr Biggs was providing a very clear message about how she saw her responsibilities for infection control, but she also made the point that despite the tone of Dr Biggs' email Dr Biggs did not resign from her position as ICD.⁷²⁴ That is correct, but Dr Biggs was also making it clear that she had no intention of carrying out her responsibilities as ICD. Her attitude demanded a prompt and effective response.

At her interview with the Internal Investigation panel on 18 June 2008,⁷²⁵ when it was put to Dr Biggs that she was ICD for the VOLH in the period December 2007 to the beginning of February 2008 Dr Biggs is noted as responding in the following way: "Firefighting. Purely emergency cover. Not aware of C.diff issues at VOL".⁷²⁶ Ms Martin did not accept that that was the way in which Dr Biggs understood the role, and thought that that Dr Biggs was "trying to put herself at arm's length from the situation".⁷²⁷

According to her first police statement of 16 March 2009, Dr Biggs again made reference to her performing "a firefighting role only...",⁷²⁸ saying:

"When I said 'firefighting' earlier in relation to my role as Infection Control Doctor I meant that I would only become involved if there was an outbreak. My belief is an outbreak is 2 or more linked infections which can be related in the same area. ... I was never informed of any issues at the VOLH".⁷²⁹

According to her second statement given on 7 May 2009, Dr Biggs explained her position thus:

"In terms of clinical advice or dealing with outbreaks relied upon me being informed and I would react to it. There was nothing pro-active ... I did not fit into the Infection Control structure as the Infection Control Doctor as it had not been clearly defined. That is where the problem was. They did however look at me as the Infection Control Doctor for the IRH, RAH, VOL and Oban".⁷³⁰

Dr Biggs' attitude to her role as ICD for the VOLH was inappropriate and professionally unacceptable. It is contradicted by the job description applicable to her position, which provided that she was to act as leader of the Infection Control Team.⁷³¹ Furthermore in her application for consultant discretionary points Dr Biggs claimed that she was the "area Infection Control Doctor to cover two consultancy vacancies..." in the period 2006 to 2008.⁷³² The purpose of this application was to receive recognition for additional work in the form of additional points, which could have an impact on salary, and what Dr Biggs held out in that application can be read as an acknowledgement that she did have ICD duties for the VOLH.⁷³³ In reality Dr Biggs was not fulfilling her duties as the ICD for the VOLH, certainly in the period from 1 January 2007 to early February 2008, and any suggestion in this application to the contrary was incorrect.

Dr Biggs' relationship with the Infection Control Nurses

Mrs Murray did not see Dr Biggs very often. She said that usually it would be at an infection control meeting,⁷³⁴ but as the Support Group last met in June 2007 and Dr Biggs ceased to attend meetings of the ACIC there was very little personal contact. Mrs Murray summed up Dr Biggs' relationship with the VOLH as "quite remote",⁷³⁵ adding that even when contact was made with Dr Biggs "you didn't always get a very satisfactory answer".⁷³⁶ In contrast, Mrs

723 [SPF01130003](#)
 724 [TRA01160052-53](#)
 725 [GOV00890099](#)
 726 [GOV00890100](#)
 727 [TRA01160067](#)
 728 [SPF01460003](#)
 729 [SPF01460004-05](#)

730 [SPF01470006](#)
 731 [GGC32170003](#)
 732 [GGC31980001](#)
 733 [TRA01150059-62](#)
 734 [TRA01010019](#)
 735 [TRA01010019](#)
 736 [TRA01010019](#)

Murray had had a “very good...working relationship” with Dr Dancer, the previous ICD at the VOLH.⁷³⁷

According to Mrs Murray, Dr Biggs had not visited the VOLH for a “few years”, a situation she found “difficult”.⁷³⁸ Dr Biggs’ lack of contribution as ICD meant that “more responsibility”⁷³⁹ was placed on Mrs Murray and on Mrs O’Neill. Mrs Murray said that when there was some contact Dr Biggs could be “abrasive”⁷⁴⁰ and could adopt a “belittling”⁷⁴¹ attitude. Mrs Murray acknowledged that Dr Biggs’ attitude meant that there was a significant problem with the leadership of the VOLH Infection Control Team which had continued for a number of years⁷⁴² and became worse following integration with GGHB.⁷⁴³

Mrs O’Neill confirmed that Dr Biggs was seldom at the VOLH and said that most contact she had with her was by telephone.⁷⁴⁴ She thought her contact with Dr Biggs would be “probably about once a month, maybe less”.⁷⁴⁵ Mrs O’Neill did think that Dr Biggs might have attended the VOLH “about twice”⁷⁴⁶ during 2007 and 2008. There was not a close and effective working relationship with Dr Biggs,⁷⁴⁷ and so far as Mrs O’Neill was concerned the Infection Control Team did not function well as a team because of Dr Biggs’ lack of involvement.⁷⁴⁸

Dr Biggs’ relationship with Annette Rankin

As the Head ICN responsible for the VOLH and the line manager for Mrs Murray, Ms Rankin was aware that there were “challenges”⁷⁴⁹ with Dr Biggs. These challenges included Dr Biggs’ antagonism towards the integration of Glasgow and Clyde and the prospect of single-system

working.⁷⁵⁰ Ms Rankin knew that there was an unsatisfactory working relationship between Mrs Murray and Dr Biggs,⁷⁵¹ but was not aware that Dr Biggs did not attend the VOLH,⁷⁵² and Mrs Murray certainly did not suggest that she told Ms Rankin that.

Ms Rankin’s evidence was that, in contrast to the ICDs in the other sectors of NHS GGC, Dr Biggs “was working against”⁷⁵³ her. From Ms Rankin’s perspective there existed an “underlying unpleasantness”⁷⁵⁴ towards her on the part of Dr Biggs. Ms Rankin was aware that Dr Biggs did not attend meetings of committees of which she was a member, and sought to put that non-attendance into context in the following way:

“Dr Biggs didn’t appear to attend anything, and it was accepted behaviour, so it wasn’t unusual to go to a meeting and Dr Biggs wasn’t present”.⁷⁵⁵

Although Ms Rankin said that she did not raise Dr Biggs’ non-attendance at committees with Mr Walsh,⁷⁵⁶ she did raise the difficulties she had with Dr Biggs with both Mr Walsh, her professional line manager, and Ms Martin, her line manager.⁷⁵⁷ When asked what Mr Walsh did about this issue Ms Rankin provided the following response:

“I think there was an acceptance that ... this behaviour wasn’t new. This wasn’t a behaviour that had manifested itself towards me or towards the infection control team. I think ... my understanding of it is this was the behaviour that had been displayed through time. So this wasn’t new behaviour that I was experiencing. Perhaps wrongly, but I accepted that, if it hadn’t been dealt with before, I don’t know what hope I had trying to address it. But I kept ... in terms of trying to provide a service, I raised my concerns”.⁷⁵⁸

737 [TRA01010020](#)

738 [TRA01010065](#)

739 [TRA01010064-65](#)

740 [TRA01010067](#)

741 [TRA01010067](#)

742 [TRA01010069](#)

743 [TRA01010071](#)

744 [TRA00950015](#)

745 [TRA00950015](#)

746 [TRA00950016](#)

747 [TRA00960012](#)

748 [TRA00960022](#)

749 [TRA01260017](#); [TRA01260037](#)

750 [TRA01260013](#)

751 [TRA01260020](#)

752 [TRA01260020](#)

753 [TRA01260037](#)

754 [TRA01260021](#)

755 [TRA01260022](#)

756 [TRA01260022](#)

757 [TRA01260017](#); [TRA01260022](#)

758 [TRA01260018-19](#)

Dr Biggs' failures

Dr Biggs was not performing her duties as ICD for the VOLH. She had minimal contact with the ICNs and provided little support and leadership. Her attitude towards Ms Rankin was counter-productive to an appropriate working relationship and unprofessional.

Dr Biggs' self-imposed restriction on her role as ICD for the VOLH as having "no responsibility for outbreaks or any infection control issues",⁷⁵⁹ or that the role was simply a "fire fighting"⁷⁶⁰ one, was without justification, whatever reservations she may have had over proposed changes to the infection control structures. Her failure to carry out her ICD duties for the VOLH in an appropriate manner was a serious failure on her part. It is almost certainly a failure that contributed significantly to the ongoing CDI problem at the VOLH and unnecessary suffering to patients.

It is worthy of note that in the course of giving her police statement of 7 May 2009 Dr Biggs was shown CDI data for a period that included 1 January 2007 to June 2008 and said that if she had been made aware of the data she "would have done something about it, an investigation would have been necessary".⁷⁶¹ She went on to say that she would have expected the ICNs to identify the issue and contact her to discuss it. As mentioned earlier, Mrs Murray did raise the number of CDI patients with her on at least one occasion. There is no doubt that the problem should have been identified locally, but neither is there any doubt that had Dr Biggs been fulfilling her duties as the designated ICD for the VOLH the problem would have been discovered. Dr Biggs had direct responsibility for infection prevention and control at the VOLH, and it was no excuse for her to suggest that she was not aware of the problem with CDI.

15.14 Knowledge of Dr Biggs' failure as Infection Control Doctor

Knowledge of Dr Biggs' behaviour

An important issue that the Inquiry has had to determine is who knew that Dr Biggs was not carrying out her responsibilities as ICD for the VOLH. A related issue is who ought to have known. A number of people knew that Dr Biggs was antagonistic towards the changes in the infection control structures, but it does not follow from that attitude in itself that she was not performing her role as ICD in an appropriate fashion. Nonetheless, there were aspects of Dr Biggs' behaviour that were well known.

Attendance at meetings

A striking example of the attitude taken by Dr Biggs is seen in a meeting that was ultimately arranged to take place at the IRH. Originally that meeting was to take place on 20 September 2007 in the infection control office in the Victoria Infirmary in Glasgow,⁷⁶² but by email dated 29 August 2007 addressed to Ms Rankin's secretary Dr Biggs intimated that she would be unable to attend because she "would not be available to travel to the Victoria".⁷⁶³ After an unsuccessful attempt to persuade Dr Biggs to travel to the Southern General Hospital instead, Ms Rankin offered to collect Dr Biggs from the car park area of the Victoria Infirmary and take her to the office where the meeting was to be held.⁷⁶⁴ Despite this, on 17 September 2007 Dr Biggs sent an email to Ms Ferguson in which she now announced that she would not be attending the meeting until she had her role clarified, as she no longer had "any control over the team that I am supposed to be leading".⁷⁶⁵ Thereafter the meeting was rearranged to take place at the IRH where Dr Biggs was based. This entailed nine people who were to attend the meeting travelling from Glasgow to Greenock. Members of the ACIC attended the meeting including Dr Reid, Ms Martin and Ms Rankin. It is unclear if Mr Walsh attended that meeting, although he did have some recollection of attending a

759 [SPF01130002](#)
760 [GOV00890100](#)
761 [SPF01470006](#)

762 [SPF00950003](#)
763 [SPF00950003](#)
764 [TRA01260014](#)
765 [SPF00950002](#)

meeting in September 2007 with Dr Biggs in connection with the same subject matter.⁷⁶⁶

It was clear to a number of people that Dr Biggs' dissatisfaction with the infection control system meant that she was generally unenthusiastic about attending meetings in connection with her role as ICD. Dr Biggs' attitude in refusing to attend the meeting planned for the Victoria Infirmary was equivocal. She appears to have at least implied that her inability to attend was because of difficulties in travelling. Ms Rankin also thought the problem was a mobility issue, and it was for that reason that she offered to assist her.⁷⁶⁷ There was evidence that Dr Biggs did have some mobility problems,⁷⁶⁸ but it is apparent that in this instance Dr Biggs' refusal to travel arose from her dissatisfaction over her role as ICD. Dr de Villiers said that at times Dr Biggs used a walking stick and that she often complained about her mobility problems, but added that her attitude to her mobility problems could be selective, as Dr Biggs was perfectly capable of attending to her private practice commitments at Ross Hall Hospital, and although she lived close to the Southern General Hospital in Glasgow she was able to travel to the IRH daily, a distance of some 27 miles.⁷⁶⁹

Dr Biggs' involvement in outbreak meetings

Dr Biggs was based at the IRH, but as the ICD for the VOLH, the RAH and the IRH she had responsibility for each of these hospitals. There was evidence that she did on occasion attend the RAH for some outbreak control meetings in connection with norovirus outbreaks,⁷⁷⁰ for there are nine sets of minutes of RAH outbreak meetings available for December 2007,⁷⁷¹ of which Dr Biggs attended two. There are 17 sets of minutes of outbreak meetings held at the RAH available

for January 2008.⁷⁷² Dr Biggs attended none. Dr Bagraade began to attend on 21 January 2008 having just taken up her post as Consultant Microbiologist.

Nor did Dr Biggs visit the RAH on other occasions.⁷⁷³ Ms Rankin said of Dr Biggs' day-to-day visibility that she had:

“visibility as an Infection Control Doctor that would appear to be within the laboratory building of Inverclyde Royal”.⁷⁷⁴

In making that statement Ms Rankin was speaking with the benefit of information subsequently obtained.⁷⁷⁵

The Infection Control Nurses and the Head Infection Control Nurse

Clearly, Mrs Murray and Mrs O'Neill were aware that Dr Biggs was not carrying out her ICD responsibilities for the VOLH. Ms Rankin, as Mrs Murray's line manager, was aware of the poor working relationship between ICNs and Dr Biggs. She was also aware that Dr Biggs did not attend meetings.⁷⁷⁶

Mrs Murray had discussions with Ms Rankin about Dr Biggs' failure to carry out her ICD duties.⁷⁷⁷ Mrs Murray told Ms Rankin that Dr Biggs was “actually not attending anywhere that happened to be outwith Inverclyde hospital”.⁷⁷⁸ Ms Rankin herself echoed Mrs Murray's view when she said in evidence that “Dr Biggs didn't appear to be involved in anything other than Inverclyde”.⁷⁷⁹ At one stage in her evidence Ms Rankin said that she did not know that Dr Biggs did not attend the VOLH. Nonetheless it is clear that Ms Rankin knew in the course of 2007 and after she became the Head ICN in April 2007 that Dr Biggs was not carrying out her ICD responsibilities for the VOLH. Ms Rankin did, however, regularly pass on her concerns to

766 [TRA01200040-42](#)

767 [TRA01260015](#)

768 [TRA01250017](#); [TRA01210036](#); [WTS02350002](#)

769 [TRA01250018-19](#)

770 [TRA01260020](#)

771 [GGC09680001](#); [GGC09690001](#); [GGC09700001](#); [GGC09710001](#); [GGC09720001](#); [GGC09730001](#); [GGC09740001](#); [GGC09750001](#); [GGC09760001](#)

772 [GGC09770001](#); [GGC09780001](#); [GGC09800001](#); [GGC09790001](#); [GGC09820001](#); [GGC09850001](#); [GGC09870001](#); [GGC09910001](#); [GGC09970001](#); [GGC09990001](#); [GGC10010001](#); [GGC10030001](#); [GGC10040001](#); [GGC10050001](#); [GGC10070001](#); [GGC10090001](#); [GGC10110001](#)

773 [TRA01260020](#)

774 [TRA01260020](#)

775 [TRA01260020](#)

776 [TRA01260020-22](#)

777 [TRA01010068](#)

778 [TRA01010068](#)

779 [TRA01260022](#)

Ms Martin and Mr Walsh in the course of 2007.⁷⁸⁰ From Ms Rankin's perspective, as set out in Section 15.13, Dr Biggs' behaviour had become "accepted behaviour".⁷⁸¹

The Infection Control Manager's knowledge

As previously mentioned, Dr Biggs expressed her dissatisfaction with her role as ICD to Mr Walsh in an email dated 1 June 2007.⁷⁸² Mr Walsh suspected that Dr Biggs might have selected him either because of his past role as Assistant Director of Nursing for NHS Argyll and Clyde, a position that included a remit for infection control, or possibly because he had been appointed to the post of Infection Control Manager.⁷⁸³ Mr Walsh's response of 5 June 2007 advised Dr Biggs to raise the issue with Ms Martin as her line manager and with Dr Jordan.

Before responding as he did, Mr Walsh discussed Dr Biggs' e-mail with Ms Martin. He was advised by Ms Martin that she would take responsibility for the immediate issue with Dr Biggs and that there was a "medium term plan"⁷⁸⁴ to replace Dr Biggs when one of two new microbiologists was appointed. Mr Walsh was not copied into the subsequent email exchanges involving Dr Biggs in which she continued to question her role and disclaimed any responsibility for the infection control service,⁷⁸⁵ and it appears that after June 2007 Mr Walsh had very little contact with Dr Biggs, who did not attend meetings of the ACIC or the BICC, of which Dr Biggs and Mr Walsh were members. His contact with Dr Biggs was limited to the meeting with her in September 2007 and "two or three other outbreak meetings".⁷⁸⁶ He was not present at the two outbreak control meetings attended by Dr Biggs in December 2007.⁷⁸⁷ He did attend outbreak control meetings in December 2007 and January 2008, but Dr Biggs was not present at those meetings.⁷⁸⁸ These outbreak meetings were not in connection with CDI.

The Inquiry accepts that Ms Rankin did pass on her concerns about Dr Biggs to Mr Walsh.⁷⁸⁹ As Mr Walsh said in evidence, he may not have been aware of the extent of the problem,⁷⁹⁰ but he could not avoid being aware that there was a problem, and he ought to have made himself aware of the extent of the problem, and to have carried out any inquiries to see if the issues raised by Dr Biggs had been resolved.⁷⁹¹

When contacted by Dr Biggs on 1 June 2007, Mr Walsh had of course still to take up post, and his response of 5 June 2007 may have been reasonable at the time,⁷⁹² but the question remains whether he should have done more thereafter to satisfy himself that any problems had been resolved.

Mr Walsh was correct in his expectation that the problem of Dr Biggs was an issue to be managed by Ms Martin.⁷⁹³ Nonetheless he had overarching responsibility for the effectiveness of the infection prevention and control system. Having become aware of the problem, and been reminded of it by Ms Rankin, it is disappointing that he did not do more to satisfy himself that the provision of the infection prevention and control service was not being placed at risk by Dr Biggs' attitude. Because Dr Biggs' responsibilities as ICD included the VOLH, the IRH and the RAH, she was a key part of the structure in so far as those hospitals were concerned. In his evidence Mr Walsh agreed that "in hindsight" he should have conducted some further inquiries to see if the problem had been resolved.⁷⁹⁴

Ms Martin's knowledge

The email exchanges between Dr Biggs and Ms Martin have already been commented upon in Section 15.13. The conclusion the Inquiry has arrived at, as discussed in Section 15.15, is that Ms Martin was not on full-time secondment in the latter part of 2007 and remained Dr Biggs' line manager. Ms Martin knew that Dr Biggs did not

780 [TRA01260016-19](#)

781 [TRA01260022](#)

782 [GGC08660001](#)

783 [TRA01200027-28](#); [TRA01200003](#)

784 [TRA01200029](#)

785 [SPF01130003](#)

786 [TRA01200054-55](#)

787 [GGC09710001](#); [GGC09720001](#)

788 [GGC09820001](#); [GGC09850001](#); [GGC09870001](#)

789 [TRA01000070-71](#)

790 [TRA01200073-74](#)

791 [TRA01200051](#)

792 [GGC08660001](#)

793 [TRA01200028-29](#); [TRA01200051](#)

794 [TRA01200051](#)

attend the VOLH.⁷⁹⁵ As already discussed in Section 15.13 she had no proper basis in fact to believe that Dr de Villiers was covering as Infection Control Doctor for Dr Biggs when he made his visits to the VOLH. It is possible to sympathise with the view that as a Consultant Microbiologist Dr de Villiers should have been alert to infection prevention and control issues during those visits, but Ms Martin should nevertheless have satisfied herself that the ICD role was being properly fulfilled in the VOLH.

Mrs den Herder's knowledge

Mrs den Herder was not copied into the email in which Dr Biggs expressed her attitude to the role of ICD, and in her evidence to the Internal Investigation on 19 June 2008 she said she did not know that Dr Biggs was not fulfilling her role as ICD.⁷⁹⁶ There is independent support for that position, in that Mrs den Herder was involved in considering Dr Biggs' application for consultant discretionary points in which Dr Biggs held out that her professional leadership included acting as "Area Infection Control Doctor to cover 2 Consultant vacancies 2006-2008".⁷⁹⁷ Furthermore, the conversation Dr Cowan had with Mrs den Herder, probably in the summer of 2007, about advertising for two microbiology posts lends some additional support to that conclusion. Dr Cowan said that Mrs den Herder told him that the ICD wanted to give up the role, which could only have been a reference to Dr Biggs. Importantly, Dr Cowan said that Mrs den Herder did not say there was any problem with the existing ICD, for if that had been the position "it would have been a different conversation with a totally different result".⁷⁹⁸ There was no reason for Mrs den Herder to refrain from discussing with Dr Cowan Dr Biggs' failure to carry out her responsibilities for infection prevention and control at the VOLH if she was aware of that failure.

What is clear is that Mrs den Herder ought to have been made aware of that failure. Ms Martin in particular ought to have made her aware of the problems with Dr Biggs.

Furthermore, as discussed in Chapter 9, Mrs den Herder herself should have paid closer attention to infection prevention and control, and in particular should have considered whether Ms Martin was an effective link to the infection prevention and control system during her secondment, even although that secondment was only part-time.

Summary of failures over Dr Biggs

The ICD has a pivotal role to play in the management of infection prevention and control. Mr Divers observed that:

"there was a key point in time when it was clear that that sector arrangement for Clyde with Dr Biggs as the Infection Control Doctor, that that was about to come apart, nothing was done to deal with it".⁷⁹⁹

He was in no doubt that if Ms Martin had had difficulty resolving the issue "she should have elevated it",⁸⁰⁰ by which he meant raising the issue with Mrs den Herder or Mr Calderwood, and if necessary with Dr Cowan and Mr Divers himself.

Ms Martin has to accept responsibility for failing to deal with the problems created by Dr Biggs in her attitude to her role as ICD. Whatever may have been Ms Martin's understanding of whether or not there was any infection control presence at any time at the VOLH, it was perfectly clear from the messages she was receiving from Dr Biggs that Dr Biggs was not fulfilling her duties as ICD. Ms Martin's failure to address the problems created by Dr Biggs was a serious failure.

The reality is that in the latter part of 2007 no-one was prepared to tackle the issues associated with Dr Biggs. By then there was a plan to replace Dr Biggs after the appointment of the two new Consultant Microbiologists, but that does not excuse the failure at the time to deal with an ICD who was not carrying out her responsibilities for the VOLH. Ms Rankin did make Ms Martin aware of her concerns, and although Ms

795 [TRA01260073](#)

796 [GOV00890122](#)

797 [GGC31980001](#)

798 [TRA01220111-112](#)

799 [TRA01250079](#)

800 [TRA01250081](#)

Rankin could have done more, she was faced with a situation in which Dr Biggs' behaviour had become "accepted behaviour".⁸⁰¹ Mr Walsh quite fairly accepted that with the benefit of hindsight he should have done more to see if the problems over Dr Biggs' role had been resolved. It was unfortunate that he did not do so at the time, but it is right to point out that he did direct Dr Biggs to her professional and line managers in the expectation that Dr Biggs' issues would be addressed. It also has to be acknowledged that Dr Biggs seemed to lack adequate professional line management support during the relevant period.

15.15 The secondment issue

The Picture Archiving Communication Systems

Ms Martin's role as General Manager of Diagnostic Services for Clyde has already been discussed at Section 15.3. In her evidence Ms Martin said that she was on full-time secondment to the Picture Archiving Communication Systems (PACS) project from August 2007 to April 2008.⁸⁰² Her evidence was that when on secondment she had no responsibilities for infection prevention and control.⁸⁰³ The assertion that Ms Martin was seconded full time to the PACS project was supported by Dr Alan Wallace the Lead Radiologist for the PACS project.⁸⁰⁴

No formal agreement

There does not appear to have been any formal written agreement setting out the terms of the secondment that Ms Martin was to take up. The action notes from a meeting of the Clyde Acute Senior Management Team of 22 September 2007 simply contain the following entry:

"PACs Update: Deborah advised that Marie had been seconded from GM role to lead on this for Clyde".⁸⁰⁵

The reference to "Deborah" is to Mrs den Herder.

801 [TRA01260022](#)
802 [TRA01160002](#)
803 [TRA01160020](#)
804 [GGC32120001](#); [TRA01260047](#)
805 [GGC04550003](#)

Ms Martin's witness statement

In her witness statement to the Inquiry Ms Martin does not mention that she was on full-time secondment. She did say that "For the few months preceding my retirement I was not actively involved in any IC function".⁸⁰⁶ Ms Martin retired in August 2008.⁸⁰⁷

The Internal Investigation

At her interview by the Internal Investigation panel on 16 June 2008 it was noted that when asked about her role Ms Martin replied by saying that she was the General Manager for Diagnostics in Clyde "including responsibility for Infection Control".⁸⁰⁸ It was also noted that when asked who reported to her in connection with infection prevention and control she first named Ms Rankin, then apparently in response to a question about medical staff said "Dr Biggs, Infection Control Doctor to end January 2008, and then Dr Bagraade came into post also".⁸⁰⁹

Ms Martin did mention her secondment in explaining why she did not attend meetings of the ACIC, and was noted as saying:

"From September last year, I couldn't go to Acute IC meetings as I was on secondment. Dr Biggs plus Jean Murray attended".⁸¹⁰

It was also noted that when asked about the secondment she said:

"Secondment was supposed to be full time but GM post was not backfilled. Nobody deputised".⁸¹¹

Finally, it was noted that she said the secondment was to the end of January.⁸¹²

Ms Martin's position

Ms Martin's evidence was that having taken up her full-time secondment post she no longer had any responsibility for infection prevention and control or indeed her other duties as General Manager of Diagnostics.

806 [WTS00810001](#)
807 [TRA01160001](#)
808 [GOV00890024](#)
809 [GOV00890024](#)
810 [GOV00890025](#)
811 [GOV00890026](#)
812 [GOV00890026](#)

Her position was that there was “a gap”⁸¹³ because her responsibilities for infection prevention and control were not taken over by somebody else. Ms Martin’s initial understanding was that Isabel Ferguson, who held a similar post to her in Greater Glasgow, would cover for her,⁸¹⁴ particularly as at that time NHSGGC was working towards full integration. She went on to say that in October 2007 she was told by Mrs den Herder that Mr Calderwood had not allowed Ms Ferguson to cover for her in that role.⁸¹⁵

Ms Ferguson’s position

As the General Manager for Greater Glasgow Laboratory Medicine and Infection Control from April 2006 to May 2008, Ms Ferguson⁸¹⁶ was the line manager for the Infection Control Doctors in the Greater Glasgow sectors. In May 2008 she also took over line management for infection control in Clyde.⁸¹⁷

Ms Ferguson, as already mentioned, was not aware of Ms Martin’s secondment at the time, nor was she aware of the proposal that she should cover for Ms Martin during that secondment.⁸¹⁸ Ms Ferguson’s understanding was that in September 2007 there was some discussion about the possibility of early integration, through which she would assume managerial responsibility for infection prevention and control for the Clyde Sector, but because the decision had already been taken that the Clyde Sector would run as a separate directorate until 2008 this was not pursued.⁸¹⁹ The issue of early integration had nothing to do with Ms Martin’s secondment.⁸²⁰ For her part, Ms Martin appeared to accept that the issue of concern to Ms Ferguson may have been early integration rather than the need to cover Ms Martin’s responsibilities for infection prevention and control because of her secondment to the PACS project.⁸²¹

Evidence adverse to Ms Martin’s position

The Inquiry is satisfied that Ms Martin participated in the PACS project. That in itself does not mean that she no longer had any responsibility for infection prevention and control. In fact when the evidence is fully considered it appears that Ms Martin continued to be involved in the management of infection prevention and control, at least to some extent.

When recalled to give further evidence Ms Martin was asked if it was still her position that a critical post such as her own was not being covered and whether she had raised that issue with anybody. She responded in the following way:

“Yes, I did complain. I did complain to Deb den Herder. I was not happy that I was really basically on a full time secondment and I still had to try to fulfil the role of the Infection Control Manager because nobody had been seconded into that. It just resulted in me working many long hours to try to fulfil that role, but I was not happy and I did complain about it”.⁸²²

In that answer Ms Martin appears to accept that she did continue to carry out infection control management responsibilities. As noted hereafter there is other evidence to support that conclusion.

Dr Bagnade’s position

When Dr Bagnade took up her post as ICD in early February 2008 she had a meeting with Ms Rankin and Ms Martin, in the course of which her role as ICD in the Clyde Sector was discussed.⁸²³ Although Dr Bagnade did not have a formal handover from Dr Biggs, she did have a meeting with Dr Biggs, attended by Ms Martin.⁸²⁴ Dr Bagnade was taking over responsibility as ICD for the VOLH and the RAH, while Dr Biggs retained responsibility as ICD for the IRH. Dr Bagnade’s line manager was Ms Martin.⁸²⁵

813 [TRA01160023](#)

814 [TRA01160021](#)

815 [TRA01160021-22](#)

816 [TRA01210085](#)

817 [TRA01210087](#)

818 [TRA01210091](#)

819 [TRA01210093](#)

820 [TRA01210094-95](#)

821 [TRA01260065](#)

822 [TRA01260062](#)

823 [TRA01020066-80](#)

824 [TRA01020085](#)

825 [TRA01020084](#)

Dr Bagnade first visited the VOLH in the second half of February⁸²⁶ and became aware of the lack of hand washing facilities. She was told by Mrs Murray that the lack of such facilities had been a longstanding problem and that new wash-hand basins had been purchased for the wards, but that due to budget restrictions they had not been installed.⁸²⁷ Dr Bagnade said she raised this issue with Ms Martin, who, according to Dr Bagnade, expressed surprise and said that she would “look into it”.⁸²⁸

Ms Martin herself said in evidence that she became Dr Bagnade’s line manager when Dr Bagnade took over from Dr Biggs.⁸²⁹ That in itself suggests that, despite Ms Martin’s protestations, she continued to be Dr Biggs’ line manager up to that point. Some aspects of the notes made by the Internal Investigation panel have already been referred to. The crux of what Ms Martin was noted as having said is that she retained her line management responsibilities.

Continuing role as General Manager

There was also a clear suggestion in documents made available to the Inquiry that Ms Martin continued to carry out certain duties in her role as General Manager of Diagnostics. At a meeting for the Clyde Acute Clinical Governance Forum on 18 September 2007 it was noted that Ms Martin gave a report on behalf of the Diagnostics Clinical Directorate⁸³⁰ intimating that the Infection Control and Blood Transfusion Committees had been integrated with Greater Glasgow.

The minutes of the following meeting of the same group on 11 December 2007 record that Ms Martin again provided a report on behalf of the Diagnostics and Clinical Directorate. That report intimated that two new consultant microbiologists were due to start and would be in post by the end of January.⁸³¹ Ms Martin’s explanation for that entry was that because she was attending anyway she was simply presenting reports

prepared by her Assistant General Managers in order to save them having to attend.⁸³²

The next meeting of that group took place on 11 March 2008 and once again Ms Martin attended. It was noted in the minutes that she provided a report on behalf of the Diagnostic Clinical Directorate, and once again that report contained matters that were not PACS issues, including intimation that the two new Consultant Microbiologists had started work at the end of January.⁸³³ Again Ms Martin explained in evidence that she was simply presenting reports from her Assistant General Managers to save them also having to attend the meeting.⁸³⁴

The email exchanges

There was also other evidence suggesting that Ms Martin continued to perform a management role in infection prevention and control. Some of the emails that she sent to Dr Biggs have already been mentioned, but in addition Dr Biggs had apparently been led to believe that Ms Martin was to hand over to Ms Ferguson, and in an email to Ms Martin dated 4 October 2007 Dr Biggs wrote as follows:

“When you meet Isobel for handover, could you make sure she knows that I am only responsible for control of Infection acute at IRH and had been doing the rest of Clyde as a voluntary help for Barbara (Weinhardt) till the new consultants start”.⁸³⁵

Ms Martin responded to that by email dated 9 October 2007 in the following way:

“as you probably gather from the letter from Deb yesterday I will not be handing over to Isobel”.⁸³⁶

In her reply on 10 October 2007 Dr Biggs commented: “I just wanted to know I am glad (glad) you are still with us”.⁸³⁷ This message appears at odds with what was said by Dr Biggs at her interview by the Internal Investigation panel on 18 June 2008, since

826 [TRA01020089-90](#)

827 [TRA01020092](#)

828 [TRA01020092](#)

829 [TRA01160006](#)

830 [GGC03780003](#)

831 [GGC15400003](#)

832 [TRA01260053](#)

833 [GGC03760003](#)

834 [TRA01260055-56](#)

835 [SPF01130004](#)

836 [INQ03990001](#)

837 [INQ03990001](#)

when asked about her relationship with Ms Martin she was noted as saying, “Good, but IC taken from Marie a year ago”.⁸³⁸

Ms Martin also received emails in connection with Mrs Murray’s phased retirement. By email dated 4 January 2008 addressed to Ms Martin, Mrs Murray set out her intentions during the phased retirement period of three months.⁸³⁹ By an email of the same date Ms Rankin provided Ms Martin with details of Mrs Murray’s infection prevention and control commitments during her phased retirement.⁸⁴⁰

The letter of 8 October 2007

Ms Martin’s email to Dr Biggs of 9 October 2007 refers to a letter from Mrs den Herder “yesterday”.⁸⁴¹ This letter, dated 8 October 2007, is addressed to “all staff, Clyde Laboratory Services”⁸⁴² and begins by intimating that Ms Martin has agreed to lead the implementation of PACS within Clyde, going on to say:

“I recognise that Marie will be required to be supported in various aspects of her management role to provide sufficient time to enable her to undertake the PACS work”.

Mrs den Herder also sets out in the letter that “Marie will retain her overall responsibility for laboratory management”,⁸⁴³ directly contradicting Ms Martin’s evidence that she was on full-time secondment to the PACS project in 2007 and 2008.

Mrs den Herder’s evidence to the Internal Investigation on 19 June 2008 was consistent with her letter of 8 October 2007. The following exchange has been noted:

“Q. Marie was seconded was that full time?
A. Initially she would be seconded out and we would back fill however this changed and she was told she could have some support but would still be GM (General Manager)”.⁸⁴⁴

838 [GOV00890099](#)
839 [GGC32980001](#)
840 [GGC33010001](#)
841 [INQ03990001](#)
842 [GGC32630001](#)
843 [GGC32630001](#)
844 [GOV00890122](#)

Ms Martin and line management

Ms Martin’s position was that her post as line manager for infection control in the Clyde Sector was not filled. When she was asked in oral evidence who was managing infection control in that sector she responded in the following way:

“Well, really, then it fell to Deb den Herder herself. Because she had allowed me to take up the secondment, so she, as my manager, it was really up to her to put someone else to fill that job, but she didn’t”.⁸⁴⁵

Ms Martin’s contact with Dr Biggs ostensibly in a line management capacity has already been discussed. Furthermore, so far as Dr Bagnade was concerned Ms Martin was her line manager when she took over as ICD for the VOLH and the RAH in early February 2008. Similarly, when Ms Rankin took up her post as Infection Control Head Nurse in April 2007, Ms Martin was her line manager.⁸⁴⁶

The Infection Control Manager’s request

When Dr Bagnade took over as Infection Control Doctor in February 2008, Mr Walsh wrote to Ms Martin by email dated 6 February 2008 asking whether there had been:

“any discussion/agreement on which of the ICDs in Clyde will represent Clyde on the Acute Board Infection Control Committees?”⁸⁴⁷

Ms Martin responded by sending an email to Dr Biggs and Dr Bagnade suggesting that Dr Bagnade could represent Clyde on the ACIC and Dr Biggs represent Clyde on the BICC. She ended the email by asking them to let her know if they were in agreement with that proposal.⁸⁴⁸ When asked about this in evidence Ms Martin provided the following explanation:

845 [TRA01160022](#)
846 [TRA00990131](#)
847 [GGC08730001](#)
848 [GGC08730001](#); [TRA01260058-59](#)

“I was trying to plug a gap there. I had obviously been approached. Nobody backfilled for me. I mean, I could see there was nobody in that role. What actually happened was people did tend to still come to me for advice because no one else backfilled the role”.⁸⁴⁹

What this shows is firstly that Ms Martin was trying to fulfil the role of manager with responsibility for infection control, as indeed she did say at one point in evidence, and secondly that Mr Walsh was proceeding on the basis that Ms Martin was the line manager.

Letter to Dr de Villiers

Another example of Ms Martin purporting to carry out line management responsibility for a third Consultant Microbiologist is a letter dated 20 December 2007 from Ms Martin to Dr de Villiers,⁸⁵⁰ in which she wrote:

“I write to confirm that from 1 February 2008 you will no longer receive the 2 EPAs vacancy recognition payment due to the successful recruitment to the Consultant vacancies”.

When asked about this in evidence Ms Martin explained that this was a matter that her Assistant General Manager Mr Bruce Barnett was dealing with, but that because it was a matter that was dealing with payment Mr Barnett thought that it would be better if the letter was signed by her.⁸⁵¹

The Assistant General Manager’s position

Mr Barnett was the Assistant General Manager for Laboratories for Clyde, a position which he held from April 2006. He had no responsibility for infection prevention and control,⁸⁵² although his line manager was Ms Martin.⁸⁵³ Mr Barnett’s reaction to the letter of 20 December 2007 to Dr de Villiers was that he would not have been able to authorise such payments or negotiate their reduction with Dr de Villiers.⁸⁵⁴ He

also pointed out that the initials LS in the reference were the initials of Ms Martin’s secretary.⁸⁵⁵

Ms Martin accepted that at least prior to August 2007 she was the line manager for Ms Rankin, Dr Biggs, Dr de Villiers and Dr Weinhardt. She also seemed to suggest, however, that so far as Dr Weinhardt and Dr de Villiers were concerned Mr Barnett was “their direct line manager and then I was above that”.⁸⁵⁶ That suggestion was also rejected by Mr Barnett,⁸⁵⁷ and it would certainly make little sense for Ms Martin to be line manager for Dr Biggs and not for the other Microbiologists.

Mr Barnett did not think that Ms Martin was on full-time secondment to the PACS project. She did not move her office or change her job title. He pointed to the letter from Mrs den Herder to all staff of 8 October 2007,⁸⁵⁸ which he understood to mean that Ms Martin’s participation in the PACS project did not mean that she relinquished her other responsibilities.⁸⁵⁹ Furthermore, according to Mr Barnett the reports that Ms Martin made to the Clyde Acute Clinical Governance Forum were not being made on behalf of her Assistant General Managers, but were made in the normal course of her being General Manager of Diagnostics and retaining managerial responsibilities for that area. The PACS update would simply have been a part of that responsibility.⁸⁶⁰

The Director’s position

The position adopted by Mrs den Herder towards the Inquiry has already been commented upon in Chapter 2. Only if Mrs den Herder’s written evidence is not disputed or can be supported by other evidence, can any reliance be placed upon it by the Inquiry.

In her letter of 22 June 2012 to the Inquiry Mrs den Herder responded to the issue of Ms Martin’s secondment in the following way:

849 [TRA01260059](#)

850 [INQ04380001](#)

851 [TRA01260061](#)

852 [WTS02340001](#)

853 [WTS02340005](#)

854 [WTS02340011](#)

855 [WTS02340011](#)

856 [TRA01260045](#)

857 [WTS02340006](#)

858 [GGC32630001](#)

859 [WTS02340008](#)

860 [WTS02340010](#)

“I understand that there is some confusion about Mrs Martin’s secondment to a role of project manager for the imaging archiving system. I can confirm that it was the initial intention to second her full time, and to transfer the control of infection control responsibilities to Ms Ferguson. This was vetoed, however, on the grounds that it would appear to pre-empt a measured process towards integration and would further negative perceptions of a Glasgow takeover. Because this was vetoed, and because other options (separate recruitment to the project management post or backfill from the redeployment pool, both of which were investigated) were not possible, it was agreed that Mrs Martin would retain responsibilities for those elements of the service that could not be delegated. This latter included the control of infection service (the remaining elements were transferred to her assistants)”⁸⁶¹

The position set out in Mrs den Herder’s letter was put to Ms Martin,⁸⁶² who rejected the proposition that she retained responsibility for infection prevention and control,⁸⁶³ but the evidence already examined in this Section contradicts Ms Martin and supports Mrs den Herder’s evidence.

The Associate Medical Director’s position

Dr Dickson succeeded Dr Jordan as Associate Medical Director in September 2007.⁸⁶⁴ On management issues he reported to Mrs den Herder.⁸⁶⁵ Dr Dickson was not made aware of the difficulties with Dr Biggs or of the email exchanges which included Dr Jordan.⁸⁶⁶ He was aware that Ms Martin had been asked to undertake a secondment, but his understanding was that she was continuing her role as General Manager with support.⁸⁶⁷

Conclusion on secondment

The Inquiry is satisfied that Ms Martin did not take up a full-time secondment position in August 2007 at the expense of her infection prevention and control management duties. She contradicted herself in evidence, maintaining on the one hand that because of her secondment there was a gap in the management structure, while on the other hand claiming that she was “working many long hours” to fulfil the management role.⁸⁶⁸

It has to be acknowledged that Ms Martin was placed in a difficult position because of the extent of her role after she took up her secondment duties. She continued to deal with a number of general management duties and infection prevention and control matters. She was considered by Mrs den Herder and others to be the responsible manager. Ms Martin said in evidence that the consequence of her secondment without cover was that there was a gap and that it was for Mrs den Herder to fill that gap.⁸⁶⁹ That assertion was incorrect for the simple reason that Ms Martin’s involvement with the PACS project was not at the expense of other duties. The intention set out in Mrs den Herder’s letter of 8 October 2007 was that Ms Martin would be able to obtain support from her assistant managers. The secondment issue does undoubtedly highlight the fact that there was a major flaw in the infection prevention and control management arrangements, but it was not the one identified by Ms Martin.

Mrs den Herder does not escape criticism for placing Ms Martin in such a difficult position, and this is also examined in Chapter 9. It is clear that Ms Martin did complain to Mrs den Herder about the pressure she was under⁸⁷⁰ because of the extent of her responsibilities. Mrs den Herder should have responded positively to those complaints, but she failed to do so. Furthermore, Ms Martin’s complaints of overwork should have alerted Mrs den Herder to the real possibility that the management of infection prevention and control was at risk of being neglected.

861 [INQ04240004-05](#)

862 [TRA01260062-63](#)

863 [TRA01260063-64](#)

864 [WTS02290001](#)

865 [WTS00820002](#)

866 [WTS02290002](#); [GGC09300001](#)

867 [WTS02290002-03](#)

868 [TRA01260062](#)

869 [TRA01160022-23](#)

870 [TRA01260062](#)

15.16 The reporting of *C. difficile* data to Health Protection Scotland and the Public Health Protection Unit

Mandatory reporting

As discussed in Chapter 6, mandatory reporting of *C. difficile* toxin positive cases was required from 1 September 2006 as part of the national surveillance system. Reporting from the Clyde Sector was carried out on a weekly basis with separate reports for each of the hospitals. For the VOLH the first stage of the reporting process was managed from the RAH.

Mr Mallon's role

In the period from 1 January 2007 to 1 June 2008 Mr John Mallon held the post of Chief Biomedical Scientist in the RAH Laboratory.⁸⁷¹ He had been directly involved in setting up the Laboratory Information Management System (LIMS) that was installed in the VOLH, the IRH and the RAH Laboratories.⁸⁷² The system in each of the laboratories was the same and as a result it was possible to recover at the IRH Laboratory data put on the system at the VOLH Laboratory.

Reporting methods – Health Protection Scotland

From 1 January 2007 to 5 February 2008 reports were sent in paper form from the laboratories to Health Protection Scotland (HPS) providing details of *C. difficile* toxin positive cases. After the installation of an electronic system known as the Electronic Communication of Surveillance in Scotland System (ECOSS) in November 2007, reports were sent to HPS both in paper form and electronically⁸⁷³ while HPS carried out a validation exercise⁸⁷⁴ to check the accuracy of the paper and electronic results. From 5 February 2008 reports were sent electronically only.

Content of the reports

The reports identified the patient's name, gender, and date of birth, as well as the ward in which the patient was being accommodated

at the time. By way of example the report for the week ending 25 January 2008 disclosed that there were three patients who were *C. difficile* toxin positive in ward F in the course of that week.⁸⁷⁵ The report was designed by Mr Mallon to be signed by a Consultant Microbiologist.

Submission of reports to Microbiologists

RAH reports were sent direct to HPS, whereas VOLH reports were sent to the VOLH Laboratory for checking and onward transmission to HPS. Before this stage, however, it was Mr Mallon's practice to have the printed reports, including the VOLH reports, sent to the Microbiologists' office in the RAH.⁸⁷⁶ So far as Mr Mallon was concerned the purpose of this part of the exercise was that a Consultant Microbiologist would have sight of not just what was happening at the RAH but also what was happening in the VOLH.⁸⁷⁷ Even after the ECOSS system was in operation the printed reports from the VOLH were sent to a Consultant Microbiologist and thereafter filed.⁸⁷⁸ That remained the position until the middle part of 2008.⁸⁷⁹

The position at the VOLH Laboratory

When the VOLH reports were received by the VOLH Laboratory they were checked by Mr Kinloch. Prior to the change to the electronic system in February 2008, if he was satisfied with the accuracy of the reports he would sign each of them on behalf of a Consultant Microbiologist, having been instructed to do so by Dr Weinhardt,⁸⁸⁰ and post them to HPS. Although Dr Weinhardt could not remember delegating that duty to Mr Kinloch, she thought it was very likely that she did so because it was important that the information contained in the reports was sent to HPS on a timely and accurate basis⁸⁸¹ and she was not on site at the VOLH.

The role of the Microbiologists

Although Dr Bagrade did not take over the responsibilities of the ICD for the VOLH

871 [TRA01100052](#)
872 [TRA01100054](#)
873 [TRA01100074-75](#)
874 [TRA01100075](#)

875 [GGC29720006](#)
876 [TRA01100066](#)
877 [TRA01100069](#)
878 [TRA01100084](#)
879 [TRA01100085](#)
880 [TRA00870034-35](#)
881 [TRA00880002-03](#)

until 4 February 2008, she did take up the post of Consultant Microbiologist on about 21 January 2008.⁸⁸² Dr Bagrade had a clear recollection of signing the reports for the RAH,⁸⁸³ and explained that in doing so she was confirming that they provided an accurate reflection of the results.⁸⁸⁴ By contrast, Dr Bagrade had no recollection of seeing the VOLH reports. Her recollection was that when all the reports were taken to the Microbiologists' office a secretary separated those requiring to be signed at the RAH, and it was only those reports that were signed by a Microbiologist in the RAH. The VOLH reports were sent to the VOLH Laboratory for signing.⁸⁸⁵

Dr Bagrade emphasised that this part of the reporting system was never designed to be a surveillance tool. It was simply a method of identifying how many patients had been diagnosed with CDI in a particular week to be submitted to HPS as part of the national surveillance programme.⁸⁸⁶ Nonetheless Dr Bagrade did say that, after she became ICD for the VOLH, if she had seen that there were three or possibly more patients who were *C. difficile* toxin positive in a particular ward in a week she would have investigated to see what was going on.⁸⁸⁷

Dr Weinhardt confirmed that she definitely had sight of the reports for the RAH,⁸⁸⁸ but the thrust of her evidence was that she had no recollection of the VOLH reports.⁸⁸⁹ She also said that as far as the VOLH reports were concerned Mr Kinloch's function was simply to check the accuracy of the data, and that he had no responsibility for monitoring the position because, according to Dr Weinhardt, that was already in place with the presence of the Infection Control Team.⁸⁹⁰ Dr Weinhardt's initial position was that if she had seen a report that indicated that there were a number of positive patients in a ward at about the same time that would

have been a matter of concern which she would probably have raised in a general way with the ICNs.⁸⁹¹ Later she said that she might have raised it in passing, but that in any event the ICNs would already know about the position from their own records.⁸⁹² Her final position was that at that time she would not necessarily have raised the issue,⁸⁹³ but that the position was different now and if she were to be in that situation today she would raise it.⁸⁹⁴

Dr Claxton took up the post of Consultant Microbiologist at the RAH on 28 January 2008.⁸⁹⁵ She also said that she looked at the reports for the RAH, but did not pay particular attention to the CDI numbers because she knew they would already have been considered by the Infection Control Team.⁸⁹⁶ She had no recollection of seeing the VOLH reports.⁸⁹⁷

Having regard to that evidence, it appears to have been the case that the microbiologists at the RAH did not see the VOLH reports before they were sent to the VOLH Laboratory.

Receipt of data by HPS

Professor Jacqui Reilly, Head of Group for Healthcare Associated Infection, HPS, provided some insight into how the reports containing the information on *C. difficile* toxin positive cases were managed once received by HPS prior to the time when the ECOS system was fully functional. Hundreds of weekly reports would be received from the laboratories, but there was no standard form of report. Although ward level information was being provided, that information was not relevant for national surveillance, and some laboratories did not send ward based information. Neither was the weekly information contained in reports of interest to HPS, because quarterly rather than weekly data were used for CDI analysis. Furthermore, paper records were destroyed once

882 [TRA01140014](#)

883 [TRA01140005](#)

884 [TRA01140007](#)

885 [TRA01140007](#)

886 [TRA01140009](#)

887 [TRA01140012](#)

888 [TRA00880005](#)

889 [TRA00880005](#); [TRA00880008](#)

890 [TRA00880006-07](#)

891 [TRA00880008-09](#)

892 [TRA00880010](#)

893 [TRA00880010-11](#)

894 [TRA00880011](#)

895 [TRA01220049](#)

896 [TRA01220073](#)

897 [TRA01220073-74](#)

information had been entered into the HPS database in accordance with a policy devised under requirements of data protection.⁸⁹⁸ In short, the whole purpose of the reporting to HPS was that of national surveillance so that the trends at Board, regional or national levels could be examined.⁸⁹⁹ HPS was not responsible for local surveillance, which was entirely the responsibility of Boards. This was clear from the guidance that had been provided over the years, including the CSBS Standards.⁹⁰⁰

The essence of the HPS position was that the system of national surveillance that followed the introduction of mandatory reporting was not intended in any shape or form to replace effective systems of local surveillance and reporting.

Reporting to the Public Health Protection Unit

Copies of the reports sent to HPS were also sent to the NHSGGC Public Health Protection Unit (PHPU) on a weekly basis in terms of a policy that required microbiologists to report to the PHPU *C. difficile* toxin positive cases that were reported to HPS.⁹⁰¹ Dr Ahmed, Consultant in Public Health Medicine and Clinical Consultant in the Public Health Protection Unit, explained that the PHPU performed a surveillance function, particularly in relation to community acquired notifiable diseases such as tuberculosis and hepatitis. The role of the PHPU was to ensure that such cases were followed up in the community, since most cases were acquired in the community.⁹⁰²

The weekly reports submitted by laboratories such as the VOLH Laboratory were a form of safety net, for although laboratories were supposed to inform the PHPU of notifiable diseases, on occasion they would forget to do so.⁹⁰³ Laboratories were therefore instructed to submit copies of the forms submitted to HPS to allow the PHPU to check they had received the relevant information on the

cases in which the unit might be interested.⁹⁰⁴ Accordingly, although CDI was included in the information submitted, it was not among the diseases on which the PHPU carried out surveillance in the community.⁹⁰⁵ Dr Ahmed went on to explain, however, that the PHPU would take action if a case of CDI was identified in the community. The identification of community acquired CDI was carried out by a clerk, and if the patient was based in a nursing home or a residential home for which the unit had responsibility then that would be followed up. On the other hand, if the case of CDI was from a hospital, the clerk would simply not do anything with it⁹⁰⁶ and the report would then be filed away.⁹⁰⁷ PHPU was not performing a surveillance function in relation to CDI that was hospital acquired: it was the role of the hospital Infection Control Team to perform that function.

No failures by HPS or PHPU

The Inquiry is satisfied that the system of reporting weekly results to HPS and the PHPU was not designed to provide those bodies with information that could have alerted them to the CDI problem in the VOLH. The reporting to HPS was part of the national surveillance programme and was not a local surveillance system. The reporting of CDI cases to the PHPU was incidental to its surveillance of community acquired notifiable diseases.

15.17 Statistical Process Control Charts

A surveillance tool

The Statistical Process Control (SPC) chart was a surveillance tool that could provide retrospective information on a monthly basis on the number of *C. difficile* toxin positive patients and trends.⁹⁰⁸ Although available in 2007 in some Board areas, SPC Charts were not introduced to the VOLH until April or May 2008.⁹⁰⁹

898 [TRA01100139-140](#)

899 [TRA01100139](#)

900 [TRA01100139](#); [GOV00160001](#)

901 [GGC00890002](#)

902 [TRA01130006-07](#)

903 [TRA01130008](#)

904 [TRA01130008-09](#)

905 [TRA01130009](#)

906 [TRA01130157](#)

907 [TRA01130157-158](#)

908 [TRA01200135](#)

909 [TRA00990095](#)

The creation of SPC Charts

The SPC Charts are the application of statistical theory to quality control.⁹¹⁰ Calculations from the data acquired on cases of CDI are used to produce an upper control limit, a centre line and a lower control line. To introduce the system it is necessary to have a minimum of two years of data⁹¹¹ in order to set the upper and lower control limits. The most recent point on an SPC Chart will be the most recent four weeks or calendar month.⁹¹² In addition to providing information on rates and trends, SPC Charts also act as a quality improvement tool, since if results below the lower control limit are achieved, both the upper and lower control limits will drop. Fewer cases will then be required to meet the new, and more demanding, upper control limit.⁹¹³

Delayed introduction to Clyde

When in use SPC Charts are made available on wards so that staff can see rates of infection. The system was seen as a “robust system”⁹¹⁴ and valuable in the management of infection prevention and control. There is, however, a time delay between occurrence of infection and the presentation of the data on the SPC Chart, and the earliest detection of outbreaks remains at ward level by the Infection Control Team.⁹¹⁵

First introduction of the SPC Chart

The SPC Chart system was first set up in Glasgow Royal Infirmary in response to an “uncontrollable level of MRSA”⁹¹⁶ in 2000, although Professor John Coia, Director of Scottish Microbiology Reference Laboratories, thought that charts might have been introduced in November 1999.⁹¹⁷ Their use contributed to a 50% reduction in new cases of MRSA in the course of 2000, and they were also being successfully used in the control of CDI.⁹¹⁸ Therefore, although in evidence Ms Rankin described the SPC Chart

system as a “relatively new concept”,⁹¹⁹ it had in fact been in existence in at least in one hospital in the former Greater Glasgow area since 2000.

Availability of SPC Charts

SPC Charts had apparently been available in certain areas of NHS GGC in 2006.⁹²⁰ Originally the plan under the annual infection control programme was to have SPC Charts in place across the whole Health Board area, including Clyde, by September 2007.⁹²¹ As already mentioned, the SPC Charts were not introduced to the VOLH until April or May 2008,⁹²² but the introduction of the system to areas other than the Clyde Sector was successfully completed within the proposed timescale.⁹²³

There appear to have been two reasons for the delay in introducing the charts to the Clyde Sector. Firstly, the definition used for HAI in the Clyde Sector differed from that in Greater Glasgow, which used the national prevalence definition. This defined HAI as an infection which occurred 48 hours after admission to hospital, whereas in the Clyde Sector the timescale used was 72 hours. Consequently all the cases of CDI in Clyde had to be reviewed in order to match the national and Greater Glasgow definition.⁹²⁴ The second reason for the delay was that the RAH did not have an electronic surveillance system⁹²⁵ for MRSA. The RAH used a T-card system, and all the relevant data were on the T-cards, so that it was necessary to examine hundreds of T-cards.

Somewhat surprisingly, Ms Rankin thought that SPC Charts had been available in the VOLH in December 2007 and included data relevant to November 2007.⁹²⁶ She said she was not aware that they had only been introduced to the VOLH after Ms Higgins took up her post as interim Lead Nurse in Infection Control in April 2008.⁹²⁷

910 [GGC15220002](#)

911 [TRA01200135](#)

912 [TRA01200135](#)

913 [TRA01200136](#)

914 [TRA01210057](#)

915 [TRA01200136-137](#)

916 [GOV00010021](#)

917 [TRA01220032-33](#)

918 [GOV00010021](#)

919 [TRA01000092](#)

920 [TRA01130139-140](#)

921 [GGC19420006](#)

922 [TRA00990095](#)

923 [GGC32180011](#)

924 [TRA01020080-83](#); [GGC32180011](#)

925 [TRA01020081](#)

926 [TRA01000093](#)

927 [TRA01000092](#)

Mr Divers' position on SPC Charts

By coincidence the SPC Chart system was introduced in the VOLH at about the time the CDI problem was becoming evident. Mr Divers regretted that the system had not been implemented more quickly in the VOLH, as he considered that the SPC Chart system offered “a level of fail-safe and cover, even if there was a series of earlier failures”.⁹²⁸ He did agree that a policy decision in 2007 to introduce the system across the Health Board area seemed to represent a long delay since the work that had been done on SPC Charts in 2000.⁹²⁹

SPC Charts – a difference?

The Inquiry considers that Mr Divers was correct in believing that, had SPC Charts been in place in 2007, an increased level of awareness would have been generated in relation to rates of CDI at the VOLH and it is likely that the CDI problem would have been discovered sooner. That having been said, the dissolution of NHS Argyll and Clyde and the integration with GGHB only took place in April 2006 and it is clear that the preparations for the introduction of the SPC Chart system in the VOLH were going to take some time. In the circumstances set out in this Section it was not unreasonable that the introduction of the SPC Chart system to the Clyde Sector, and the VOLH in particular, suffered some delay in comparison to other areas of NHS GGC. It must also be stressed that SPC Charts are not a substitute for acute observation in real-time. The yellow T-cards should have alerted the Infection Control Nurses to the extent of the problem with CDI at the VOLH. The Access database was also a source that should have been used to identify rates and trends of CDI.

15.18 The VOLH Laboratory accreditation

The responsible body

Clinical Pathology Accreditation (UK) Limited (CPA) is the body responsible for the accreditation of laboratories in Scotland. Accreditation is granted if after assessment the Laboratory is in full compliance with internationally laid down standards for quality and competence.⁹³⁰ A Laboratory can also be granted conditional approval if there are non-compliances with the standards. Non-compliances can be graded as critical or non-critical. All issues of non-compliance must be addressed for accreditation to be obtained, although critical non-compliance has to be responded to more urgently.⁹³¹ New and more exacting standards were published in 2004.⁹³²

Non-compliances

The VOLH Laboratory was inspected by CPA on 29 January 2003 and granted conditional approval.⁹³³ That remained the position until further inspection by CPA on 18 and 19 September 2007,⁹³⁴ when the VOLH Laboratory was again granted conditional approval. Mr Kinloch said that after the 2003 inspection the technical non-compliances were corrected.⁹³⁵ He thought that accreditation had not been granted thereafter because of problems over consultant microbiologist cover, although such cover was provided from April 2006 when Dr Weinhardt became Head of Department for the VOLH Laboratory.⁹³⁶

The September 2007 inspection produced a list of 43 non-compliances.⁹³⁷ These included the failure for some years to conduct staff annual joint reviews. There was, however, a timetable available for such reviews to take place in late 2007 and early 2008.⁹³⁸ Mr Kinloch explained that joint reviews had not taken place because he thought the Laboratory would have been closed prior to

928 [TRA01250080-81](#)
929 [TRA01250117-118](#)

930 [INQ03060001](#)
931 [TRA00860008](#)
932 [TRA00860002](#); [TRA00860011](#); [INQ03060001](#)
933 [GGC30370001](#)
934 [TRA00870056-57](#); [TRA00870125](#)
935 [TRA00870056-62](#)
936 [TRA00850100](#); [TRA00870071-72](#)
937 [GGC30380001](#); [GGC30360001](#)
938 [GGC30380001](#)

the notice of the pending CPA visit,⁹³⁹ and having had notice of the CPA visit in advance he had prepared a timetable showing planned staff reviews.⁹⁴⁰ The inspection report also included criticisms of document control and of a lack of auditing of the time taken between receipt of a specimen and entry into the LIMS system. The inspection identified the fact that the date of the entry into the LIMS system could in fact be the day after receipt by the Laboratory,⁹⁴¹ as discussed in Chapter 14. There was no audit system in place at that time,⁹⁴² but an audit was carried out after the inspection.⁹⁴³ The Laboratory did not obtain accreditation until January 2009,⁹⁴⁴ by which time all the non-compliances identified at the 2007 inspection had been rectified.⁹⁴⁵ The Laboratory closed in January 2010.⁹⁴⁶

The Inspectors' overview report

Although the list of non-compliances might suggest management and organisational problems, the CPA inspectors' overview report described the Laboratory as well managed and well led.⁹⁴⁷ The numerous document control issues disclosed by the inspection were explained by the fact that the Laboratory was in a transitional phase of migrating to an electronic system. The inspectors concluded that despite the number of non-compliances the quality of the service provided was not being compromised.⁹⁴⁸

Despite the tenor of the overview report, the extent of the non-compliances shows that the general management of the microbiology service did need to be improved. This is not a criticism of Dr Weinhardt, who had been placed in a difficult position as a result of the manner in which the microbiology service was being run in 2007. The Laboratory management of faecal samples sent for *C. difficile* toxin testing is considered in Chapter 14.

939 [TRA00870063](#)
940 [TRA00870063-64](#)
941 [GGC30360031](#)
942 [TRA00870067](#)
943 [TRA00870067](#)
944 [GGC30510002](#)
945 [TRA00860013](#)
946 [GGC30370001](#)
947 [GGC30570004](#)
948 [GGC30570005](#)

15.19 Risk registers

Risk management

As discussed in Chapter 7, the importance of managing the risk of HAI in Scotland has been recognised since at least April 2001, the date of publication of the report of the Joint Scottish Executive Health Department Working Group chaired by Mr Richard Carey. Reference has also already been made to the consultation document produced in 2004, "The Risk Management of HAI: A Proposed Methodology for NHS Scotland consultation document".⁹⁴⁹ The Scottish Government proposals following that consultation process were not published until November 2008,⁹⁵⁰ but prior to that, in October 2005, NHS Quality Improvement Scotland (NHSQIS) published national standards in clinical governance and risk management⁹⁵¹ which acknowledged that "Organisations that manage risk effectively and efficiently are more likely to achieve safe and effective care".⁹⁵² It was a mandatory requirement that NHS Boards had systems in place to manage risk.⁹⁵³

An important strategy for the management of risk is the use of risk registers. The creation and maintenance of a risk register ensures that risks relevant to a particular area of health care have been identified. Where possible, risks are removed, but otherwise the risk register ensures that appropriate controls and precautions are in place to prevent those risks materialising.⁹⁵⁴

The key to the creation of a risk register is risk assessment. That involves assessing the nature of the risk and the likelihood of the risk occurring. The assessment reviews the controls already in place and evaluates what additional controls may be necessary. Within an organisation such as NHSGGC, risk registers should be maintained at different levels including hospital level.⁹⁵⁵

949 [INQ03820004](#)
950 [INQ03930001](#)
951 [INQ04970001](#)
952 [INQ04970009](#)
953 [INQ04970009](#)
954 [TRA01040047](#); [QIS02200005](#)
955 [EXP02820027-30](#); [TRA01040047-50](#)

NHSGGC Risk Register Policy

NHSGGC implemented a Risk Register Policy on 1 April 2006,⁹⁵⁶ acknowledging in that document that:

“The continuing development of a comprehensive risk register is a core part of risk management activity”.⁹⁵⁷

The objectives of the risk register included achieving proactive rather than reactive management in order to reduce the likelihood that risks will occur, and ensuring that all significant risk register management concerns were properly considered and communicated to the Board.⁹⁵⁸ The Chief Executive had overall responsibility for having an effective risk register management system in place by ensuring that appropriate structures were in place and adequate resources were available to provide effective risk management throughout the Health Board area.⁹⁵⁹ Under the policy Directors had to ensure that a comprehensive risk register was established and maintained for their areas so as:

“to provide an accurate account of the risks preventing the achievement of objectives for their area of responsibility”.⁹⁶⁰

The risk register system was intended to operate on three main levels; at the corporate level, the directorate level, and the clinical services and operational service level. The policy set out who was to be responsible for these levels of risk registers and who should monitor them. It also set out what was to be involved in the risk register process, how risk was to be assessed and the sources of information for the risk registers.⁹⁶¹ The Risk Register Policy was updated in April 2007 without any significant revision.⁹⁶²

Operational risk registers in the VOLH

There were generic operational risk registers available for the wards in the VOLH with some reference to infection prevention

and control issues. The risk register for the Cardiac Care Unit for 2006 to 2007 identified “isolation procedure” as a high risk and described the existing controls as “inadequate”.⁹⁶³ The risk register for ward 6 for the period from 20 September 2006 to a review date of 31 March 2007⁹⁶⁴ identified isolation procedures as a low risk and the controls in place as adequate.⁹⁶⁵ The ward F risk register dated 2 February 2008 identified isolation procedures as a medium risk and also described the controls in place as adequate.⁹⁶⁶

The operational risk registers in the VOLH generally tended to identify contamination of equipment and needle-stick injuries as risks.⁹⁶⁷ Risks relating to the condition of the hospital environment were also identified. The risk register for ward 3 for 2006 to 2007 identified the high risk of slipping on the “wet bathroom and ward floor due to water spillage from shower”,⁹⁶⁸ and recorded that the existing controls were inadequate. A similar entry on shower spillage into the ward is made in the risk register for the Cardiac Care Unit for the same period.⁹⁶⁹

At least two ward risk registers identified the fact that windows were dangerous to use.⁹⁷⁰ The problem with a wandering patient in ward F has already been identified in Chapter 12, and the risk register dated 2 February 2008 does identify as a medium risk a confused patient entering the “wrong room”,⁹⁷¹ describing the controls in place as adequate. Only the risk register for the Renal Unit for the period 21 March 2006 to March 2007 refers to HAIs as a high risk requiring action,⁹⁷² including adherence to infection control policies and procedures.⁹⁷³

956 [QIS02200001](#)
 957 [QIS02200003](#)
 958 [QIS02200003](#)
 959 [QIS02200003](#)
 960 [QIS02200004](#)
 961 [QIS02200004-10](#)
 962 [GGC04850001-02](#)

963 [GGC04880004](#)
 964 [GGC04910001](#)
 965 [GGC04910005](#)
 966 [GGC04950002](#)
 967 [GGC04880002](#); [GGC04880010](#); [GGC04880012](#);
[GGC04880013](#); [GGC04880016](#); [GGC04890002](#);
[GGC04910003](#)
 968 [GGC04880002](#)
 969 [GGC04880005](#)
 970 [GGC04880002](#); [GGC04880005](#)
 971 [GGC04950005](#)
 972 [GGC04880010](#)
 973 [GGC04880012](#)

The corporate risk register

The risk register maintained at corporate level was intended to identify those risks that had been assessed as being high or very high. The corporate risk register dated January 2008⁹⁷⁴ does not identify HAI as a risk. The updated risk register of December 2008⁹⁷⁵ does, and describes the further action required to reduce the risk.⁹⁷⁶

Risk register for healthcare associated infections (HAIs)

A risk register specifically for infection prevention and control for the Acute Services Division was first discussed at a meeting of the ACIC on 26 November 2006. There was some further discussion on the topic at the following meeting on 23 January 2007.⁹⁷⁷ Thereafter at the meeting of 15 May 2007 it was reported that the ICNs had met and had identified a number of risks for incorporation in the risk register.⁹⁷⁸

By the time of the ACIC meeting of 24 July 2007⁹⁷⁹ Ms Rankin had taken on responsibility for the work necessary for the proposed risk register.⁹⁸⁰ At the meeting itself Ms Rankin advised that she expected that a draft would be ready to be submitted to the next meeting,⁹⁸¹ and at the following meeting Ms Rankin intimated that she had submitted a draft to Dr Reid.⁹⁸² Ms Rankin explained in evidence that the risk register was in draft form as there were areas such as antimicrobial prescribing which were outside her remit and needed to be completed by others, although at that stage she and the Lead Nurses in Infection Control had identified relevant risks for infection prevention and control and she had included those risks in the draft.⁹⁸³ The draft risk register required to be reviewed and approved by the ACIC itself.⁹⁸⁴

Ms Rankin's draft risk register

The draft infection prevention and control risk register did not make specific mention of CDI, but it did mention MRSA.⁹⁸⁵ It identified non-compliance with infection control policies resulting from cross infection as a risk,⁹⁸⁶ and the actions to be taken included education of staff about infection prevention and control policies and monitoring of monthly HAI rates.⁹⁸⁷ In the section headed "outbreaks" a generic outbreak is defined as "Two or more linked cases (or isolates) within a healthcare premises".⁹⁸⁸ Closure of a ward to admissions and curtailment of transfers to other healthcare establishments are included in the controls required to deal with an increased incidence of cases in a ward.

Completion of the risk register

There was some further discussion of the risk register for infection prevention and control at meetings of the ACIC in 2008. At the meeting of 25 March 2008 it was noted that the infection prevention and control risk register was not completed and still required some work.⁹⁸⁹ That risk register is mentioned again at the next meeting on 3 June 2008, with a note that Ms Rankin was to report back to the next meeting.⁹⁹⁰ No update was provided at the meeting of 30 September 2008, but at the meeting of 3 December 2008 there was some discussion and some amendments to the draft were considered. It was at that meeting that the decision was taken that the infection prevention and control risk register could be made "live".⁹⁹¹

The delay in completion

It seems that from the time the risk register for infection prevention and control was first considered by the ACIC in November 2006 it took just over two years for a final version to be approved. Mr Calderwood agreed that "looking back, it does seem rather a long time".⁹⁹² What is more, it appears that CDI did not feature in earlier drafts, and that it

974 [GGC14610001](#)

975 [GGC14620001](#)

976 [GGC14620006](#)

977 [GGC02320001-02](#)

978 [GGC02310001](#)

979 [GGC02330001](#)

980 [TRA01000046](#)

981 [GGC02330001](#)

982 [GGC02300002](#)

983 [TRA01000047](#)

984 [TRA01000048](#)

985 [GGC31250002](#)

986 [GGC31250003](#)

987 [GGC31250003](#)

988 [GGC31250009](#)

989 [GGC01890003](#)

990 [GGC01870003](#)

991 [GGC01880004](#)

992 [TRA01240015](#)

was only at the meeting of 3 December 2008 that the decision was taken for CDI to be included.⁹⁹³

Although the methodology for the risk registers for HAI was not published by the Scottish Government until November 2008, the consultation process had begun in 2004. The need for the management of risk generally had been emphasised by NHS QIS in October 2005.⁹⁹⁴ The NHSGGC Board's response in putting in process the preparation of the risk registers in November 2006 was a perfectly adequate one, and an example of a Board applying the best practice at the time based on the guidance available. Thereafter, however, there was undue delay in putting in place a risk register dealing with infection prevention and control.

Whether having such a risk register more quickly would have made any difference to the CDI problem that developed at the VOLH is difficult to say. The opinion of Mrs Perry was that the risk had to be adequately described and the appropriate controls put in place. Further, she considered that a failure to do so could impair the work necessary to prevent a HAI like CDI.⁹⁹⁵ The identification of HAI and CDI in particular as a risk on the risk register would have raised awareness of such a risk, and that is undoubtedly what the Board set out to do in November 2006. It has to be recognised that when that process began it was one of the many issues facing the Board at a time of significant change, and that the emergence of the VOLH CDI problem did increase the level of attention paid to infection prevention and control after June 2008.⁹⁹⁶

15.20 Hygiene, environment and audits

Importance of cleanliness

The national *C. difficile* guidance published in 1994,⁹⁹⁷ and still relevant to Scotland in 2007 and 2008, emphasised the importance of personal and environmental cleanliness

to the prevention and control of CDI.⁹⁹⁸ The intention in this Section is to consider a number of issues relating to hygiene and environment at the VOLH in the period prior to June 2008. It examines how well the Cleanliness Champions Programme (CCP) was implemented, and also reviews how conducive certain environmental factors were to the spread of an infection such as CDI.

As explained in Chapter 3, CDI produces spores that enable it to survive in the environment for significant periods of time. Healthcare staff or patients can have frequent contact with contaminated areas such as toilets and surfaces, with the result that an infection can be spread easily by hand transfer. Hand hygiene in particular is of extreme importance in the prevention of the spread of an infection like CDI, but so too are environmental factors. It is obvious, for example, that damaged surfaces make cleaning more difficult, for the removal of micro-organisms is harder from damaged or irregular surfaces than smooth surfaces.⁹⁹⁹ The NHSScotland Code of Practice for the Local Management of Hygiene and Healthcare Associated Infection (2004)¹⁰⁰⁰ provides that patients, staff and visitors have "a right to, and expect, a safe physical healthcare environment".¹⁰⁰¹ The Code recognises that cleanliness is essential to this right and expectation.

The Cleanliness Champions Programme

The background to the creation of the Cleanliness Champions Programme has been discussed in Chapter 7. When launched in September 2003 as part of the first HAI Task Force Plan the CCP was viewed as an important aspect of infection prevention and control.

As explained in Chapter 7, in a letter dated 18 March 2005 addressed to Chief Executives, NHS Boards and Nursing Directors, the Chief Nursing Officer sought to reinforce the importance of the nursing contribution to the "culture" of "infection

993 [GGC01880004](#)

994 [INQ04970001](#)

995 [TRA01050168](#)

996 [TRA01220144-145](#)

997 [INQ01700001](#)

998 [INQ01700025](#)

999 [EXP02820075-76](#)

1000 [GOV00090001](#)

1001 [GOV00090019](#)

control is everyone's responsibility".¹⁰⁰² The Chief Nursing Officer required all grade G Sisters/SCNs to "undertake the Cleanliness Champions educational programme forthwith",¹⁰⁰³ and went on to say that local implementation should take account of workload and available access to the required IT resources.¹⁰⁰⁴

Initial G grade completion target – July 2007

At the request of the Inquiry NHSGGC provided details of the healthcare staff at the VOLH who had completed the programme since the time of its launch in September 2003 including the period 1 January 2007 to 1 June 2008.¹⁰⁰⁵

The Inquiry has examined the rates of CDI at the VOLH in a number of different wards. Wards 3, 5, 6, 14, 15 and F have come under particular scrutiny. Despite the terms of the Chief Nursing Officer's letter of 18 March 2005, and so far as the Inquiry can determine from the documents submitted by NHSGGC, prior to January 2007 possibly only five members of the nursing staff from these particular wards had completed the programme.

The need for improvement

It is apparent that in the course of 2007 some consideration was given to the need to increase the number of nurses who had completed the CCP. At the meeting of the Professional Nursing Forum of 27 February 2007, which covered the three Clyde hospitals, it was agreed that the priority would be nursing staff at grades G and F completing the CCP.¹⁰⁰⁶ This equates generally to Sisters (SCNs) and Deputy Sisters. At the next meeting of that group on 27 March 2007 it was noted that the majority of Ward Managers had commenced the CCP but were finding it very difficult to find time to complete the programme.¹⁰⁰⁷

At the meeting of the Professional Nursing Forum of 26 April 2007 a target was set

that all G grade nurses in Clyde were to have completed the CCP by 31 July 2007.¹⁰⁰⁸ Any G grade nurse who had not registered had to do so and would have up to 30 September 2007 to complete it. F grade nurses were also given a deadline of 30 September 2007 to complete the programme.¹⁰⁰⁹ Clearly there was a desire that nursing staff at those grades proceed expeditiously towards completion of the programme. So far as the Inquiry can ascertain, it seems that in the VOLH only one additional G grade nurse from the wards of particular interest to the Inquiry completed the programme by the 31 July 2007 deadline. Two grade F nurses and a grade D nurse also completed the programme prior to that date.

It appears to have been the case that in 2007 NHSGGC was underperforming generally in relation to healthcare staff completing the CCP. At the ACIC meeting of 15 May 2007 Ms Rankin reported that "the board was significantly off target".¹⁰¹⁰ She also reported that a one year post of Practice Development Nurse – Infection Control Champion was being advertised in order to lead the programme.

The VOLH perception

In the VOLH there was a perception that progress was being made. At the Sisters' meeting on 28 June 2007 Mrs Rawle, Lead Nurse for the Rehabilitation and Assessment Directorate, is noted as having advised the meeting that:

"it was now alright to roll out the training to E grades, provided all G and F grades had been done".¹⁰¹¹

The training records, however, do not bear out that degree of progress.¹⁰¹² Furthermore, in the period of 31 July 2007 to the end of December 2007 only three nurses in the wards of particular interest to the Inquiry completed the programme. Two were at grade G level and one at grade F.

1002 [GOV00440010](#)

1003 [GOV00440011](#)

1004 [GOV00080002](#)

1005 [INQ05250001](#); [GGC26620001-03](#)

1006 [GGC15090002](#)

1007 [GGC15100002](#)

1008 [GGC15110002](#)

1009 [GGC15110002](#)

1010 [GGC02310004](#)

1011 [GGC03980002](#)

1012 [GGC26620001](#)

An overview of the position at the VOLH

Table 15.10 has been compiled from the information supplied to the Inquiry by NHSGGC on the nursing staff levels in wards at the VOLH¹⁰¹³ and from the training records.¹⁰¹⁴ The ward staffing levels have been taken from the figures available for January 2008.¹⁰¹⁵ The Table provides a

breakdown of the nurses who completed the CCP in the wards of particular interest to the Inquiry. This is divided into the pre-1 January 2007 period, the early period (1 January 2007 to 30 November 2007) and the focus period (1 December 2007 to 1 June 2008).

Table 15.10 Nurses who completed CCP by ward prior to 1 June 2008

Ward	Number of nursing staff	Before 01/01/07	Early period 01/01/07 to 30/11/07	Focus period 01/12/07 to 01/06/08	Total
3	18	0	2	0	2 (11%)
5	23	1	2	0	3 (13%)
6	16	0	2	0	2 (13%)
14	12	1	1	0	2 (17%)
15	13	3	0	0	3 (23%)
F	14	0	0	0	0 (0%)
Total	96	5	7	0	12 (13%)

Table 15.11 shows during which period the G grades (Sisters/Ward Managers) and F grades (Deputy Sisters) for each ward completed the CCP.

Table 15.11 Period during which Sisters and Deputy Sisters completed CCPs

Ward	Before 01/01/07	Early period 01/01/07 to 30/11/07	Focus period 01/12/07 to 01/06/08	Post 01/06/08
3		Deputy		Sister
5	Deputy	Sister		
6		Deputy + Sister		
14	Deputy	Sister		
15	Deputy + Sister			
F				Sister
MAU				Sister + Deputy

1013 [GGC21710001-22](#)1014 [GGC26620001-03](#)1015 [GGC21710001-22](#)

Ward F

According to the training records supplied to the Inquiry, Sister Gargaro, SCN on ward F, did not complete her CCP until 8 October 2008. In her statement she indicated that she had completed the programme in early 2007.¹⁰¹⁶ This was incorrect, and in fact no nurses in ward F had completed the CCP prior to 1 June 2008.

Time taken to complete the programme

As already explained, the CCP involved no more than 20 hours of online learning and was capable of being completed in 16 weeks. The SCNs at the VOLH took between nine and 31 months to complete the programme,¹⁰¹⁷ the average being around 23 months. Table 15.12 sets out the time taken to complete the CCP by SCNs associated with the wards of particular interest to the Inquiry.

Table 15.12 Time taken to complete CCP by Ward Managers

Ward	Date completed	Months to complete
15	8 August 2006	9
6	26 June 2007	15
14	27 August 2007	15
5	5 November 2007	25
3	24 September 2008	31
F	8 October 2008	29

Inaction

It seems that little was done when the set completion targets were not met. There is no evidence that failures to meet the targets were discussed at a senior level, and it is clear that the programme did not receive the priority it should have received. So far as the VOLH was concerned, the completion rate of the programme in the period prior to June 2008 was extremely slow. A more determined attitude to infection prevention and control would have provided more impetus to the implementation of the programme.

Terminal cleans

In the Scottish Executive Policy document, “The NHSScotland National Cleaning Services Specification”, published in May 2004, a terminal clean is defined as the procedure required:

“to ensure that an area has been cleaned/ decontaminated after a patient with an alert organism or communicable disease has been nursed in the area, in order to render it safe for the next patient”.¹⁰¹⁸

The Board’s Infection Control Manual contained policies providing guidance on terminal cleans¹⁰¹⁹ and the twice daily cleaning,¹⁰²⁰ of isolation rooms.

Based upon information made available to the Inquiry by NHSGGC,¹⁰²¹ Table 15.13 provides details of full ward terminal cleans that took place at the VOLH in the period from December 2007 to June 2008. Because outbreaks of CDI were not identified prior to May 2008, there were no ward terminal cleans or ward closures in response to CDI

1016 [GGC26620002; WTS01920005](#)

1017 [GGC26620001-06](#)
 1018 [HFS00070190](#)
 1019 [GGC00780285](#)
 1020 [GGC00780288](#)
 1021 [GGC15790001](#)

until then, although some of the ward terminal cleans which were carried out in response to norovirus outbreaks are likely to have coincided with CDI outbreaks. There

were in addition 283 terminal cleans of single rooms and patient bays in the VOLH in that same period¹⁰²² in response to suspected or confirmed infection.

Table 15.13 VOLH terminal cleans December 2007 to June 2008

DATE	WARD	REASON FOR TERMINAL CLEAN
21/12/07	6	Norovirus outbreak
28/12/07	F	Norovirus outbreak
07/01/08	15	Norovirus outbreak
10/01/08	14	Norovirus outbreak
16/01/08	14	Norovirus outbreak
24/01/08	15	Norovirus outbreak
11/02/08	14	Norovirus outbreak
25/02/08	F	Norovirus outbreak
25/04/08	F	Norovirus outbreak
14/05/08	6	Preventative measure as part of management of three linked 027 C.diff cases at VOLH and RAH
15/05/08	3	Preventative measure as part of management of three linked 027 C.diff cases at VOLH and RAH
26/05/08	15	Preventative measure as part of management of three linked 027 C.diff cases at VOLH and RAH
28/05/08	14	Preventative measure as part of management of three linked 027 C.diff cases at VOLH and RAH
16/06/08	5	Preventative measure as part of response to retrospective outbreak
17/06/08	3	Preventative measure as part of response to retrospective outbreak
20/06/08	F	Preventative measure as part of response to retrospective outbreak
24/06/08	14	Preventative measure as part of response to retrospective outbreak
25/06/08	15	Preventative measure as part of response to retrospective outbreak

1022 [GGC15790001](#)

Some environmental issues

From April 2007 Mr John Menzies was the Site Estates Manager at the VOLH,¹⁰²³ responsible for the day-to-day maintenance of the buildings and engineering services.¹⁰²⁴ From 2004 to April 2007 he had been the Estates Project Manager for the VOLH.¹⁰²⁵ In essence his job involved ensuring that proper planned maintenance systems were in place.¹⁰²⁶

Mr Menzies explained that in the years leading up to June 2008 there was limited funding available for the effective maintenance of the VOLH.¹⁰²⁷ There was a belief that the future of the VOLH was in doubt, and the maintenance budget was used primarily in an attempt to keep the environment of the VOLH as safe as possible.¹⁰²⁸ He gave the example of how damage to floor coverings was addressed in the period up to June 2008. A high number of slips, trips and falls had been reported because of the state of the floor coverings,¹⁰²⁹ for which the obvious solution would have been to replace the flooring. Instead, because of budgetary constraints, minor repairs were carried out using tape to cover gaps in joints in the floor coverings.¹⁰³⁰ Mr Menzies said this made cleaning more difficult.¹⁰³¹ There were also serious problems with the internal fabric of the building because of lack of resources.¹⁰³² The evidence of patients and families on the condition of the VOLH is addressed in Chapter 11, and much of their evidence on the condition of the VOLH in the period 2007 to June 2008 was supported by Mr Menzies.

The walk rounds

On 23 and 27 May 2008 Ms Higgins led an inspection of areas in the VOLH. Having succeeded Mrs Murray on 9 April 2008,¹⁰³³ she asked for the environmental audit results for the VOLH,¹⁰³⁴ and was reassured by

what appeared to be satisfactory scores,¹⁰³⁵ but when she discovered in May 2008 that there was a problem with CDI in ward 6 she decided to organise the inspections.¹⁰³⁶ Ms Higgins thought Mrs O'Neill accompanied her on 23 May,¹⁰³⁷ and those involved on 27 May 2008 included Mr Menzies and Mrs O'Neill.¹⁰³⁸ Two reports of these inspections were prepared.¹⁰³⁹

The report of 23 May 2008 was solely on the inspection of the ward 6 area.¹⁰⁴⁰ A significant number of environmental issues were discovered in the course of that inspection, including the following:

- Many visitor chairs were non-intact
- Areas of the floor were non-intact and covered in adhesive tape
- There was a lack of wash-hand basins within the ward
- Linen was stored within patient bed areas
- Weighing scales in the toilet were very dusty
- There was no wash-hand basin in the treatment room
- Many bags of linen and waste and Book Club books were stored in the sluice area
- Pressure-relieving cushions were being shared by patients¹⁰⁴¹

Ms Higgins explained that matters such as the storage of linen in patient areas were not good practice, particularly if a patient has diarrhoea, and that linen should be stored separately to prevent possible contamination.¹⁰⁴² Pressure-relieving cushions should not be used by different patients without being cleaned in line with the decontamination policy.¹⁰⁴³ Ms Higgins was concerned that what she discovered in ward 6 did increase the risk of cross-contamination of an infection like CDI.¹⁰⁴⁴

1023 [TRA01120001](#)

1024 [TRA01120003](#)

1025 [TRA01120003](#)

1026 [TRA01120008](#)

1027 [TRA01120018](#)

1028 [TRA01120018-19](#)

1029 [TRA01120020-21](#)

1030 [TRA01120021](#)

1031 [TRA01120021](#)

1032 [TRA01120027](#)

1033 [TRA00990003](#)

1034 [TRA00990033](#)

1035 [TRA00990034](#)

1036 [TRA00990055-56](#)

1037 [TRA00990055](#)

1038 [GGC07560006](#)

1039 [INQ04080001](#); [GGC07560006](#)

1040 [INQ04080001](#)

1041 [TRA00990049-54](#)

1042 [TRA00990051](#)

1043 [TRA00990052](#)

1044 [TRA00990055-56](#)

Most of the remaining areas of the VOLH were inspected in the course of the inspection of 27 May 2008, including the medical assessment unit and wards 3, 5, 14, 15 and F.¹⁰⁴⁵ Of greatest concern to Ms Higgins was the lack of wash-hand basins in most of the areas visited, which she said created the greatest risk of cross infection. There were patient toilets that had no wash-hand basins,¹⁰⁴⁶ and patient bays in the medical assessment unit and ward 3 had no wash-hand basins, so that staff and patients were required to leave these areas and use wash-hand basins in the main ward areas when they wished to wash their hands.¹⁰⁴⁷

There were areas where surfaces and floors were non-intact.¹⁰⁴⁸ The floors in areas in ward 14 required immediate attention because of the poor state of repair.¹⁰⁴⁹

Dust was seen on items such as an emergency trolley,¹⁰⁵⁰ roof vents,¹⁰⁵¹ and a bath aid.¹⁰⁵² There was a soiled commode in ward 3,¹⁰⁵³ and many of the commodes were found not to be fit for use and required to be replaced urgently.¹⁰⁵⁴ A toilet seat in ward 5 was seen to be soiled. Clean linen was stored beside dirty linen.¹⁰⁵⁵ The cleaning issues identified by Ms Higgins were the responsibility of the nursing staff and not the domestic staff.¹⁰⁵⁶

Ms Higgins said that she was disappointed and surprised by what she discovered during the inspections. She thought she had assurances that the environment of the VOLH was satisfactory because of the environmental audit scores that had been reported.¹⁰⁵⁷

Following upon the inspection of 27 May 2008, a further assessment was carried out

on 11 June 2008 by a group including Mr Menzies. Areas that required immediate action included a review of bed spacing, which was “minimal”, throughout the hospital, the replacement of commodes and a review of the shortage of wash-hand basins.¹⁰⁵⁸

The inspection findings again fit well with some of the evidence provided by patients and families about the condition of the VOLH described in Chapter 11.

Purchase of wash-hand basins in 2006

The inspections of 23 and 27 May 2008 identified the lack of appropriate numbers of wash-hand basins as the most concerning issue. The shortage of wash-hand basins was well known and had been identified in environmental audits.¹⁰⁵⁹ Mr Menzies, however, said he was not aware of the shortage,¹⁰⁶⁰ although he was aware that there were no wash-hand basins in some of the toilets in the VOLH.¹⁰⁶¹

Ten new wash-hand basins and associated fittings were purchased for the VOLH in early 2006.¹⁰⁶² The Scottish Executive had provided a sum in the region of £25,000 to NHS Argyll and Clyde for the specific purpose of putting improvements in place in connection with HAI,¹⁰⁶³ and it appears that £4500 of that sum was provided to the estates department of the VOLH and used to purchase the wash-hand basins.¹⁰⁶⁴ The purpose was not to install wash-hand basins in new locations where there ought to have been wash-hand basins, for example in toilets, but to replace old wash-hand basins and fittings that were no longer fit for purpose.¹⁰⁶⁵

In anticipation of the work being carried out in early 2006¹⁰⁶⁶ Mrs Murray prepared a replacement plan with details of the locations as well as an explanation of why the replacements were required, which included the poor state of some wash-hand basins and

1045 [GGC07560006](#); [TRA00990037](#)
 1046 [GGC07560008](#); [GGC07560010](#)
 1047 [GGC07560008](#); [GGC07560009](#)
 1048 [TRA00990037-38](#); [GGC07560009](#); [GGC07560010-11](#)
 1049 [GGC07560011](#)
 1050 [GGC07560007](#)
 1051 [GGC07560007-08](#); [GGC07560012](#)
 1052 [GGC07560011](#)
 1053 [GGC07560009](#)
 1054 [GGC13240010](#)
 1055 [GGC07560012](#)
 1056 [TRA00990046-47](#)
 1057 [TRA00990040](#)

1058 [GGC13240010](#)
 1059 [TRA00950031-32](#); [TRA01010046](#)
 1060 [TRA01120030](#)
 1061 [TRA01120030](#)
 1062 [TRA01120031-32](#); [INQ05260003](#)
 1063 [TRA01020031](#)
 1064 [INQ05260003](#)
 1065 [TRA01020032](#)
 1066 [INQ00440001](#); [WTS01170024](#)

the widespread absence of elbow taps. There were cracked wash-hand basins in ward 15, some taps were not working properly, and in the sluice of the day hospital the wash-hand basin taps did not work at all.¹⁰⁶⁷ Mrs Murray's programme also set out the order of priority of items to be replaced.

The Estates Manager at the time of the purchase was Mr John Gilmore, who left that position on 27 March 2007.¹⁰⁶⁸ The wash-hand basins and fittings were not installed prior to his departure due to lack of funds in the building budget.¹⁰⁶⁹ All available plumbing funding was used during that period to target operational priorities.¹⁰⁷⁰

In her evidence Mrs Murray said that she was "pushing"¹⁰⁷¹ for the wash-hand basins to be installed, but that there was reluctance by anyone to accept responsibility for the cost of the installation.¹⁰⁷² Although the position is far from clear, it appears that some wash-hand basins had been installed in a piecemeal fashion as replacements¹⁰⁷³ by the time Mrs Murray left in March 2008.

Mr Menzies only became aware of the purchase of the wash-hand basins and fittings when he was interviewed by the Health and Safety Executive in March 2009.¹⁰⁷⁴ He carried out some inquiries at that time and ascertained that no money had been made available to allow the installation programme to go ahead.¹⁰⁷⁵ He also checked to see if there were wash-hand basins in storage and could not find any.¹⁰⁷⁶ Annual stocktaking had ceased a few years previously and so, according to Mr Menzies, he would not be aware of the existence of the wash-hand basins unless it was drawn to his attention.¹⁰⁷⁷

At the Infection Control Working Group Meeting held on 14 May 2008 it was noted

that wash-hand basins and taps had been purchased for the VOLH but no money had been made available to install them. The minutes record that the estimated cost of installation was £1000, and that Ms Martin was asked to identify a source of funding.¹⁰⁷⁸ It may therefore be that the absence of wash-hand basins in storage when Mr Menzies checked in 2009 can be explained by the fact that any wash-hand basins that had not been installed prior to May 2008 were installed after that meeting.

Reaction to the inspection findings

A number of witnesses in senior posts were asked about their reactions to the reports of the inspections of 23 and 27 May 2008. Ms McNamee said she was surprised to discover that there was a lack of wash-hand basins in the VOLH. She had practised as an ICN in all the hospitals in North Glasgow and had never come across a situation where there were no wash-hand basins in patient bathrooms or any bay area.

Ms Harkness had responsibility for RAD areas including wards 14, 15 and F from 1 September 2007, the date of integration. She was also surprised by some of the findings that were made. She had not been aware that the flooring or the showers were in the state that they were in. Nor was she aware that there was a lack of wash-hand basins.¹⁰⁷⁹ She would have expected such issues to be highlighted in the environmental audits. If not addressed at that point, she would have expected them to be "escalated" to her for priority funding.¹⁰⁸⁰ She understood that the environmental audits for these wards had scored at an acceptable level and she therefore did not intervene.¹⁰⁸¹ As discussed later in this Section, however, the lack of wash-hand basins and the non-compliance with appropriate standards were issues raised in audits.

Mr Calderwood was also surprised at the findings, particularly in relation to the wash-hand basins. He would have expected action to have been taken by NHS Argyll and

1067 [INQ00440001](#)
1068 [INQ05260001-02](#)
1069 [INQ05260004](#)
1070 [INQ05260004](#)
1071 [TRA01020034](#)
1072 [TRA01020034](#)
1073 [TRA01020034](#)
1074 [TRA01120032](#)
1075 [TRA01120035](#)
1076 [TRA01120032](#)
1077 [TRA01120033-34](#)

1078 [GGC01280004](#)
1079 [TRA01180133-34](#)
1080 [TRA01180134-35](#)
1081 [TRA01180134](#)

Clyde.¹⁰⁸² Mr Divers could not comprehend how there could have been a difficulty in installing wash-hand basins that had been purchased,¹⁰⁸³ although he accepted that the uncertainty over the future of the VOLH had led to reluctance to commit major sums of money to its refurbishment. His conclusion was that there had developed a “mind set” that “well, things don’t get done around here”.¹⁰⁸⁴

The response to the Stoke Mandeville report on environmental issues

Following upon the report on the CDI outbreaks at Stoke Mandeville Hospital by the Healthcare Commission for England and Wales,¹⁰⁸⁵ all NHSGGC site managers were asked to review matters highlighted in the report that were relevant to their location.¹⁰⁸⁶ Such a review of facilities services was carried out in the VOLH on 14 February 2007 by Ms Catriona Sweeney, the Site and Facilities Manager, Mrs Lena Keeley, the Assistant Domestic Services Manager, and Mrs O’Neill,¹⁰⁸⁷ and identified cluttered environments and a lack of storage facilities.¹⁰⁸⁸ When the position was reviewed in February 2008 the problem of lack of storage space still existed, and this was confirmed by the inspections in May 2008.

The review in February 2007 also identified poor maintenance of the fabric of the VOLH and equipment as issues of concern.¹⁰⁸⁹ It noted that the Estates Department did not have a budget for painting and fabric repairs, and that all repairs were either of an emergency nature or when there was a breakdown.¹⁰⁹⁰ There was no change in the position at the review in February 2008 or at the time of the May 2008 inspections. The response to Stoke Mandeville and other outbreaks is considered more generally in Chapter 18.

Audits

Infection control audits, including audits of the hospital environment, hand hygiene and isolation precautions, were to be carried out on an annual basis in the VOLH.¹⁰⁹¹ Mrs Perry explained that the purpose of such audits is to assess compliance against set standards. An overall percentage score is calculated under reference to criteria set out in the audit tool, and an audit score below 70% should be considered one which requires immediate remedial action.¹⁰⁹² The audit tool used in the VOLH was based on an audit system that was widely used by Infection Control Teams across the United Kingdom at the time.¹⁰⁹³ Once the audit had been completed the ICN would send an action plan to the SCN and expect to receive feedback once the actions in the plan had been completed.¹⁰⁹⁴

Hand hygiene audits

Although the audit tool included a section dealing with hand hygiene, other specific hand hygiene audits were carried in the VOLH by Mr Stefan Morton, the Hand Hygiene Coordinator.¹⁰⁹⁵ This was a more thorough assessment.¹⁰⁹⁶ Table 15.14 has been compiled from the audits carried out by Mr Morton and displays the compliance scores of all staff at the VOLH.¹⁰⁹⁷ The groups which would have the most contact with patients are nursing and medical staff. The nursing staff generally performed better than the medical staff, and indeed in some instances the comparison is quite marked.

1082 [TRA01240088](#)

1083 [TRA01250129](#)

1084 [TRA01250131](#)

1085 [INQ02890001](#)

1086 [GGC07790001](#)

1087 [GGC20710001](#)

1088 [GGC20710001-02](#)

1089 [GGC20710003](#)

1090 [GGC20710003](#)

1091 [WTS00870020](#)

1092 [TRA01040042](#); [EXP02800026](#)

1093 [TRA01040042](#)

1094 [TRA00960018](#)

1095 [TRA00960006](#)

1096 [TRA00960006](#)

1097 [GGC02940003](#); [GGC02930003](#); [GGC03010003](#); [GGC03020003](#); [GGC02950003](#); [GGC02960003](#); [GGC02970003](#); [GGC02980003](#); [GGC03030003](#); [GGC03050003](#); [GGC03040003](#); [GGC02890003](#); [GGC02880003](#); [GGC02900003](#); [GGC02920003](#); [GGC02910003](#)

Table 15.14 Hand Hygiene Audit - Compliance of staff

Ward	Date	Staff Group Compliance			
		Nurse (%)	Medical (%)	AHP* (%)	Others (%)
3	28/02/2007	78	25	67	50
	12/06/2008	92	33	0	100
4	08/04/2008	100	75	0	33
	17/06/2008	92	100	0	100
5	09/07/2007	82	0	83	67
	12/06/2008	100	67	0	25
6	10/07/2007	92	67	50	50
	12/06/2008	88	67	83	100
F	09/07/2007	89	100	100	20
	25/02/2008	64	0	100	100
	17/06/2008	100	75	100	25
14	28/02/2007	90	33	100	40
	16/06/2008	86	50	100	100
15	10/07/2007	88	100	63	0
	25/02/2008	100	80	80	50

*AHP - Allied Health Practitioners

Table 15.15 has been compiled from the overall compliance scores compiled separately by Mr Morton and by the ICNs. It is to be noted that the audit tools used to assess compliance are different, but in the majority of cases there are no significant differences between the two scores. Mrs

Perry explained that that spread of results is what she would expect from any audit programme.¹⁰⁹⁸ Scores in the region of 70% to about 85% would normally include an improvement plan, and 85% to 100% was often seen as acceptable practice.

Table 15.15 Overall compliance in hand hygiene audits

Ward	Year	Overall compliance (Stefan Morton) (%)	Overall compliance (Infection Control Audit) (%)
3	2007	60	71
	2008	85	95
4	2007	0	78
	2008	85	0
	2008	95	0
5	2007	80	78
	2008	80	0
6	2007	80	80
	2008	85	86
F	2007	75	87
	2008	70	0
	2008	80	0
14	2007	70	76
	2008	85	83
15	2007	65	84
	2008	75	0

0 = no information available

Environmental audits

Table 15.16 sets out the compliance scores for environmental audits assessed by ICNs. This includes items of equipment relevant to infection control, among them commodes. Of the ten audits carried out during that

particular period, in seven instances commodes did not comply with standards. The letter X denotes non-compliance, and the reasons for non-compliance have been set out in the third column of the table where available.

Table 15.16 Environmental audits

Ward	Year	Overall compliance (%)	Commodes non-compliant
3	01/10/2007	70	X
	09/05/2008	75	X (Stained underside and frame)
4	07/08/2007	83	X (Frames need thorough clean)
5	07/08/2007	81	X (Ingrained dirt and rusted)
6	29/04/2007	65	X (Dirty - faeces)
	08/05/2008	71	X (Faecal staining)
F	12/10/2007	88	
14	08/08/2007	78	X (Dirty)
	04/2008	83	
15	14/06/2007	90	

The environmental audits also highlighted the inadequate number of wash-hand basins and fittings. All of the wards listed in Table 15.16 were assessed as having either an inadequate number of wash-hand basins or wash-hand basins and fittings that did not conform to the required standards.

Auditing of infection control policies

The *C. difficile* Policy and the Loose Stools Policy contained audit tools¹⁰⁹⁹ detailing the criteria that had to be met. Table 15.17¹¹⁰⁰ sets out the audit tool in the *C. difficile* Policy. The policies provide that the audits were to be carried out by the Infection Control Team or by a member of the ward staff or healthcare worker.¹¹⁰¹

Table 15.17 Audit criteria

	Criteria	Score Yes, No, Not applicable
1.	Patients with CDAD are nursed in a single room with their own toilet facilities/commode.	
2.	Linen from isolated patients is disposed of as fouled/infected.	
3.	Patients with CDAD have been allocated their own equipment.	
4.	All commodes in use are visibly clean.	
5.	There are no extraneous items in isolation rooms.	
6.	There is no fabric furniture in use in clinical areas.	

When asked specifically about auditing the implementation of the *C. difficile* Policy Mrs O'Neill said she had not been aware of the existence of the audit tool and that no such audits were carried out.¹¹⁰² She only became aware of the tool after June 2008, and since then audits have been carried out in compliance with the policy. Because of the absence of appropriate auditing there was previously no formal assurance that policies like the *C. difficile* and Loose Stools Policies were being properly applied in practice.¹¹⁰³

Nursing feedback to audits

The system of audits involved the ward implementing an action plan and feeding back to the ICNs that appropriate remedial action had been taken. A lack of resources meant that action to resolve the wash-hand basin problem or even any problems

with commodes could not be taken.¹¹⁰⁴ The process of acting upon the audit findings was locally managed,¹¹⁰⁵ and there was no follow-up through the managerial structure when problems identified could not be remedied.¹¹⁰⁶

Summary

The picture that emerges from the evidence set out in this Section, and further developed in Chapter 8, is that of a hospital dogged by uncertainty before and after the dissolution of NHS Argyll and Clyde. NHSGGC inherited a hospital in which underinvestment in maintenance and infrastructure had existed for a number of years. The environmental deficiencies had existed in the years prior to

1102 [TRA00950025](#)

1103 [TRA01040038](#); [EXP02820026](#)

1099 [GGC00780257](#); [GGC00780262](#); [GGC27590006](#)

1100 [GGC01010006](#)

1101 [GGC00780257](#); [GGC00780262](#); [GGC27590006](#)

1104 [WTS01170020-21](#)

1105 [WTS01170020](#)

1106 [TRA01050004-05](#)

dissolution and persisted afterwards without resolution. Mrs Murray did say that defective commodes might eventually be replaced but it was a “drip, drip sort of situation”, and they were “always working with equipment that was in some measure of bad state of repair”.¹¹⁰⁷ There was an acceptance that because of the lack of investment the improvements were not going to happen.¹¹⁰⁸ Until a decision on the VOLH’s future could be made the problem of lack of investment could not be addressed. This is considered in Chapter 8.

The infection control audit process did identify key areas of persistent non-compliance, but there was no effective process of ensuring managerial awareness at a level where appropriate action could be taken. Environmental issues that had a clear impact on infection prevention and control were not addressed. Patients were put at risk. Staff morale was affected. Uncertainty led to the acceptance of the unacceptable from the perspective of patient safety.

15.21 Changes after June 2008

Significant changes

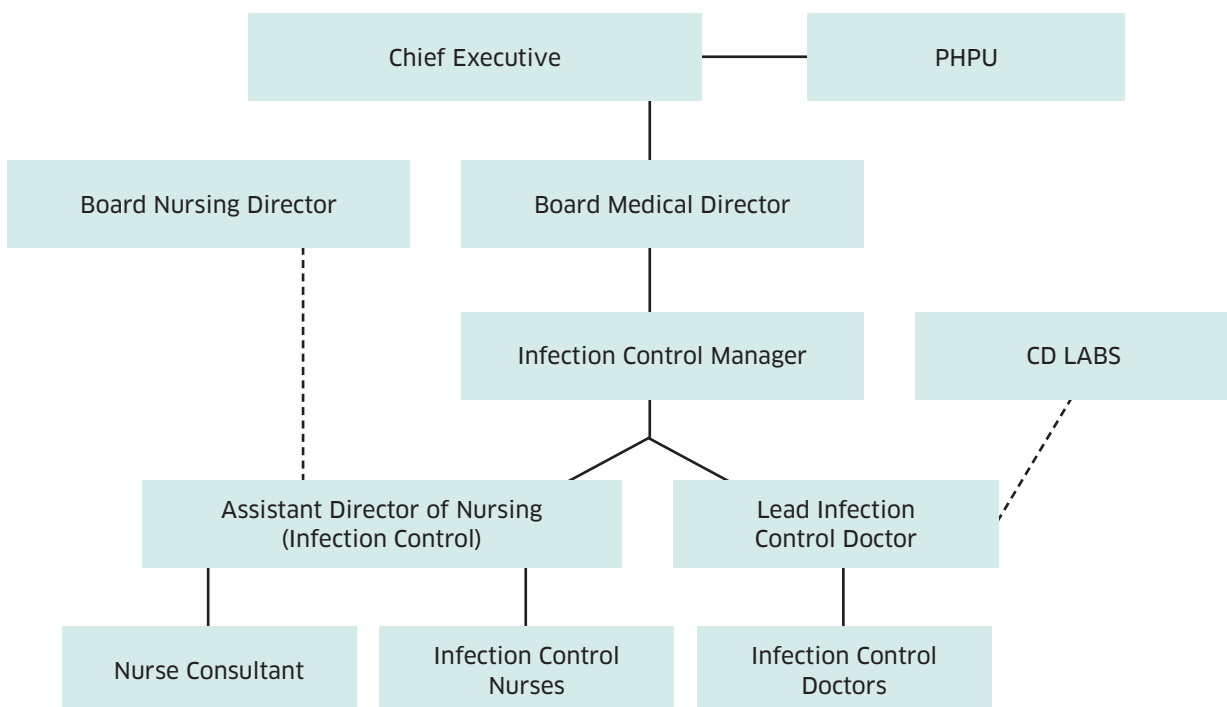
The NHSGGC Board responded promptly to the discovery of the failures that had occurred in the VOLH prior to June 2008 and made important changes to the infection control structures. The intention in this Section is to identify the more significant changes made after June 2008.

As discussed earlier, the Chief Executive is responsible for ensuring that there is successful infection prevention and control throughout the Health Board area. From January 2009 Dr Cowan had responsibility for the oversight of the infection prevention and control arrangements, although the Chief Executive maintained ultimate responsibility.¹¹⁰⁹

Infection prevention and control management structure

A revised management structure was approved in December 2008 and fully implemented by February 2009.¹¹¹⁰ Figure 15.8¹¹¹¹ sets out the revised structure.

Figure 15.8 Infection control management structure 2009 onwards



1107 [TRA01010029](#)

1108 [TRA01010027](#); [WTS01170021](#)

1109 [GGC04500001-02](#); [TRA01220137](#)

1110 [GGC32220166](#); [TRA01220138](#)

1111 [GGC32220170](#)

Board to ward accountability is provided by a single management structure with the Board Medical Director, as the accountable executive officer, reporting to the Chief Executive. The Board Medical Director is now required to bring infection control and HAI reports to every Board meeting. This is to be the first item on the agenda.¹¹¹² As already mentioned in Section 15.5 the Infection Control Manager’s role and job description were revised to include operational management responsibility for all ICNs and ICDs. The Infection Control Manager has to report directly to the Board Medical Director, and included among his duties is the provision of monthly reports to directors detailing agreed infection control data.¹¹¹³

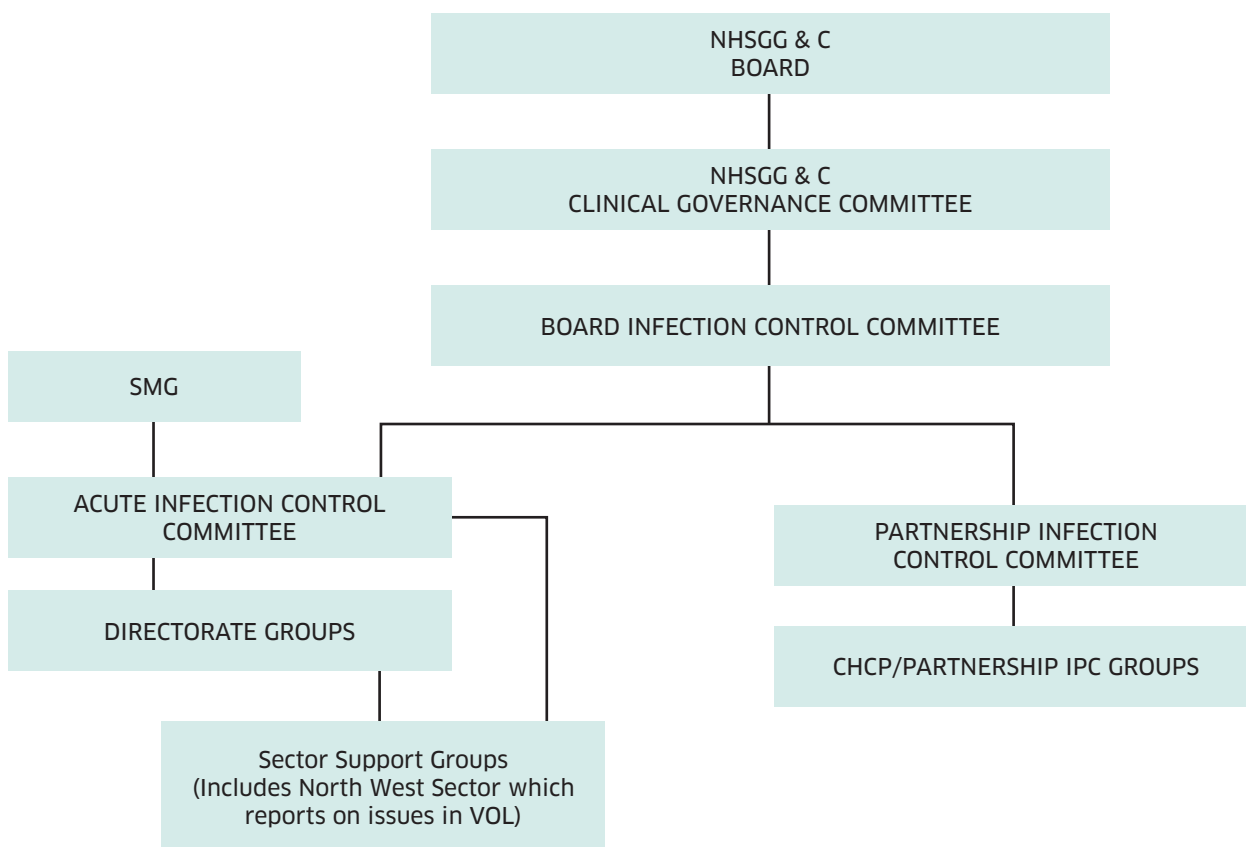
A new post of Assistant Director of Nursing (Infection Control) has been created to provide managerial and professional

leadership to all the ICNs in NHSGGC. Included in the post holder’s duties is the role of assisting the Infection Control Manager in discharging his responsibilities. A post of Lead Infection Control Doctor has also been created to provide professional and managerial leadership to the ICDs in NHSGGC. The job description provides that a specific proportion of time is to be devoted to that role, and included among the post holder’s duties is that of providing expert advice to the Infection Control Manager and Board Medical Director.¹¹¹⁴

The committee structure

There have also been changes to the infection prevention and control committee structure. Figure 15.9¹¹¹⁵ sets out the revised structure. The VOLH is now under the jurisdiction of the North West Sector.

Figure 15.9 Infection control committee structure 2009 onwards



1112 [GGC0450003](#)
 1113 [GGC0450004](#)

1114 [GGC0450005](#)
 1115 [GGC32220170](#)

Governance accountability and reporting arrangements

There have been significant changes made to the reporting arrangements and to the

monitoring and reporting system for HAI such as CDI. Table 15.18¹¹¹⁶ summarises some important aspects of these changes in the Acute Division.

Table 15.18 Infection control report - Timetable for CDI

Frequency	Report	Issued to
Twice weekly	Lead Nurses Report Verbal - Tuesday Written - Friday	Assistant Director of Nursing (Infection Control) On call Microbiologists and Clinical Coordinators
Weekly	Infection Control Weekly Update report - includes breaches in the UCL* in any ward. Any instances where two cases of HAI CDI have been identified in a two week period. Any deaths related to CDI. Any other significant clinical incidents.	Board Nurse and Medical Directors Chief Operating Officer and Chief Executive Officer Acute Directors Infection Control Manager Lead Infection Control Doctor
Monthly	Directorate Reports - includes results of Hand Hygiene Audits, Infection Control Audits, trajectories to meet HEAT targets, failure to isolate, Directorate SPC Charts, any wards that have breached their UCL.	Acute Directors
Monthly	Statistical Process Control Charts	Senior Charge Nurses and Lead Nurses
Monthly	Assistant Director of Nursing (Infection Control) - Infection Control Update	Heads of Nursing (Acute) Acute Nurse Director
Bi monthly	Healthcare Associated Infection Reporting template	NHS Board and Quality and Performance Committee ACIC Board Infection Control Committee Senior Management Team (Acute) Antimicrobial Utilisation Committee
Bi monthly	Sector Report from Lead Nurse, Infection Control	ACIC

*UCL - Upper Control Limit

Infection prevention and control education and training

The intention is that all Lead Nurses for Infection Control are to be educated to Master's level. As at 2012, of the five Lead Nurses, three had obtained a Master's degree. A fourth had completed the Master's degree course and the fifth Lead Nurse had 20 years' experience, a BSc degree in Health Studies and a diploma in Infection Control. All Senior ICNs are educated to diploma level and all other ICNs are required to complete a course of training within a year of commencement.¹¹¹⁷ Formal appraisals of each member of the Infection Control Team are carried out on an annual basis.¹¹¹⁸

The Cleanliness Champions Programme has already been discussed in Section 15.20. The uptake of the programme by members of staff at the VOLH increased significantly after June 2008.

The NHSGGC Infection Control Team now provides a programme of education and training in infection prevention and control.¹¹¹⁹ The Infection Control Team at the VOLH provides education on infection prevention and control to all grades of staff. Furthermore, a course of mandatory education update training was developed in 2010 to 2011 across the Acute Division. Infection prevention and control is a core part of this training.¹¹²⁰

In 2008 the Board launched an in-house education package known as Training Tracker. The programme contains 18 online education modules accessible to all staff in NHSGGC. The Infection Control Team supports the delivery of this education programme through continuous updating of the programme to reflect current policy and practice.¹¹²¹ Table 15.19¹¹²² sets out the training tracker modules taken at the VOLH in 2009 to 2011, and the number of staff members who undertook the modules.

1117 [GGC32220176](#)
1118 [GGC32220176](#)

1119 [GGC32220175](#)
1120 [GGC32220179](#)
1121 [GGC32220178](#)
1122 [GGC32220178](#)

Table 15.19 Training Tracker Modules taken at VOLH (2009-2011)

Year	2009	2010	2011
HAI Induction	20	124	170
Admission Assessment	6	76	59
Hand Hygiene	25	154	320
Influenza (including H1N1)	1	45	166
Standard Precautions	12	127	276
Transmission Based Precautions	5	89	152
Decontaminating Equipment and Environment	6	92	158
Outbreaks	5	75	132
Tuberculosis	7	66	126
MRSA	9	84	142
<i>C. difficile</i>	25	79	200
Measles	5	51	114
Rubella	5	44	110
Care Bundles	4	53	122
Policy Documents and SOPs	3	48	119
<i>Staphylococcus aureus</i> Bacteraemia	5	48	114
Understanding Statistical Process Control Charts	0	39	107
Blood borne Viruses	0	0	143
Totals	132	1294	2730

Infection prevention and control policies

The infection prevention and control policies have all been updated since 2009. The Outbreak Policy is updated on a yearly basis and all other policies are updated on a three year programme.¹¹²³

An audit programme to monitor compliance with the infection prevention and control policies is now in place in addition to the

Infection Control Safe Patient Environment Audit discussed below.¹¹²⁴

Infection Control Safe Patient Environment Audit

This audit is to be undertaken in every ward on at least an annual basis. The scoring system and the re-audit cycle are set out in Table 15.20.¹¹²⁵

1123 [GGC32220179](#)

1124 [GGC32220180](#)

1125 [GGC32220181](#)

Table 15.20 Scoring system and re-audit cycle

	Gold - 91% or above	Re audit in one year
	Green - 80-90%	Re audit in one year
	Amber - 66-79%	Re audit in six months
	Red - less than 66%	Re audit in three months

The audit is carried out by the Infection Control Team. After the audit has been completed the issues raised must be responded to by providing an action plan to the Infection Control Team within one month.¹¹²⁶ The Assistant Director of Nursing (Infection Control), the General Manager and

the Head of Nursing are to be informed of all red audit scores. Table 15.21¹¹²⁷ sets out the results obtained from the Infection Control Safe Patient Environment Audit in 2010 and 2011 before and after the refurbishment of the VOLH.

Table 15.21 Infection Control Safe Patient Environment Audits 2010-2011

Pre Refurbishment	Post Refurbishment	2010	2011
Ward 6	Ward 6 Surgical	84% Green	93% Gold
Ward 5 Surgical	Ward 5 Outpatient Oncology	97% Gold	Oncology OP 97% Gold Haematology OP 98% Gold
Ward 14 RAD	Ward 14 RAD	88% Green	85% Green
Ward 15 RAD	Ward 15 RAD	85% Green	90% Green
Ward F RAD	Closed	89% Green	Closed
Lomond Ward Medical	Lomond Ward Medical	96% Gold	97% Gold
Ward 4 (CCU) Medical	Outpatient B department	86% Green	96% Gold
Ward 3 Medical	Ward 3 AMRU	84% Green	93% Gold

Risk management in infection prevention and control

In Section 15.19 it was pointed out that infection prevention and control was not specifically incorporated into the risk register process until December 2008. NHSGGC now has a risk management strategy that takes into account the Scottish Government proposals contained in “The Risk Management of HAI: A Methodology for NHSScotland” published in 2008.¹¹²⁸ Each clinical directorate in the Acute Division includes infection prevention and control risks in its individual directorate risk register. Furthermore, the Infection Control Manager has the responsibility for the overarching infection control risk register, which is monitored by the ACIC and reviewed annually.¹¹²⁹

Public focus patient involvement

NHSGGC pursues a policy that treats patient experience and involvement as an important element in the infection prevention and control programme. The Patient Experience Steering Group is a forum that is intended to facilitate effective involvement by members of the public in the work of the Health Board. A member of the Infection Control Team attends meetings of this group to ensure, for example, that members of the public participate in the development of the Infection Control Programme.¹¹³⁰ Members of the public are also entitled to participate fully at meetings of the BICC.¹¹³¹

Corporate inspection team

The NHSGGC Board has established an inspection regime in which multidisciplinary teams of four to six members inspect hospitals following the methodology adopted by the Healthcare Environment Inspectorate (HEI).¹¹³² The Board envisages that by undergoing such inspections frontline staff and the clinical environment will be appropriately prepared for both planned and unplanned visits from the HEI team. Issues raised from these site inspections are reported to the directorate head. An

inspection team could include the Assistant Director of Nursing (Infection Control), a Lead ICN and also a patient representative.¹¹³³

Environmental changes after June 2008

Between June 2008 and June 2012 the sum of £4,687,667 was invested in improving the healthcare and general environment at the VOLH.¹¹³⁴ All wards have been upgraded with the provision of additional wash-hand basins, new preparation areas, additional storage facilities, upgraded ward pantries and domestic service rooms.¹¹³⁵ New floors have been laid and redecoration has taken place. There has been a reduction in bed numbers in the wards and all beds in the hospital are at least 2.7m apart.¹¹³⁶ There are more single rooms available.¹¹³⁷ There can be no doubt that, after years of uncertainty and underinvestment, the VOLH has been transformed by the investment made by the Board.

15.22 Conclusion

The personal and system failures in infection prevention and control identified in this Chapter had a profound impact upon the care provided to patients at the VOLH. The suffering and the deaths in which CDI was either the cause or a contributory factor have been considered in other Chapters.

Local personal failures by Mrs Murray were compounded by Dr Biggs’ attitude to her ICD duties for the VOLH. Those personal failures were serious, but the individuals concerned should not be used as scapegoats for the extent and duration of the CDI problem. There were other significant failures.

The failure to tackle Dr Biggs in an effective way permitted her attitude towards her responsibilities to subsist. Tolerance of her behaviour as accepted behaviour¹¹³⁸ was a significant failure in management that made a real contribution to the ongoing CDI problem at the VOLH.

1128 [IN003930001](#); [GGC32220181-182](#)

1129 [GGC32220182](#)

1130 [GGC32220183-184](#)

1131 [GGC32220183](#)

1132 [GGC32220186](#)

1133 [GGC32220186](#)

1134 [GGC32220385](#)

1135 [GGC30410003](#)

1136 [GGC32220388-389](#); [GGC30410003](#)

1137 [GGC30410003](#)

1138 [TRA01260022](#)

The infection control committee structure became unfit for purpose. The reporting system was inadequate and failed to ensure that there was ward to Board and Board to ward accountability. Had the committee structure functioned properly and adequate reporting systems been in place, the local failures would have been identified much sooner.

It is evident that the health professionals employed at the VOLH failed to identify the extent of the CDI problem over a period of about 18 months. A culture had developed at the VOLH where CDI was tolerated and infection prevention and control was not a priority. Dr Cowan said that what happened produced a “seismic change”¹¹³⁹ in the attitude to infection prevention and control, with it now at “the front of everybody’s mind”.¹¹⁴⁰ It is to be regretted that the creation of that cultural change had to be driven by failures that should not have happened.

NHSGGC did learn lessons from the failures that created the persistent CDI problem at the VOLH. The threat of closure of the VOLH has been removed by significant investment. The arrangements for the management of infection prevention and control have been replaced by what appears to be an effective system geared to ensuring that the Chief Executive and the Board are fully aware of numbers and rates of CDI.

15.23 Recommendations

Recommendation 42: Health Boards should ensure that all those working in a healthcare setting have mandatory infection prevention and control training that includes CDI on appointment and regularly thereafter. Staff records should be audited to ensure that such training has taken place.

Recommendation 43: Health Boards should ensure that Infection Control Nurses and Infection Control Doctors have regular training in infection prevention and control, of which a record should be kept.

Recommendation 44: Health Boards should ensure that performance appraisals of infection prevention and control staff take place at least annually. The appraisals of Infection Control Doctors who have other responsibilities should include specific reference to their Infection Control Doctor roles.

Recommendation 45: Health Boards should ensure that where a manager has responsibility for oversight of infection prevention and control, this is specified in the job description.

Recommendation 46: Health Boards should ensure that the Infection Control Manager has direct responsibility for the infection prevention and control service and its staff.

Recommendation 47: Health Boards should ensure that the Infection Control Manager reports direct to the Chief Executive, or at least to an executive board member.

Recommendation 48: Health Boards should ensure that the Infection Control Manager is responsible for reporting to the Board on the state of healthcare associated infection in the organisation.

Recommendation 49: Scottish Government should re-issue national guidance on the role of the Infection Control Manager, stipulating that the Infection Control Manager must be responsible for the management of the infection prevention and control service.

1139 [TRA01220147](#)

1140 [TRA01220147](#)

Recommendation 50: Health Boards should ensure that there is 24 hour cover for infection prevention and control seven days a week, and that contingency plans for leave and sickness absence are in place.

Recommendation 51: Health Boards should ensure that any Infection Control Team functions as a team, with clear lines of communication and regular meetings.

Recommendation 52: Health Boards should ensure that adherence to infection prevention and control policies, for example the *C. difficile* and Loose Stool Policies, is audited at least annually, and that serious non-adherence is reported to the Board.

Recommendation 53: Health Boards should ensure that surveillance systems are fit for purpose, are simple to use and monitor, and provide information on potential outbreaks in real time.

Recommendation 54: Health Boards should ensure that the users of surveillance systems are properly trained in their use and fully aware of how to use and respond to the data available.

Recommendation 55: Health Boards should ensure that numbers and rates of CDI are reported through each level of the organisation up to the level of the Chief Executive and the Board. Reporting should include positive reporting in addition to any exception reporting. The Chief Executive should sign off the figures to confirm that there is oversight of infection prevention and control at that level.

Recommendation 56: Health Boards should ensure that infection prevention and control groups meet at regular intervals and that there is appropriate reporting upwards through the management structure.

Recommendation 57: Health Boards should ensure that the minutes of all meetings and reports from each infection prevention and control committee are reported to the level above in the hierarchy and include the numbers and rates of CDI, audit reports, and training reports.

Recommendation 58: Health Boards should ensure that there is lay representation at Board infection prevention and control committee level in keeping with local policy on public involvement.

Recommendation 59: Health Boards should ensure that attendance by members of committees in the infection prevention and control structure is treated as a priority. Non-attendance should only be justified by illness or leave or if there is a risk of compromise to other clinical duties in which event deputies should attend where practicable.

Recommendation 60: Health Boards should ensure that programmes designed to improve staff knowledge of good infection prevention and control practice, such as the Cleanliness Champions Programme, are implemented without undue delay. Staff should be given protected time by managers to complete such programmes.

Recommendation 61: Health Boards should ensure that unannounced inspections of clinical areas are conducted by senior infection prevention and control staff accompanied by lay representation to examine infection prevention and control arrangements, including policy implementation and cleanliness.

Recommendation 62: Health Boards should ensure that senior managers accompanied by infection prevention and control staff visit clinical areas at least weekly to verify that proper attention is being paid to infection prevention and control.

Recommendation 63: Health Boards should ensure that there is effective isolation of any patient who is suspected of suffering from CDI, and that failure to isolate is reported to senior management.

Recommendation 64: Health Boards should ensure that cohorting is not used as a substitute for single room isolation and is only resorted to in exceptional circumstances and under strict conditions of dedicated nursing, with infected patients nursed in cohort bays with en-suite facilities.

Recommendation 65: Health Boards should ensure that appropriate steps are taken to isolate patients with potentially infectious diarrhoea.

Recommendation 66: Health Boards should ensure that the healthcare environment does not compromise effective infection prevention and control, and that poor maintenance practices, such as the acceptance of non-intact surfaces that could compromise effective infection prevention and control practice, are not tolerated.

Recommendation 67: Health Boards should ensure that, where a local Link Nurse system is in place as part of the infection prevention and control system, the Link Nurses have specific training for that role. The role should be written into job descriptions and job plans. They should have clear objectives set annually and have protected time for Link Nurse duties.

Chapter 16

Death certification

Introduction

When a person dies in Scotland a licensed medical practitioner normally issues a medical certificate with the cause of death (a death certificate). This Chapter examines how death certification was carried out in the VOLH. Dr Simon Mackenzie, an expert on death certification commissioned by the Inquiry, prepared a report for the Inquiry in which the process is set out.¹ Dr Mackenzie was a member of the working group of the HAI Task Force that produced the supplementary guidance on death certification in October 2011² referred to later in this Chapter, and death certification is an area in which he had a particular interest.³

16.1 Form of death certificate

Background

The death certificate is in a form prescribed by the Registration of Births, Still-births, Deaths and Marriages (Prescription of Forms) (Scotland) Regulations 1997, made under the Registration of Births, Deaths and Marriages (Scotland) Act 1965, and a sample can be found in training material provided to the Inquiry.⁴ It complies with the recommendations of the World Health Organization and is designed to allow comparison of Scottish data with data from other jurisdictions for epidemiological purposes.

Important details

Death certificates require the recording of the time and place of death as well as details of the cause of death. The section of the death certificate which is devoted to the cause of death is divided into two parts. Part I deals with the direct cause of death and any conditions giving rise to that. Part II deals with other conditions which have contributed to death but are not part of the main sequence of events leading to death.⁵

In Part I the direct or immediate cause of death is stated first. Thereafter information is provided about the disease or condition

which started the process. The last reference in Part I should be to the main disease that led to death.⁶ This is known as the underlying cause of death and is important for epidemiological purposes.

In Part II the doctor should state any significant condition or disease or accident which contributed to the death but which was not part of the sequence leading directly to death.

Professional judgement

Death certification, Dr Mackenzie emphasises, is a matter of professional judgement. A doctor issuing a certificate needs to make a judgement as to which of the illnesses suffered by a patient should be in Part II. Part II need not list every medical condition that the person had, since the judgement of the doctor may be that some of them were of no relevance to the death.⁷

Where a death occurs in hospital, the death certificate is normally completed by a doctor employed at the hospital. It is then handed over, usually to a relative or to the undertaker, and presented to the Registrar of Births, Deaths and Marriages, who records other personal information as well as the cause of death. The death certificate is retained by the Registrar, who will provide the person registering the death with an extract from the register showing the information recorded.

16.2 The 1999 guidance on death certification and VOLH practice

The purpose of the 1999 Guidance

Guidance on the completion of death certificates was issued by the Registrar General for Scotland in January 1999.⁸ Dr Mackenzie explained that the underlying purpose of this was to help doctors certify a death in a reliable, accurate and consistent manner to produce the most accurate medical certificate of the cause of death that can realistically be achieved.⁹

1 [EXP02730001](#)

2 [EXP02730008](#)

3 [TRA01070004](#)

4 [INQ00790010-11](#)

5 [INQ00790005](#)

6 [INQ00790003](#)

7 [TRA01070018](#)

8 [INQ00790001](#)

9 [TRA01070007](#)

According to the guidance:

“It is best if a consultant, general practitioner or other experienced clinician certifies the death. For a death in hospital, a doctor with provisional or limited registration should certify the death only if he or she is closely supervised and the experienced clinician is content that the causes of death are accurately recorded”.¹⁰

Scottish practice

According to Dr Mackenzie, however, consultants in Scotland were rarely involved in death certification in 2007 and 2008.¹¹ This observation is confirmed for the VOLH by an examination of extracts from the Register relating to cases investigated by the Inquiry. Thirty-three extracts¹² were reviewed in cases where death was certified at the VOLH, and that examination disclosed that none of the 33 death certificates was signed by a permanent Consultant. Eleven were signed by experienced clinicians, two by a Senior House Officer, and the remaining 20 were signed by junior doctors.

It is not to be inferred from this that the Consultants were never consulted before the certificate was completed. In three cases, entries in patient records suggest that junior doctors did contact the Consultants.¹³ Additionally, in the case of deaths at night, there is a pattern of junior on-call doctors and integrated care GPs leaving it to day-time medical staff to sign the certificate.¹⁴ This practice allows a more senior doctor to review what should be included in the certificate, and in some instances the certificate has been signed by a more senior doctor. In the majority of cases, however, the certificate was ultimately signed by another

junior doctor without any recorded consultation with more senior staff.

The Procurator Fiscal

Before issuing a death certificate, the doctor concerned is obliged to consider whether or not the death should be reported to the Procurator Fiscal. The Procurator Fiscal is a lawyer in public service whose best known role is that of local public prosecutor, but the Procurator Fiscal has a separate duty, similar to that of the coroner in England and Wales, to investigate all sudden, suspicious, accidental, unexpected and unexplained deaths, and any deaths occurring in circumstances causing serious public concern.

Guidance is issued by the Crown Office and Procurator Fiscal Service (COPFS) in a publication entitled “Death and the Procurator Fiscal”. This has been updated on a number of occasions and the edition applicable during 2007-2008 was issued in November 1998.¹⁵

That publication sets out certain categories of death to be reported to the Procurator Fiscal and includes:

“any death as a result of medical mishap, and any death where a complaint is received which suggests that medical treatment or the absence of treatment may have contributed to the death”.¹⁶

Section 3 provides further explanation of this category. No explicit reference to healthcare associated infection (HAI) is made, and neither does *C. difficile* infection (CDI) fall readily within the scope of Section 3.

The guidance also lists among the deaths to be reported “any death due to notifiable infectious disease”.¹⁷ These diseases are specified in Appendix 1 of the Guidance but CDI is not among them.

10 [INQ00790002](#)

11 [TRA01070009-10](#)

12 INQ00730001; INQ00960001; SPF00020001; SPF00030001; SPF00040001; SPF00050001; SPF00060001; SPF00070001; SPF00080001; SPF00090001; SPF00110001; SPF00120001; SPF00140001; SPF00150001; SPF00160001; SPF00170001; SPF00180001; SPF00190001; SPF00200001; SPF00210001; SPF00220001; SPF00230001; SPF00250001; SPF00260001; SPF00270001; SPF00290001; SPF00300001; SPF00330001; SPF00340001; SPF00350001; SPF00360001; SPF00370001; SPF00380001

13 GGC00580196; GGC00430035; GGC00450019

14 GGC00070025; GGC00560064; GGC00080088

15 [INQ01370001](#)

16 [INQ01370003](#)

17 [INQ01370003](#)

16.3 Accuracy in death certification in the VOLH

Role of death certification

In his evidence Dr Mackenzie stressed the importance of accuracy in death certification:

“One of the uses of death certification is to understand what the health needs of the population are. Therefore, it is extremely helpful to know what the patterns of illness leading to death are”.¹⁸

Professor George Griffin, an infectious diseases expert commissioned by the Inquiry, had this to say on the role of death certification:

“Death certification is an important role of the doctor. Accuracy is crucial in order to allow collation of data at population level to enable definition of trends and potential public health measures to prevent diseases. In the case of the Vale of Leven cohort described in this report, in seven of the 28 cases in the focus group judged to have *C. difficile* as a cause of or contributory factor to death, this organism was not stated. Such omission would potentially therefore reduce the ability to determine the importance of this infection as a cause or contributory factor to death. Thought needs to be given on advice to doctors completing death certificates. Such advice needs to be incorporated into medical education at undergraduate and postgraduate level”.¹⁹

Subsequently in his evidence he went on to say that it is also “very important for the family ... to know what their loved one has died of”.²⁰

Lack of accuracy

The lack of accuracy in practice was acknowledged at the time the VOLH outbreak came to light. Dr Bob Masterton, Medical Director, NHS Ayrshire and Arran, presented a paper on death certification issues to the emergency meeting of the HAI Task Force on

4 July 2008,²¹ called as a result of actions arising from the outbreak of CDI at the VOLH and the announcement of an Independent Review. In the paper he referred to a number of earlier studies casting doubt on the accuracy of a significant proportion of death certificates, although it is not clear from the citations in his paper where these studies were undertaken. He identified a number of problems:²²

1. Lack of experience/knowledge
2. Lack of knowledge of deceased
3. Quality assurance (or the lack of it)
4. Error rates
5. Lack of specificity
6. Omission of sensitive information
7. Multiple pathology (many possible causes of death)
8. Medical terminology (a marked variability in terms used to describe the same or similar conditions)

Dr Masterton highlighted the difficulty in assessing whether the increase in reference to CDI should be ascribed to increased laboratory testing and heightened clinical appreciation of the condition, as much as to a genuine increase in numbers. He also drew attention to the difficulty in interpreting the significance of laboratory findings of *C. difficile* prior to death.²³

Dr Masterton’s concern over the need for accuracy of death certificates and the lack of accuracy in practice is echoed by Professor Griffin.²⁴ His analysis of patients who contracted CDI and subsequently died has already been considered in Chapter 4.

Professor Griffin’s conclusion

In summary, Professor Griffin concluded that during the focus period 28 patients should have had CDI mentioned on their death certificates and seven of those patients did not. He also concluded that six patients who died outwith the focus period should have had CDI referred to in their death certificates and three of those patients did not.

18 [TRA01070013-14](#)
19 [EXP02780006-07](#)
20 [TRA00730051](#)

21 [GOV00710091](#)
22 [GOV00710092-93](#)
23 [GOV00710093](#)
24 [EXP02780006-07; TRA00730051-52](#)

Other experts

Medical experts commissioned by the Inquiry broadly supported the views of Professor Griffin. In particular, Dr Mary Harrington, in her evidence to the Inquiry expressed a number of concerns over death certification in cases examined by her. These included entries without a medical history to support the diagnosis, lack of adequate medical assessment to allow conclusions to be drawn as to the cause of death,²⁵ and failure to consider the potential consequences of a recent fall.²⁶ According to the COPFS guidance in force, a recent fall should have led to the death being reported to the Procurator Fiscal as potentially arising due to an accident or associated with a lack of medical care.

Other medical experts expressed similar concerns in a number of the cases they examined. These were with regard to the omission of *C. difficile* from the death certificate and more generally over incorrect causes of death listed.²⁷

Reference has been made previously to the absence of death certificates signed by permanent consultants and to the lack of recorded consultation between junior and senior doctors over the content of death certificates. Nevertheless, of those cases in which CDI does not appear on the certificate, but ought to in the view of Professor Griffin, analysis does not identify any greater degree of accuracy in those certificates completed by senior staff or discussed with them.

Finally, it is apparent from both Dr Mackenzie's evidence and Dr Masterton's paper that concern over the accuracy of death certification at the time was not restricted to the NHSGGC area. In view of this the Inquiry has not attempted any comparative exercise with other areas, and has confined its examination to the death certificates in cases within its remit.

16.4 Updated guidance

The 2008 guidance

Significant developments have taken place in the guidance available to doctors on death certification since the VOLH CDI problem emerged. In October 2008, COPFS issued an updated version of "Death and the Procurator Fiscal". Deaths to be reported now include:

"any death due to a disease, infectious disease or syndrome which poses an acute, serious public health risk including....any hospital acquired infection".²⁸

Section 9 of this edition, entitled "Deaths associated with medical or dental care", also specifies explicitly that deaths from HAIs must be reported.²⁹

The 2009 guidance

Further guidance was issued in September 2009 by the Chief Medical Officer of the Scottish Government in a document entitled Guidance on completion of medical certificates of the cause of death.³⁰ This reminds practitioners that they are required to report to the Procurator Fiscal any death where a HAI is recorded as the underlying or contributory cause of death, and explains:

"Reporting of an HAI related death will not necessarily lead to action on the part of the Procurator Fiscal, but will allow local Area Procurator Fiscal offices to identify any clusters of HAI related deaths that may imply an acute serious public health risk in addition to the monitoring undertaken by Health Boards, supported by Health Protection Scotland (HPS), General Register Office for Scotland (GROS) and Information Services Division (ISD)".³¹

The Chief Medical Officer also provides further guidance on who should certify deaths:

"In hospital, there may be several doctors in a team caring for the patient. The consultant in charge of the patient's care is ultimately responsible for ensuring the

25 [TRA00590035-36](#)

26 [TRA00580130](#)

27 EXP00900014; EXP00910011; EXP00980023-25; EXP01120023; EXP01230012

28 [GGC11640003](#)

29 [GGC11640005](#)

30 [INQ00540001](#)

31 [INQ00540022](#)

death is properly certified, as subsequent enquiries about the patient, such as results of post-mortem or ante-mortem investigations, will be addressed to the consultant”.³²

The 2011 guidance

The 2008 guidance was further supplemented in October 2011 by a letter from the Chief Medical Officer entitled “Accurate recording of deaths from healthcare associated infection and action”,³³ which required Health Boards to:

- Ensure that systems are in place whereby deaths where an HAI is recorded on the death certificate are reported to the Infection Control Manager
- Ensure consistent and reliable systems to identify *C. difficile* and MRSA associated deaths
- Conduct rapid event investigation for all deaths where *C. difficile* or *Staphylococcus aureus* bacteraemia (SAB) contributed to the death
- Develop and implement processes to convey timeously the weekly and quarterly death data for *C. difficile* and MRSA from National Records of Scotland to the Infection Control Manager
- Assure themselves that all doctors employed by Health Boards are appropriately trained in completion of death certificates³⁴

Boards are also encouraged to establish liaison with the local Procurator Fiscal for more co-ordinated action.

Additional guidance issued in the Chief Medical Officer’s letter includes the following:

- “Death certificates for patients who have died in hospital should only be completed after discussion with a consultant. Ideally this will be the patient’s named consultant³⁵

- Wherever possible, medical staff should discuss the death certificate with the relatives of the deceased³⁶
- Boards should ensure they have reliable systems in place to identify, as a minimum, *C. difficile* and MRSA associated deaths”³⁷

16.5 Collation, analysis of data and future changes

The Procurator Fiscal’s role

Despite the terms of the Chief Medical Officer’s guidance of September 2009, the Crown Office and Procurator Fiscal Service (COPFS) does not in fact collate information on HAI related deaths. It considers that this is best done by other bodies.³⁸

National Records of Scotland

Certain information on the number of HAI related deaths is recorded by National Records of Scotland (NRS), previously known as the General Register Office for Scotland (GROS). Mr Frank Dixon, a Vital Events Statistician, at the then GROS, described to the Inquiry their system of coding of information on deaths:

“It is to produce internationally comparable statistics on causes of death, so that we can compare our deaths, from whatever cause, with those of England, Wales, Northern Ireland, other European countries, and other countries around the world. If we are all coding to the same standards, applying the same rules, using the same standard death certificate layouts, then our statistics should be comparable”.³⁹

Registrars also have a statutory duty to provide information on deaths to Chief Medical Officers and to Health Boards.

Since September 2008, GROS has published on its website information on deaths where *C. difficile* is mentioned on the death certificate. This is done in order to assist organisations with an interest in the issue, but although it collates and publishes this

32 [INQ00540006](#)

33 [INQ02980001-02](#)

34 [INQ02980001-02](#)

35 [INQ02980003](#)

36 [INQ02980003](#)

37 [INQ02980005](#)

38 [INQ05090001-02](#)

39 [TRA01070060](#)

raw data, GROS does not itself operate any form of surveillance system.⁴⁰ Indeed, as explained by Professor Jacqui Reilly, Head of Group for Healthcare Associated Infection, HPS, there is no national surveillance of mortality rates *C. difficile* or any other infections in Scotland,⁴¹ nor is there any mandatory local surveillance beyond the requirement upon Boards to identify deaths associated with CDI.⁴²

A national survey

Only one, limited, national survey appears to have been carried out. Following identification of the VOLH outbreak, Health Boards in Scotland were required by the Scottish Government to collect data retrospectively on the numbers of cases and deaths due to *C. difficile* Associated Disease (CDAD) by hospital and month for the period 1 December 2007 to 31 May 2008. HPS was in turn asked to collate these data and comment on whether there were other unidentified outbreaks and excess deaths associated with CDAD in acute hospitals in NHSScotland.

The resulting HPS report, entitled “Report on Review of *Clostridium difficile* Associated Disease Cases and Mortality in all Acute Hospitals in Scotland from December 2007 – May 2008”,⁴³ was published in July 2008. By then the mandatory national surveillance programme of the incidence of CDAD in those aged 65 and over, introduced in 2006 and discussed earlier in Chapter 6, had been running for less than two years, and the introduction to the report stated:

“It has always been the intention to link CDAD case data held by HPS to mortality data, and this was already highlighted as a step in the development of the surveillance system once the monitoring of CDAD cases was fully established”.⁴⁴

The report identified a number of hospitals in which death rates warranted further investigation, and in particular found that

fatality rates at the VOLH were “significantly higher than expected”,⁴⁵ but it did not carry out an analysis of the reasons for those rates. The executive summary of the report notes:

“There are no routine systems for monitoring deaths associated with HAI in Scotland other than registration of death certificates by GROS. This is the same across the UK, and when mortality is investigated, special retrospective studies are required. No routine surveillance system in the UK would have identified this excess of mortality”.⁴⁶

Among the report’s recommendations was the following recommendation:

“Routine national monitoring of CDAD mortality is unlikely to be productive in informing action to reduce the incidence of CDAD. However, if there is a decision to collect mortality data in relation to CDAD this should be carefully designed and planned, and consideration given to data definitions and data collection criteria. Further discussion should take place on the most appropriate national agency to undertake these reviews”.⁴⁷

Such monitoring may not, as is remarked previously, reduce the incidence of CDI, but as Professor Griffin has observed, patients with CDI are often very vulnerable, and small changes in clinical state caused by *C. difficile* colitis may have profound effects.⁴⁸ A closer analysis of the incidence of mortality might well contribute to a reduction in the number of deaths. Given:

- the importance apparently ascribed by the Chief Medical Officer in his guidance of September 2009 to identification of clusters of deaths
- the intention of HPS to link case data to mortality
- the variation in death rates observed by HPS in the 2007 – 2008 study, and
- the availability of data

40 [TRA01070071-72](#)

41 [TRA01100126](#)

42 [TRA01100126](#)

43 [HPS01570001](#)

44 [HPS01570005](#)

45 [HPS01570024](#)

46 [HPS01570003](#)

47 [HPS01570045](#)

48 [EXP02780003](#)

there is a real need for a system of national monitoring to be in place. A proposal was made by the Medical and Dental Defence Union of Scotland (MDDUS) in its closing submission to the Inquiry⁴⁹ that the Scottish Government should identify a national body to take responsibility for analysing and warning Health Boards of trends in deaths from HAIs. Scottish Ministers in their response suggested that this is unnecessary,⁵⁰ citing the changes already put in place in recording of information. But in the absence of any analysis at national level, the existence of regional variation in case fatality rates (such as those identified by HPS in 2008), will not be apparent, nor can any attempt be made to identify the reasons for these variations.

Future changes

The Certification of Death (Scotland) Act 2011⁵¹ is designed to introduce a system of independent scrutiny of death certification to improve the quality and accuracy of the information on death certificates and to improve public health information. It introduces a system of review of death certificates by Medical Reviewers through random scrutiny. This Act received the Royal Assent on 20 April 2011 but is not yet fully in force.

The policy objectives and aims of this legislation are set out in the Policy Memorandum⁵² published at the time the Bill was introduced to the Scottish Parliament. They are:

- To introduce a single system of independent, effective scrutiny applicable to deaths that do not require a Procurator Fiscal investigation
- To improve the quality and accuracy of the medical certificate of cause of death (MCCD) form
- To provide improved public health information and strengthened clinical governance in relation to deaths

The proposed new system covers only those cases which are not examined by the Procurator Fiscal. Medical Reviewers and Senior Medical Reviewers will be appointed and will review death certificates both by random selection and at the request of interested persons. If the Medical Reviewer does not approve the certificate, he or she may ask the medical practitioner who signed it to issue a new certificate. If the medical practitioner does not issue a new certificate, then the matter will be referred to the Senior Medical Reviewer, who may in turn refer the certificate to the Procurator Fiscal for investigation into the cause of death. Medical Reviewers will also provide training, guidance and support to those required to complete death certificates.

16.6 Conclusion

The lack of significant consultant involvement in death certification at the VOLH in the 2007 to 2008 period reflected the general practice in Scotland at that time. This was despite guidance that envisaged consultant involvement. Furthermore, as discussed in Chapter 14, the opportunity for Consultant involvement at the VOLH was limited by the shortage of consultant cover. This practice at the VOLH is therefore not to be seen as a criticism of the VOLH Consultants. Nonetheless, the practice should never have developed.

The guidance in place at the time had been issued in January 1999 and by 2007-2008 it was inadequate and outdated. Death certification was viewed as a low priority despite the important role it plays, as already discussed in this Chapter.

The examination of the death certificates carried out by Professor Griffin and the other medical experts commissioned by the Inquiry, and in particular the inaccuracies identified by them, revealed a lack of understanding of the way in which death certificates should be completed, particularly in relation to when *C. difficile* should be recorded as a primary cause and as an underlying cause of death. For that reason, the Inquiry endorses the provision in the Chief Medical Officer's 2011 guidance that Boards should assure

49 [INQ04880117](#)

50 [INQ05050017](#)

51 Certification of Death (Scotland) Act 2011 (asp 11).

52 [INQ05130004](#)

themselves that all doctors employed by them are appropriately trained in the completion of death certificates.⁵³ The comprehensive guidance issued by the Chief Medical Officer and its particular focus on HAI was a welcome development.

The Chief Medical Officer's expectation in 2009 was that reporting HAI related deaths to the Procurator Fiscal would allow a Procurator Fiscal to identify "clusters of HAI related deaths".⁵⁴ The function of COPFS is, however, to investigate, and it does not have a surveillance function of the kind envisaged by the Chief Medical Officer. Nevertheless the Inquiry would agree with the principle underlying the Chief Medical Officer's expectation that monitoring HAI mortality rates, and *C. difficile* deaths in particular, at national level might contribute to a reduction in the number of deaths.

16.7 Recommendations

Recommendation 68: Health Boards should ensure that where a death occurs in hospital the consultant in charge of the patient's care is involved in the completion of the death certificate wherever practicable, and that such involvement is clearly recorded in the patient records. Regular auditing of this process should take place.

Recommendation 69: Health Boards should ensure that if a patient dies with CDI either as a cause of death or as a condition contributing to the death, relatives are provided with a clear explanation of the role played by CDI in the patient's death.

Recommendation 70: Crown Office and the Procurator Fiscal Service (COPFS) should review its guidance on the reporting of deaths regularly and at least every two years.

Recommendation 71: Scottish Government should identify a national agency to undertake routine national monitoring of deaths related to CDI.

53 [INQ02980004](#)

54 [INQ00540022](#)

Chapter 17

Investigations from
May 2008

Introduction

This Chapter outlines and reviews the reports of two investigations by NHSGGC which took place as an early response to events at the Vale of Leven Hospital (VOLH). These are:

- Vale of Leven Internal Investigation report, 11 July 2008.¹
- The Report of the Outbreak Control Team (OCT), October 2008.²

17.1 The Independent Review

In addition to these two internal reports, on 18 June 2008 the Cabinet Secretary for Health and Wellbeing announced an Independent Review of the cases of *C. difficile* Infection (CDI) at the VOLH.³ Its remit was to review procedures in place at the VOLH over the period December 2007 to 1 June 2008, and it was led by Professor William Cairns Smith, OBE, Professor of Public Health at the University of Aberdeen.⁴

The report of the Independent Review was published in August 2008. It made a number of recommendations, including a recommendation that an independent audit be conducted of the implementation of its recommendations by the end of 2008.⁵ That audit was carried out by the Independent Review Team in December 2008.⁶ In a follow-up report published in January 2009⁷ the team concluded that “rapid and very significant progress”⁸ had been made in implementing its recommendations at the VOLH.

17.2 Vale of Leven Internal Investigation Report

Background

Mr Robert Calderwood, then the Chief Operating Officer of NHSGGC Acute Services, gave evidence that he became aware of the CDI cases and associated deaths on 9 June 2008.⁹ As a response to this knowledge he then commissioned an internal investigation.

1 [GGC00610001](#)
2 [GGC00600001](#)
3 [GOV00030004](#)
4 [GOV00030009](#)
5 [GOV00030022](#)
6 [GOV00020010](#)
7 [GOV00020001](#)
8 [GOV00020019](#)
9 [TRA01240093](#)

The Investigating Team

The Internal Investigation Team drew from senior staff in the Board and consisted of Ms Rosslyn Crocket, Board Nurse Director and Director of Women and Children’s Services; Mrs Jane Grant, Director of Surgery and Anaesthetics; and Mrs Anne MacPherson, Associate Director of Human Resources.

Professor Brian Duerden, an Infection Control expert commissioned by the Inquiry, noted that the team:

“did not include anyone with specific expertise, qualification or training in infection prevention and control or the public health aspects of outbreak investigation”.¹⁰

This was not intended as a criticism but rather as an observation that the team conducting the investigation would view it differently to someone with infection control expertise.

Mr Alex Smith, an NHS management expert commissioned by the Inquiry, thought that it might have been beneficial to include a non-executive Board member or a representative from internal audit as part of the team. His view was that this would have provided a degree of impartiality.¹¹

Scope of review

The team worked to the following remit:

“The purpose of this investigation is to review all correspondence from April 2006 with regards to the Vale of Leven *C Difficile* issue and, in particular, from December 2007 with regards to who knew about the *C Diff* cases, what action did they take and who did they report matters to”.¹²

In his evidence to the Inquiry, Mr Calderwood agreed that he was concerned to find out who knew what. In particular, he was keen to find out if management staff knew anything about the cases of CDI, and if so what action they took.¹³

10 [TRA01060021](#)
11 [EXP02800018](#)
12 [GGC00610002](#)
13 [TRA01240072](#); [WTS00880019](#)

Clearly, the team had a very limited remit,¹⁴ but as a consequence of the information the team gathered during its investigation it did not in fact limit its conclusions to the terms of that remit.¹⁵

How the team approached the review

The team began its work around 12 or 13 June 2008,¹⁶ the investigation was conducted within one month, and the report was issued on 11 July 2008. At the meeting of the Acute Operational Management Group on 10 July 2008¹⁷ it had been agreed to circulate the report to directors and to reconvene the meeting on 11 July to comment on any matters of fact. The report would then be submitted to the Independent Review Team chaired by Professor Cairns Smith. The Acute Operational Management Group agreed that the report would be submitted to Dr Syed Ahmed, Chair of the OCT, as an individual and for onward transmission to the Independent Review Team, but was not for wider circulation at that stage.

Mrs Grant explained in her evidence how the group tackled its work.¹⁸ None of the team was familiar with the VOLH, so they established a working base there. According to Mrs Grant, this allowed them to establish who the individuals involved were and how the hospital worked¹⁹ and in addition to familiarise themselves with relevant paperwork and correspondence.

The team interviewed around 40 staff representing the relevant directorates at the VOLH. They spoke to the senior management teams of Clyde Acute Directorate and the Rehabilitation and Assessment Directorate (RAD) including Mrs Deborah den Herder, Director, Clyde Acute Services, NHSGGC and Ms Anne Harkness, Director of Rehabilitation and Assessment, as well as infection control staff, ward medical and nursing staff, and facilities and estates staff. The team did not speak to Mrs Jean Murray, the former

Lead Nurse for Infection Control, as she was unavailable, but Dr Elizabeth Biggs, the Infection Control Doctor, was interviewed by the team.²⁰ The team also reviewed contemporary documentation.

The Clyde Directorate

The team examined the minutes of meetings of the Clyde Management Team for the period 29 August 2006 to 1 May 2008²¹ and noted that healthcare associated infection (HAI) was mentioned on one occasion over that period. A similar exercise was carried out in relation to the minutes of the Clyde Clinical Governance Committee. Here, the team discovered that there was no mention of any specific infection control issues with regard to the VOLH.²² The performance of these committees in relation to infection prevention and control has already been considered in Chapter 15. The team did not explore why there was not greater reference to infection prevention and control at these committee meetings.

Rehabilitation and Assessment Directorate

The minutes of the meetings of the RAD Management Team and the RAD Clinical Governance Forum were also examined.²³ The team noted that in the period from 19 September 2007 to 28 May 2008 seven meetings of the RAD Management Team took place and that none of the Clyde hospitals was discussed.²⁴ The team noted too that within a similar period the RAD Clinical Governance Forum had five meetings, and that although there was evidence of infection prevention and control being discussed at the meetings of 13 February 2008 and 16 April 2008 there was no mention of any specific incidents of CDI at the VOLH.²⁵

Minutes of infection control meetings

Minutes of the Board, Acute and Clyde Infection Control Meetings were also reviewed by the team over the relevant period. The team concluded from these that attendance at the Board Infection Control Committee by

14 [TRA01060023](#)
15 [TRA01240072](#)
16 [TRA01140122](#)
17 [GGC02050001-02](#)
18 [TRA01140123](#)
19 [TRA01140123](#)

20 [GOV00890099-101](#)
21 [GGC00610006](#)
22 [GGC00610007](#)
23 [GGC00610008](#)
24 [GGC00610008](#)
25 [GGC00610008](#)

representatives from Clyde directorate was “sporadic”,²⁶ noting that at the September and December 2007 meetings no representatives from Clyde were present.²⁷ Professor Duerden agreed that the Clyde attendance at this Committee was inadequate.²⁸

The team did note that an outbreak of CDI in a care home was discussed at a meeting of the Acute Infection Control Committee on 24 July 2007 but that there was no mention of the VOLH.

The Clyde Infection Control Group minutes

The team reported that two separate groups met within Clyde: the Support Group, which operated as Clyde’s Infection Control Committee, and a Working Group, which operated at a level below. It was noted that these groups met infrequently and that the last meeting of the Support Group was in July 2007.²⁹ The failure of these two groups is discussed in Chapter 15. Professor Duerden observed that this reflected a “dangerous breakdown” in the local oversight of infection prevention and control.³⁰ The report does not explore why these groups ceased to meet or whether this was significant in the management structure.

Other meetings

The team also examined the minutes of meetings held monthly by ward Sisters and noted that infection control issues were discussed.³¹ A review of the minutes of the monthly Facilities Management Team disclosed that there had been very limited debate on infection prevention and control issues in the VOLH.³²

Minutes of the Clean Bill of Health Committee were also examined. The purpose of that committee included looking at the overall cleanliness of hospital sites.³³ Seven sets of minutes were looked at covering the period

from June 2006 to February 2008, and no major problems were identified at the VOLH in those minutes.³⁴

Internal Investigation conclusions from examination of minutes

In her evidence Mrs Grant said that the team concluded from its examination of the minutes of the meetings referred to previously, and other minutes of meetings, that there was no clear evidence that “people had been aware of what was going on”.³⁵ By this she meant the nature and extent of the CDI problem at the VOLH.

Surveillance data

The team examined how data on CDI were collected and noted in the report that the data were collected manually, expressing the view that this method of surveillance was “unusual” and in contrast to other areas, which had “electronic models”.³⁶ The team also noted that since May 2008 Statistical Process Control Charts (SPCs) had been introduced.³⁷ The report commented that staff seemed to have limited understanding of the implications of the charts produced, and recommended a more comprehensive awareness programme to ensure that all staff were aware of the charts and how to interpret them.³⁸

There is no mention in the report of the infection prevention and control database which was in existence at the VOLH and which could have been used to monitor the number and trends of *C. difficile* cases. Mrs Grant did say in evidence that Mrs Helen O’Neill, Infection Control Nurse at the VOLH, mentioned the database in the course of her interview,³⁹ but that the conclusion they arrived at was that the database was not being used to generate any information.⁴⁰ As discussed in Chapter 15, that was correct, but the database should have been used to generate information for circulation within the infection prevention and control structure.

26 [GGC00610014](#)

27 [GGC00610014](#)

28 [EXP02810004](#)

29 [GGC00610015](#)

30 [EXP02810004](#)

31 [GGC04020001](#); [GGC04010003](#); [GGC03980002](#);
[GGC03970002](#); [GGC03950001](#); [GGC03920006](#);
[GGC14820002](#); [GGC14810002](#); [GGC14800001](#)

32 [GGC00610010](#)

33 [GGC00610010](#)

34 [GGC00610010](#)

35 [TRA01150011](#)

36 [GGC00610013](#)

37 [GGC00610013](#)

38 [GGC00610013](#)

39 [TRA01150018](#)

40 [TRA01150019](#)

Outbreak Policy

Compliance with the NHSGGC Outbreak Policy was examined. The team found that the laboratory complied with the policy in that any increase in the number of specimens was reported to the Infection Control Team. The policy said that if single rooms were not available patients should be “cohorted”,⁴¹ but the team was told by Lead Nurses that cohorting was a “rare occurrence” and that most patients were nursed in single rooms.⁴² The Loose Stools Policy also stated that patients should be isolated at the onset of diarrhoea. Analysis undertaken by the Inquiry, however, shows that the general practice adopted at the VOLH was not to isolate patients with loose stools until the diagnosis of *C. difficile* was confirmed, either by the laboratory or by the Infection Control Nurse. Once a positive diagnosis was made most patients were placed in a single room. The isolation of patients is fully explored in Chapter 15.

Environmental audits

The team also undertook a review of environmental audits of wards at the VOLH, and its report identified failures in the audit system. The scoring system that was in use could indicate overall compliance while hiding important underlying failures. The information was only received by the ward manager, and neither the Lead Nurse nor the estates team automatically received the results of the audit. Action plans in response to the audit were inconsistent, and there was no evidence that progress was monitored by the Infection Control Team.⁴³

Staff governance

The report concluded that there was no problem with nurse staffing levels. This was based on evidence from interviews with all Senior Charge Nurses/Ward Managers and Lead Nurses/Clinical Service Managers, who confirmed that they did not have staffing problems. They said that they had a low turnover of staff, that sickness absence was well controlled, and that they had not

needed to raise staffing issues with General Managers.⁴⁴

This view contrasts with evidence the Inquiry heard to the effect that nurses were not able to complete certain documentation because of the “firefighting” in the wards.⁴⁵ This is explored further in Chapter 12.

Mrs Grant agreed in her evidence that the ward Senior Charge Nurses did describe some of the issues they had with staffing.

“I think they did describe – you know, within a ward you do have sometimes two people off sick and long term sick does cause you some issues”.⁴⁶

The team did not think, however, that there were sustained staffing difficulties at the VOLH or that there was a problem with accessing bank staff if required.

The report notes that the medical management structure had not been well developed and that clinical directors had only recently been appointed in some areas. Full integration of the medical management model was seen as important in the transition process.

Under the heading of “Leadership” the report comments on general management based on some observations made during interviews. In her evidence, Mrs Grant explained that:

“in certain areas, the concept of general management was not as well developed as might be anticipated after 2 years of the current structure and, with the proposed full integration on 1 July 2008, it will be important to re-emphasise the initial concepts agreed in April 2006”.⁴⁷

The team felt that it was useful to be clear about reporting arrangements as one or two staff had said that they were not clear who their line manager was or about their roles and responsibilities.⁴⁸

41 [GGC00610014](#)

42 [GGC00610014](#)

43 [GGC00610016](#)

44 [GGC00610017](#)

45 [TRA01150022](#)

46 [TRA01150022](#)

47 [TRA01150023](#)

48 [TRA01150024-25](#)

Effectiveness of the report

It can be seen from the previous discussion that the Internal Investigation Team's narrow remit did not prevent the team from considering issues outwith that remit. The scope of the investigation broadened and comments were made on other issues as a result of the information gathered during the investigation. As Mr Calderwood explained, however, the work of the Internal Investigation Team was overtaken by the establishment of the Independent Review chaired by Professor Smith.⁴⁹ NHSGGC was invited to assist with the Independent Review rather than to continue with its own Internal Investigation, and at that point the Internal Investigation stopped.⁵⁰

Mr Smith acknowledged that the "commissioning of the report was an important and appropriate action",⁵¹ and that it identified learning opportunities at an early stage. Given greater time he would have expected conclusions and more recommendations, but it was critical to have early identification of key issues and of actions which should be taken.

Professor Duerden was more critical of the Internal Investigation in a number of ways. The report did not, for example, identify errors or failures which must have been present to allow an outbreak to occur and to go unnoticed for a number of months.⁵² The team did not establish the scale, extent and timeframe of any outbreak and without that starting point Professor Duerden found it difficult to see how the team could fulfil even its limited remit of establishing who knew about the cases of CDI.

The fact, unknown to Professor Duerden, that the work of the Internal Investigation Team was ended prematurely is sufficient mitigation to allow this part of the Board's response to the VOLH CDI problem to escape specific criticism by the Inquiry. The Inquiry accepts that Mr Calderwood was anxious to discover who knew what about the CDI problem at the VOLH.

The Internal Investigation report did identify a number of learning opportunities in corporate, clinical and staff governance. Under the heading "Clinical Governance", for example, the report proposed that:

"Each Directorate's Clinical Governance Committee should have a standing item on Control of Infection".⁵³

That was entirely appropriate, and the need for data on infection prevention and control to be made available at meetings is discussed in other Chapters of this Report.

17.3 Outbreak Control Team Investigation

Background

The events leading to the setting up of the OCT investigation have been discussed in Chapter 4. The OCT was chaired by Dr Ahmed, and the team included other key Health Board staff such as Mr Thomas Walsh, Infection Control Manager and Dr Andrew Seaton, Lead Infectious Diseases Physician, as well as an epidemiologist and consultant microbiologist from HPS. Dr Linda Bagraade, who by this time was the Infection Control Doctor for the VOLH, was also a member. Professor Duerden felt it was an appropriately constituted group.⁵⁴

The OCT first met on 10 June 2008 and held six meetings. The report of the team's findings was published in October 2008.

Remit

The remit of the OCT was to:

- Co-ordinate the investigations of all aspects of this outbreak
- Ensure that all control measures were in place including treatment of cases
- Co-ordinate communication between the Board and external agencies including the media
- Make recommendations to the Board on its findings⁵⁵

49 [TRA01240116](#)

50 [TRA01240116](#)

51 [EXP02800018](#)

52 [TRA01060025](#)

53 [GGC00610003](#)

54 [TRA01060033-34](#)

55 [GGC00600012](#)

Outbreak period

The report identified the outbreak period as 1 December 2007 to 31 May 2008. That period had been focussed upon by the local Infection Control Team because of press enquiries about the number of deaths in the six months up to June 2008. Prior to the creation of the OCT, 55 cases of CDI had been identified by the Infection Control Team, and that was the number of cases adopted by the OCT in its report.⁵⁶ Isolates were available for ribotyping from 16 patients, and out of these 14 were identified as ribotype O27. This supported the view that the cases represented an outbreak, with mainly the same strain being transmitted across the patient population.

At the time of the OCT investigation, 28 patients were thought to have died, and CDI was thought to have caused or contributed to the death of 18 of those patients.⁵⁷ As explained in Chapter 4, the Inquiry has revised the number of patients who contracted CDI and who died with CDI causing or contributing to their death. Within the Inquiry's remit there were 43 patients who died having suffered from CDI, and for 34 of these patients CDI was a causative factor in their deaths, either as a cause of death or as a contributory cause of death.

Discussion of the number of cases

There was some discussion during Mr Calderwood's evidence to the Inquiry about email communication between him and Dr Ahmed on 5 November 2008⁵⁸ in which Mr Calderwood wrote:

"Syed, in essence, what I am trying to say is that any allegation of management inaction cannot be held to have affected the care of the 55 and 18. Indeed, my own view is I think we could suggest that at best, had management action been initiated in late January, the number of *C.diff* cases that may have been reduced is a number less than 30 and the deaths which might have been averted is not 18

but is a lesser number 18 less the four who died in December less the two who died in the community and less the one who died in June, i.e. 11 patients".⁵⁹

The email appeared to be putting forward arguments that might be seen to minimise the extent of the CDI problem, but Mr Calderwood disagreed with such an interpretation. He explained that he was trying to create a timeline of those patients who had contracted CDI which was considered to be community acquired as opposed to hospital acquired, and to establish the point at which the system should have caught up and identified an outbreak.⁶⁰

Mr Calderwood took late January as a starting point. Dr Ahmed did not agree with this approach. He could not say with any confidence that the outbreak occurred in late January, and was of the view that it might have started before that.⁶¹ As discussed in Chapter 15, Dr Ahmed was right to be cautious, because there was a significant CDI problem prior to January 2008.

Mr Thomas Divers, Chief Executive, did not think that Mr Calderwood's comments were an attempt to minimise the impact of the *C. difficile* infection problem:

"I think Robert was genuinely exercised about trying to understand, as best all of us could, what had happened here. The reality is there was a huge volume of cases that actually were involved in this, and my final take on this was: the Fiscal is starting work, he needs the OCT report. And, in essence, I shut the debate down and told Syed to send the OCT report off, and I told Robert I was doing that".⁶²

Identification of outbreaks

The OCT concluded that the number of cases of CDI "at the VOLH for the six-month period from 1 December 2007 to 31 May 2008 was more than expected for the hospital, based on the historical data".⁶³ The OCT looked at

56 [GGC00600005](#)

57 [GGC00600005](#)

58 [GGC16670002](#)

59 [GGC16670002](#)

60 [TRA01240089-92](#)

61 [TRA01240092-93](#)

62 [TRA01250137](#)

63 [GGC00600064](#)

overall numbers and did not identify clusters within that six month period,⁶⁴ but there was no real dispute that there had been outbreaks.

The OCT also concluded that the fatality rate among those patients affected by CDI appeared to be higher than reported from elsewhere, and noted from the patient records of deceased patients that they were vulnerable due to their age and other existing clinical conditions.⁶⁵

Surveillance systems

The OCT concluded that the surveillance system that was in place at the time of the outbreaks was inadequate to alert the local Infection Control Team to “trends over time”.⁶⁶

The surveillance system in use at the VOLH, which has already been described in Chapter 15, used a coloured card (T-Card) system which identified individual infections by colour. As discussed in Chapter 15, the T-card system could have provided a snapshot of what was happening, as there would have been a cluster of yellow cards showing the number of patients on each ward with CDI. The T-cards, however, could not show trends or patterns over time, and certainly in that sense the surveillance system was inadequate.⁶⁷

No mention is made in the OCT report of the infection prevention and control Access database, which could have provided regular surveillance reports.⁶⁸ Professor Duerden explained that he would have expected some members of the OCT to be aware of the database, including Mr Walsh, Dr Bagnard, and Ms Annette Rankin, the Head Infection Control Nurse.⁶⁹

The local surveillance arrangements for *C. difficile* at the VOLH were described by the OCT as being “in transit” during this period.⁷⁰

64 [TRA01060033](#)

65 [GGC00600007](#)

66 [GGC00600031](#)

67 [TRA01060036-37](#)

68 [EXP02810005](#)

69 [TRA01060039](#)

70 [GGC00600064](#)

This was a reference to the introduction of the SPC Chart system. The relevance of the SPC Charts to acute *C. difficile* surveillance is discussed in Chapter 15.

Cleaning and hand hygiene

The OCT concluded that cleaning of the VOLH environment was regularly audited as part of the national monitoring mechanism, using the National Cleaning Services Specification. Monitoring data for the six months during the outbreak period did not identify any significant issues over cleanliness of the patient care environment.⁷¹ Nor did data for the VOLH provide any evidence that the hospital was underperforming on hand hygiene when compared to other acute hospitals in NHS GGC.⁷²

Antimicrobial prescribing

A policy of antimicrobial prescribing was in place at the VOLH during the period examined by the OCT. The OCT report acknowledges, however, that there were no formal arrangements in place to monitor antibiotic use or to audit compliance with the antimicrobial prescribing policies. The Antimicrobial Management Team carried out a subsequent audit on behalf of the OCT which showed that the use of some broad spectrum antibiotics at the VOLH was higher than in other hospitals in Clyde.⁷³ Antibiotic prescribing policies are discussed in detail in Chapter 13.

Clinical environment

The OCT reported that the clinical environment where some of the patients were managed did not have adequate facilities for the practice of good infection control procedures, but went on to conclude that there was:

“no evidence that this has in any way affected the clinical treatment of CDAD patients and/or their outcome”.⁷⁴

Environmental factors are considered in detail in Chapter 15. It suffices to say here that it should have been obvious to the OCT that, for example, a shortage of hand washing facilities could affect patient safety.

71 [GGC00600007](#)

72 [GGC00600006](#)

73 [GGC00600040-41](#)

74 [GGC00600007](#)

Recommendations by the Outbreak Control Team

The OCT report made the following recommendations:

- “Based on the lessons learnt from this outbreak, the NHS Board should review and clarify roles, responsibilities and communication chain for HAI throughout the organisation
- The programme of work to improve the structural environment of the VOLH should continue and an assessment of more significant works should be completed to facilitate optimum infection control practice
- The Antimicrobial Management Policy and the *Clostridium difficile* treatment protocol should be implemented in areas covering both primary and secondary care prescribing activities in NHSGGC. The Antimicrobial Management Policy should be audited at regular intervals
- A system should be developed to monitor the number of deaths of patients with CDAD and these should be regularly reviewed by the local ICT
- The local surveillance system should be regularly monitored to ensure that it is fit for purpose and if necessary updated based on national guidance. Local surveillance data should continue to be fed back to the senior charge nurses and lead nurses of the wards. In addition, data should be held on the number of new cases of severe alert organisms (*Clostridium difficile* and MRSA) per ward, per directorate and per site
- Education with regard to infection control and HAI issues should be available for all staff and the uptake of training should be monitored
- NHS Board should continue to work closely with Public Focus Patient Involvement (PFPI) and Patient Public Focus (PPF) leads for Community Health Care Partnerships (CHCPs) to review communication methods and materials used to communicate with patients and relatives and also with the wider community on HAI issues
- Clinicians completing a DNAR order must ensure that the decision making process is

fully documented and this decision must be prominently displayed in the casenote”⁷⁵

Some criticism of the Outbreak Control Team report

Professor Duerden was critical of the OCT report. In particular he said that the OCT report had started to look at the outbreak but it had not come to clear conclusions about the real cause and pattern of the outbreak. This was in part due to the lack, even at this stage, of a detailed timeline demonstrating which patients had become infected, in which wards, and any relationship between the patients. A detailed timeline was critical to an understanding of the pattern of an outbreak.⁷⁶ He suggested that the report was very weak in describing the activities which occurred during the outbreak period, but acknowledged that it did recognise the gaps in the infection prevention and control arrangements.⁷⁷

It is worthy of note that, following the outbreak of salmonella at the Victoria Infirmary in 2005, the Watt Group report criticised an aspect of the OCT report into that outbreak on the basis that:

“the Report did not document the fundamental aspects of the likely spread of infection, nor give details of key infection control issues relevant to the outbreak”.⁷⁸

The Watt Group recommended:

“that all OCT reports should provide sufficient details of the key factors in the spread of infection to allow proper audit”.⁷⁹

For the reasons given by Professor Duerden, this recommendation was not fully reflected in the VOLH OCT report.

Neither were individual or corporate failures identified in the report. Professor Duerden would have expected some sort of comment on the reasons why the increased number of cases had not been brought to the attention

75 [GGC00600066-67](#)

76 [TRA01060032](#)

77 [EXP02810005](#)

78 [GOV00130025](#)

79 [GOV00130025](#)

of the Infection Control Doctor and the infection control committee structure.⁸⁰ Counterbalancing these criticisms, however, is the explanation by Dr Ahmed that the OCT was not looking to see if there had been systemic failures because the team was aware of other investigations taking place, including those of the Health and Safety Executive and the Independent Review Team.⁸¹ The OCT did not wish to encroach upon these other investigations, and the decision was taken to conclude its investigations on 16 July 2008. It was for that reason that the OCT did not contact Dr Biggs,⁸² although it did conclude that there was a lack of Infection Control Doctor leadership at the VOLH.⁸³

Dr Ahmed said that the key purpose of the OCT was to “control the outbreaks”.⁸⁴ The purpose was not “to forensically examine ... case by case the detail of the outbreak”,⁸⁵ it was to identify the problem and to deal with it in order to protect public health.⁸⁶ There is no suggestion that this goal was not achieved.

Despite the reasons provided by Dr Ahmed for the OCT’s approach, it has to be emphasised that any outbreak investigation should be able to define an outbreak in terms of the number of patients affected and over what period. It should also define the timelines of cases and any evidence of links in time and place between cases. This information defines an outbreak and is central to any investigation into aspects of an outbreak.

17.4 Conclusion

This Chapter has examined only that part of the NHSGCC Board’s response to the occurrence of CDI at the VOLH that is reflected in the work of the Internal Investigation or of the OCT. Other aspects of the Board’s response, including the Board’s approach to the examination of patient records, the

substantial investment into the VOLH, and the changes in antimicrobial prescribing are discussed in other Chapters of this Report.

As set out in this Chapter, the Internal Investigation had a limited remit and had its deliberations curtailed by the appointment of the Independent Review. A similar fate befell the OCT’s investigation. Both investigations did produce lessons to be learned or recommendations that were entirely appropriate.

It is apparent that the message from nurses in their evidence to the Inquiry that shortage of staff meant that they were “firefighting” was not one conveyed to these investigations. Neither investigation examined nursing and medical care for the simple reason that that was not covered by their respective remits. In his witness statement to the Inquiry Mr Calderwood set out his understanding of the care given to patients who suffered from CDI at the VOLH in the following way:

“However, the findings of the outbreak control team and independent review team show that every patient with C.diff at the Vale of Leven during these six months was identified and given the appropriate nursing care”.⁸⁷

Mr Calderwood’s reference in these remarks to the Independent Review is misleading, but not deliberately so. Professor Smith has confirmed to the Inquiry that his review did not look at general nursing care. That was outwith the team’s remit, and a longer period would have been necessary to conduct such a review.⁸⁸

As explored in other Chapters of this Report, what Mr Calderwood said was not accurate. There were failures in care. Mr Calderwood agreed in evidence that evidence of lack of appropriate care planning or stool charts and a failure to isolate patients would cause him to “retract”⁸⁹ that statement. He said he would reflect on the facts emerging from the Inquiry.⁹⁰

80 [TRA01060035](#)

81 [TRA01140048](#)

82 [TRA01140053](#)

83 [GGC00600031](#)

84 [TRA01140055](#)

85 [TRA01140048](#)

86 [TRA01140048](#)

87 [WTS00880019](#)

88 [WTS02140005](#)

89 [TRA01240086](#)

90 [TRA01240086](#)

Both the Internal Investigation, despite its narrow remit, and the OCT did focus on issues of infection prevention and control. Surprisingly, however, neither explored what role, if any, was played by the infection prevention and control Access database. As already mentioned in this Chapter, Mrs Grant did say that the existence of the database had been mentioned by Mrs O'Neill. Had the OCT in particular focused on the existence of the database then that could have prompted some inquiry into what role it might have played in the past and why it was not in use in 2008. These are issues that are explored in Chapter 15.

As observed earlier, it should have been obvious to the OCT that environmental factors and lack of facilities could affect patient safety. The Inquiry is not otherwise inclined to criticise the manner in which the two investigations approached the specific tasks that they undertook, particularly because these investigations were overtaken by the setting up of the Independent Review.

17.5 Recommendations

Recommendation 72: Health Boards should ensure that a non-executive Board member or a representative from internal audit takes part in an Internal Investigation of the kind instigated by NHSGCC.

Recommendation 73: Health Boards should ensure that OCT reports provide sufficient details of the key factors in the spread of infection to allow a proper audit to be carried out, as recommended in the Watt Group Report.

Chapter 18

Experiences of *C. difficile* infection
within and beyond Scotland

Introduction

The aim of this Chapter is to examine reports of other outbreaks of *C. difficile* infection (CDI) in order to consider whether lessons could have been learned from them to prompt an examination of infection prevention and control practices at the VOLH and the care of patients suffering from CDI. There will be a particular focus on the reports published on outbreaks of CDI at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust (Stoke Mandeville), and Maidstone and Tunbridge Wells NHS Trust (Maidstone and Tunbridge Wells).

The Inquiry is aware of outbreaks of CDI, and of the 027 strain that is discussed in this Chapter, in other parts of the world. Professor Poxton described in his evidence and his report the development of the 027 strain, firstly in Montreal and thereafter in other parts of North America and in Western Europe.¹ Information published by the Canadian Medical Association Journal in 2006,² drawing on data from 2003 onwards, disclosed that with the emergence of the 027 strain there was an increased severity of infection as well as a significantly increased mortality rate. Professor Poxton drew attention to the fact that surveillance systems in some parts of the world are in their infancy, so that the information available is limited.³ While statistical data on rates of infection are available from Canada, no reports of detailed investigation of the management of any particular outbreak appear to have been published.

Given these limitations, in contrast to the detailed investigations carried out into 027 outbreaks within the United Kingdom, the Inquiry has concluded that further examination of the management of CDI, and of the 027 strain in particular, in North America would not be a useful exercise.

18.1 The 027 strain

A hypervirulent strain

Chapter 3 explains the different strains of *C. difficile* and how strains can be identified. At the time of the Stoke Mandeville and Maidstone and Tunbridge Wells reports in 2006 and 2007, and in the aftermath of those outbreaks, the 027 strain was seen as a “hypervirulent” strain because it caused more severe disease and more deaths.⁴ Professor Ian Poxton, Professor of Microbial Infection and Immunity at the University of Edinburgh, emphasised in evidence, however, expressing a view echoed by Professor Duerden,⁵ “All *Clostridium difficile* toxin-producing strains are to be worried about.”⁶

Over the years it became more apparent that some of the outbreaks that involved the 027 strain were not particularly severe, although others were devastating and fatal.⁷ There is no doubt, however, that at the time of the outbreaks at Stoke Mandeville and Maidstone and Tunbridge Wells the 027 strain was seen as important because of the clinical severity associated with it.⁸

Recognition of the 027 strain in Scotland

The hypervirulent nature of the 027 strain was recognised in Scotland before the discovery of the CDI problem at the VOLH. The Health Protection Scotland (HPS) weekly report dated 19 September 2006 recognised that it was a virulent strain and that it had been the strain which caused most of the cases in the outbreak at Stoke Mandeville.⁹ The HPS weekly report dated 7 November 2007 intimated that there had been a case of CDI with the 027 strain in a hospital in the west of Scotland, and that this was the second reported case of the 027 strain in Scotland.¹⁰

The HAI Task Force Delivery Plan “Project Initiation Document” designed to develop a programme for reduction of *C. difficile* in July 2007 also described the 027 strain as hypervirulent.¹¹

1 [TRA00090037-38](#); [EXP00690021-24](#)

2 [INQ05290001](#)

3 [EXP00600005](#)

4 [TRA00090037-42](#)

5 [TRA01050053-54](#)

6 [TRA00090042](#)

7 [TRA01050053](#)

8 [TRA01050055](#)

9 [GOV01110001](#)

10 [INQ03650001](#)

11 [HPS00250001](#)

The point to be made here is that, whatever change there may have been in the state of knowledge about the virulence of the O27 strain since the discovery of the CDI problem at the VOLH, prior to and indeed up until then it was being viewed as a hypervirulent strain capable of causing very severe disease and death. That is the context in which any response in Scotland to its emergence must be considered.

18.2 The Stoke Mandeville, and Maidstone and Tunbridge Wells reports

Two important reports

The Stoke Mandeville, and Maidstone and Tunbridge Wells reports,¹² both of which arise from outbreaks in England that occurred within recent years, provide important lessons on infection prevention and control and on patient care.

Stoke Mandeville

In July 2006 the Healthcare Commission in England published the report into outbreaks of CDI at Stoke Mandeville.¹³ This examined two outbreaks, the first between October 2003 and June 2004 and the second between October 2004 and June 2005. In the first outbreak there were 174 CDI cases with 19 deaths definitely or probably due to CDI. In the second there were 160 CDI cases with 19 further deaths definitely or probably due to CDI.¹⁴

Any comparison of these figures with figures for the VOLH must of course take account of the fact that Stoke Mandeville was a much larger hospital with around 460 beds.¹⁵ As already mentioned in Chapter 8, by 2008 the bed complement in the VOLH was about 136. Yet, as set out in Chapter 4, in the period 1 January 2007 to 31 December 2008, 143 patients who were or had been patients in the VOLH tested positive for CDI. CDI was a causal factor in the deaths of at least 34 of those patients.

Some Stoke Mandeville issues

The following factors were among those identified in the Stoke Mandeville report as contributing to the outbreaks:¹⁶

- The poor state of repair of the buildings
- Failure to isolate patients with diarrhoea
- Difficulty in isolating patients due to lack of side rooms
- Excessive movement of patients
- Shortages of nurses
- Lack of facilities for hand washing
- Poor storage facilities
- Low priority afforded to infection control
- Failure to ensure that the governance structure identified issues of patient safety

The following aspects of the management of patients with CDI were identified:¹⁷

- Fluid balance was given little attention
- Poor care planning and nursing assessments

The Stoke Mandeville report found that by the time its investigations were carried out certain precautions had already been taken. As early as 2003 the policy on use of broad spectrum antibiotics at Stoke Mandeville had been changed in response to cases of CDI,¹⁸ although the report does not make clear who prompted that change. Guidelines for antibiotic use were thereafter regularly reviewed. The outbreak committee had also identified a need for new wash-hand basins and new partitions, which were in place by July 2004.¹⁹

In 2004 samples were sent to the Anaerobe Referencing Laboratory in Cardiff for typing, which led to the identification of many cases as due to the O27 strain. There was concern that the clinical picture was more severe than usually associated with CDI outbreaks, but the O27 strain was then thought to be rare in the United Kingdom and its significance was not generally recognised.

12 [INQ02890001](#); [INQ02870001](#)

13 [INQ02890001](#)

14 [INQ02890006](#)

15 [INQ02890021](#)

16 [INQ02890007-09](#)

17 [INQ02890033](#)

18 [INQ02890026](#)

19 [INQ02890027](#)

Stoke Mandeville recommendations

The Stoke Mandeville report included recommendations that were highly relevant to the problems identified by this Inquiry at the VOLH. In relation to standards of care, for example, the report stressed that in the clinical management of patients with *C. difficile* good records had to be kept of fluid management, and that the standard of documenting and implementing decisions about clinical management had to be improved. There were also important recommendations on issues such as adequate levels of staffing, management involvement in infection prevention and control, training, clinical governance, and the management of risk.²⁰

Maidstone and Tunbridge Wells

In October 2007 the Healthcare Commission published its report into outbreaks of *C. difficile* at Maidstone and Tunbridge Wells.²¹ The report examined the period from April 2004 to September 2006,²² and identified two outbreaks occurring during that period. The first of these was in the autumn of 2005, but had not been identified by the Trust and consequently was not declared. The second was declared on 12 April 2006. During the two outbreaks more than 500 patients developed CDI.²³ The report estimated that there were approximately 90 deaths where *C. difficile* was definitely or probably the main cause of death.²⁴

Again any comparison with figures for VOLH must take account of the fact that at the time the Trust had 857 to 900 beds spread over three hospitals.²⁵

Some Maidstone and Tunbridge Wells issues

Among the issues identified in the report were:

- Ineffective local surveillance²⁶
- Limited use of stool charts²⁷
- Unnecessary administration of broad spectrum antibiotics²⁸

- Inadequate fluid management²⁹
- Dissatisfaction among patients and families over information provided³⁰
- Lack of hand basins, lack of sluice space, inadequate storage in wards³¹
- Limited availability of microbiologists, few visits to wards³²
- Microbiologists and infection control nurses not working closely together³³
- Link nurse scheme not well established³⁴
- Inadequate level of training on infection control³⁵
- Heavy reliance on bank and agency staff³⁶
- Complex governance structure did not ensure operational problems and risks to patients identified³⁷
- Little leadership to, or monitoring of, directorates by governance and risk committee³⁸
- Absence of information on *C. difficile* for Board³⁹
- Perception that priorities of leadership were finance, access targets, and reconfiguration of services⁴⁰

Maidstone and Tunbridge Wells recommendations

The Maidstone and Tunbridge Wells report's recommendations bore a significant degree of similarity to those of the Stoke Mandeville report. Once again clinical governance and the management of risk were identified as important issues, with emphasis on the point that control of infection needed to be seen as an integral part of clinical governance. Recommendations were also made on standards of care, including specific reference to the importance of treating *C. difficile* as a diagnosis in its own right that necessitated

20 [INQ02890093-95](#)

21 [INQ02870001](#)

22 [INQ02870005-06](#)

23 [INQ02870005](#)

24 [INQ02870006](#)

25 [INQ02870020-21](#)

26 [INQ02870026](#)

27 [INQ02870034](#)

28 [INQ02870035](#)

29 [INQ02870036](#)

30 [INQ02870042](#)

31 [INQ02870048](#)

32 [INQ02870056](#)

33 [INQ02870057](#)

34 [INQ02870057](#)

35 [INQ02870060](#)

36 [INQ02870069](#)

37 [INQ02870088](#)

38 [INQ02870088](#)

39 [INQ02870091-92](#)

40 [INQ02870097](#)

regular review. One recommendation emphasised the importance of basic aspects of nursing care that required nurses to administer medication appropriately and to take steps to prevent pressure damage. The importance of prudent prescribing of antibiotics, whereby the narrowest possible spectrum antibiotics were prescribed for the shortest period possible, was also highlighted.

18.3 The NHS Greater Glasgow and Clyde response to Stoke Mandeville, and Maidstone and Tunbridge Wells

A level of awareness

It is apparent that quite a number of NHSGGC staff were aware of the Stoke Mandeville report.⁴¹ The chair of the Acute Control of Infection Committee (ACIC), Dr Robin Reid, had read it, although not an infection control professional, and he was in little doubt that Infection Control Doctors and Infection Control Nurses would have been aware of it.⁴² Professor John Coia, Director of Scottish Microbiology Reference Laboratories, could not recollect any discussion of the Stoke Mandeville and Maidstone and Tunbridge Wells reports at the meetings of the ACIC, of which he was a member, but he was able to say that there was “a lot of discussion of both these reports within the infection control community within Greater Glasgow...”.⁴³

The Nurse Consultant for Infection Control, Ms Sandra McNamee, had read the Stoke Mandeville⁴⁴ and Maidstone and Tunbridge Wells reports⁴⁵ and used them to inform her own practice. She explained to the Inquiry that she had reviewed both reports and extracted those parts she felt ought to be in the infection control programme. She went on to say, however, that “unfortunately the reports in their entirety didn’t go to any of the committees that I’m aware of”.⁴⁶ She did not believe that any steps were taken to inform staff at hospital level of the lessons to be learned from the two incidents.⁴⁷

On the other hand, Dr Syed Ahmed, Consultant in Public Health, NHSGGC, said that although it is not recorded in the minutes of the Board Infection Control Committee these reports were discussed there and responded to by making changes to policies.⁴⁸

Some practical steps

According to Mr Thomas Walsh, the Infection Control Manager (ICM), he discussed the Maidstone and Tunbridge Wells report with Ms McNamee. They followed that up with two additional educational components for the online training modules and an improved patient and relative leaflet. He said that the Maidstone and Tunbridge Wells report was one of the reasons that CDI was considered for the statistical process control charts described in Chapter 15.⁴⁹ He also said that he carried out what he described as a “gap analysis”, with a particular focus on policies.⁵⁰

The VOLH response

Notably, there were actions taken at the VOLH that can be directly attributed to the Stoke Mandeville report.⁵¹ A meeting took place at the VOLH on 16 February 2007 to discuss facilities services at the hospital in the light of issues raised in the Stoke Mandeville report.⁵² This was attended by Mrs Catriona Sweeney, Site and Facilities Manager, Mrs Lena Keeley, Assistant Domestic Services Manager and Mrs Helen O’Neill, Infection Control Nurse. Although the original instruction to carry out this review has not been seen by the Inquiry, it is apparent from later correspondence that it was issued to all NHSGGC site managers.⁵³

The meeting identified several concerns related to areas highlighted in the report.⁵⁴ Storage issues and poor housekeeping practices were noted in some wards and departments. Poor maintenance of fabric and equipment was also identified. It was noted that estates had no budget for painting

41 [INQ02890001](#)

42 [TRA01180055](#)

43 [TRA01220034](#)

44 [INQ02890001](#)

45 [INQ02870001](#)

46 [TRA01210028](#)

47 [TRA01210029](#)

48 [TRA01130028-31](#)

49 [TRA01200103](#)

50 [TRA01200104](#)

51 [INQ02890001](#)

52 [GGC07790002](#); [INQ02890001](#)

53 [GGC07790001](#)

54 [GGC07790002-06](#); [GGC20710001-05](#)

or fabric repairs, and that all repairs were of an emergency nature. There was a need for supervisors to be vigilant in observing domestic staff to ensure compliance with infection control requirements.

The same team conducted a review in February 2008.⁵⁵ In a number of instances problems had not been resolved, which is of course a cause for concern. But what these meetings and reviews do demonstrate is that it was possible and relatively easy for local consideration to be given to the immediate relevance of issues identified in the Stoke Mandeville report⁵⁶ and to possible solutions.

Presentations to staff at the VOLH

As mentioned in Chapter 15, in early 2007 Mrs Jean Murray, Interim Lead Nurse for Infection Control, gave a presentation on CDI to doctors which was based to a large extent on the Stoke Mandeville report. She dealt with the infection control aspects, while Dr Barbara Weinhardt, Consultant Microbiologist, dealt with the pathology, biology and microbiology.⁵⁷ Mrs Murray gave a further presentation to nurses on 8 May 2007.⁵⁸

Mrs Murray explained that one of the principal reasons for focusing on the Stoke Mandeville report was her recognition of a number of similarities between the environment at the VOLH and that described in the report, in particular poor maintenance and lack of isolation facilities.⁵⁹ Taken as a whole that presentation covered many of the problems identified in the Stoke Mandeville report, including poor infection prevention and control practices and the importance of prudent antibiotic prescribing.⁶⁰

The practices of infection control staff at VOLH are examined in greater detail in Chapter 15. At this point the Inquiry simply notes this further example of local consideration being given to issues raised in the Stoke Mandeville report.

Failure to apply lessons

It can be seen, therefore, that NHSGGC did respond to the Stoke Mandeville and Maidstone and Tunbridge Wells reports. What is unfortunate, however, is that the NHSGGC Board did not consider the lessons learned from the Stoke Mandeville report or indeed the Maidstone and Tunbridge Wells report as a checklist against which to assess the operation of infection prevention and control at the VOLH.

18.4 NHS Quality Improvement Scotland response

Role of NHS Quality Improvement Scotland

The role of NHS Quality Improvement Scotland (NHS QIS) is set out in Chapter 6. It was to take the lead in improving the quality of care and treatment delivered by NHSScotland. Its declared key functions were:

- Providing clear advice and guidance on effective clinical practice
- Setting clear clinical and non-clinical standards of care
- Reviewing and monitoring the performance of NHS services
- Supporting NHS staff in improving services, and
- Promoting patient safety and implementation of clinical governance⁶¹

Reference to the Stoke Mandeville report by NHS Quality Improvement Scotland

The background to the publication of standards for HAI infection prevention and control is considered in Chapter 6. These standards were originally published in December 2001. The Stoke Mandeville report⁶² was one of a substantial number of documents referenced in the draft of the revised standards,⁶³ issued in August 2007, and revised standards were published by NHS QIS in March 2008.⁶⁴

55 [GGC20710001](#)

56 [INQ02890001](#)

57 [TRA01010042](#)

58 [GGC17790002](#)

59 [TRA01010044](#)

60 [INQ0301001-05](#); [INQ03010015](#)

61 [INQ00840027](#)

62 [INQ02890001](#)

63 [GGC17380002](#)

64 [INQ00840001](#)

These standards did not in themselves anticipate or entail review by Health Boards of their policies or practices. They were:

“written with the overall intention that meeting them should not require NHS boards to introduce new initiatives or create new pieces of evidence unless absolutely necessary, but rather should allow NHS boards to build upon work already being done”.⁶⁵

As the document explained:

“These standards are one part of the drive for a safer NHS Scotland, so should be seen as complementary to HAI and patient safety work undertaken by other bodies”.⁶⁶

No guidance appears to have been issued, or review conducted, by NHS QIS specifically in the light of the Stoke Mandeville or Maidstone and Tunbridge Wells reports.

The Inquiry notes that since the period under scrutiny the functions of NHS QIS have been taken over by Healthcare Improvement Scotland (HIS).

18.5 The response to the Stoke Mandeville, and Maidstone and Tunbridge Wells reports by Health Protection Scotland

Health Protection Scotland

The role of Health Protection Scotland (HPS) is discussed in Chapter 6. To summarise: HPS was formally established in 2005 as successor to the Scottish Centre for Infection and Environmental Health.⁶⁷ It has responsibility for implementing health protection programmes and policies, for providing expert advice on policy development, and for implementing a quality assurance framework for health protection at local, regional and national levels. It also has responsibility for public communication and advice on health protection issues in line with Scottish Government policy.⁶⁸

65 [INQ00840004](#)

66 [INQ00840005](#)

67 [INQ04900005](#)

68 [INQ04900007](#)

The Healthcare Associated Infection Task Force

The relationship between HPS and the Healthcare Associated Infection (HAI) Task Force is also considered in Chapter 6. The work of HPS in connection with HAI is overseen by the Task Force.⁶⁹ Led by the Chief Medical Officer, with members drawn from Health Boards, NHS QIS, HPS and elsewhere, the HAI Task Force was responsible for leading the programme of work detailed in the Scottish Executive Action Plan to reduce the risk to patients, staff and visitors from HAI (2002 to 2005),⁷⁰ and for its own subsequent Delivery Plans (2006 to 2008,⁷¹ 2008 to 2011⁷²).

Development of policies and guidance

The national policies and guidance in place in Scotland on HAI, and on *C. difficile* in particular, are considered in Chapter 7. Policies and guidance were being developed before the publication of the Stoke Mandeville report.⁷³ They continued to be developed between then and the publication of the Maidstone and Tunbridge Wells report,⁷⁴ and thereafter. The following list of guidance documents published prior to June 2008, with dates of issue, was provided to the Inquiry by HPS:⁷⁵

- Standard Infection Control Precautions (SICPs), published September 2006
- CDAD Reduction Programme established, February 2007
- Project initiation document on the ‘CDAD Reduction Programme’ submitted to HAI Task Force, July 2007
- Collaboration with National Education Scotland (NES) on developing on-line training material for junior doctors initiated May 2007, completed May 2009
- Electronic *C. difficile* network (‘shared space’ on NHS e-Library server), established August 2007

69 [INQ04900010](#)

70 [GOV00100001](#)

71 [GOV00150001](#)

72 [GOV00140001](#)

73 [INQ02890001](#)

74 [INQ02870001](#)

75 [HPS00170003](#)

- CDAD care bundle initiated in October 2007, published/distributed, March 2008
- Transmission Based Precautions (policies), published April 2008

This demonstrates a continuing awareness of the need for additional and updated guidance on infection prevention and control.

Nevertheless, to measure the extent to which the lessons of the Stoke Mandeville and Maidstone and Tunbridge Wells reports were being learned in Scotland it is a useful exercise to identify the developments that took place in Scotland **expressly or even implicitly** in the light of these reports.

Some consideration of Stoke Mandeville and Maidstone and Tunbridge Wells reports

The Project Initiation Document produced by the HAI Task Force in July 2007 for the development of a programme for reduction of healthcare associated CDI in Scotland identified HPS as the lead organisation and explained by way of introduction that:⁷⁶

“The incidence of healthcare associated CDAD (*C. difficile* Associated Disease) in Scotland has steadily increased in the period 1994 to 2006. Recently a new emerging hypervirulent strain (PCR ribotype O27), which causes more severe disease, has caused large outbreaks in England, Europe and North America”.⁷⁷

Specific mention is also made of the Healthcare Commission’s recommendations contained in the Stoke Mandeville report,⁷⁸ in particular those relating to hospital management, risk management, clinical governance and links to external health organisations.

The tasks identified in that document were:

- Review existing local, national and international guidelines for prevention and control of CDAD to adapt appropriate guidance for Scotland

- Review existing interventions and quality improvement tools to produce and provide an agreed set of interventions
- Produce a model policy for prevention and control of CDAD
- Produce educational material for healthcare staff and the public
- Establish a communication network of key persons involved in infection control⁷⁹

At a later stage the HAI Task Force also considered the Maidstone and Tunbridge Wells report.⁸⁰ This was soon after its publication, the subject being raised at the HAI Task Force meeting of 30 October 2007 by the Chief Nursing Officer, Professor Paul Martin. He advised the meeting:

“that he proposed to issue a letter to Chief Executives (copied to Chairs) of NHS Boards, reminding them of their responsibilities to minimise and manage risk and to ensure that actions are in place to avoid any similar outbreaks”.⁸¹

Professor Martin’s letter

Professor Martin’s letter was issued on 8 November 2007.⁸² The principal subject matter was the need to maintain good communication channels between Boards and the Scottish Government in the event of an outbreak. There is no explicit reference to Maidstone and Tunbridge Wells in the letter, but he urges each Chief Executive to:

“ensure that your Board undertakes an immediate and thorough review of its local infection control policies to help minimise the risk of any outbreaks occurring”.⁸³

Asked in the course of his evidence what response he would have expected to the letter, Professor Martin explained:

“We would expect, and did expect, the Chief Executives and the Boards through the infection control committees and, indeed, through their clinical governance

76 [HPS00250001](#)

77 [HPS00250001](#)

78 [INQ02890001](#)

79 [HPS00250002](#)

80 [INQ02870001](#)

81 [GOV01210007](#)

82 [GGC14420004](#)

83 [GGC14420004](#)

machinery to do a review, to make sure that the systems and the processes were in place, that policies were in place, that staff in all of the settings knew how to respond if there were issues raised, education was happening, et cetera”.⁸⁴

That expectation was not spelled out in his letter, which referred only to a review of infection control policies.

Mr Walsh's response

On 12 November 2007 Mr Walsh circulated the Chief Nursing Officer's letter of 8 November to a number of health professionals including Ms McNamee, Ms Annette Rankin, Head Infection Control Nurse, and Dr Ahmed. In his covering email he explained:

“In practice as Board ICM and Nurse Consultant, Sandra and I already undertake this function. The letter merely requires inclusion of a couple of additional SGHD (Scottish Government Health Department) email addresses to the distribution of updates from NHSGCC”.⁸⁵

The “function” referred to was that of informing key contacts in the Scottish Government of major incidents and outbreaks of infection – an issue raised in Professor Martin's letter.

No mention is made by Mr Walsh of any review of policies. Mr Walsh explained in his evidence to the Inquiry that revision of infection control policies is an ongoing process, not one triggered by such reminders,⁸⁶ and it certainly does appear that, for example, the Loose Stools Policy was reviewed in December 2007.⁸⁷

In the absence of any specific reference to the Maidstone and Tunbridge Wells report,⁸⁸ it does not appear to the Inquiry that the Chief Nursing Officer's letter could have been expected to trigger a review of infection control policies specifically in the light of

that report. It is therefore no surprise to the Inquiry that Professor Martin's expectation of a more extensive review of systems and processes was not realised. This is not to be seen as a criticism of Professor Martin, whose purpose in sending out the letter was well intentioned, or of Mr Walsh, who provided a satisfactory reason for his response. Nevertheless, the lesson to be learned from this episode is that of the importance of absolute clarity in communication when dealing with important aspects of infection prevention and control. Had the letter been more specific then it is very likely that NHSGCC would have carried out the kind of review described by Professor Martin in his evidence. That kind of thorough review would have provided an opportunity to identify problems discussed in this Report in connection with infection prevention and control at the VOLH.

HPS retrospective summary

A retrospective summary of HPS developments up to March 2008 in the field of guidance and surveillance relating to CDI was provided to the Inquiry. This explains that the development of a national guidance document on prevention and control of CDI was scheduled in 2007, but was not commenced then as a joint European systematic review that was going to provide the evidence base for the Scottish document was still in production. Because of the severity of the VOLH CDI problem, however, the SGHD required in June 2008 that HPS deliver a draft of the guidance by August 2008, a period for production of guidance considerably shorter than recommended by medical guideline bodies. The first version of the national guidance on CDI was published in October 2008. A CDI checklist for NHSScotland was published by HPS in September 2008.⁸⁹

Further reference to national guidance and to the checklist will be made later. It suffices to note at this point that by September 2008 the Stoke Mandeville report⁹⁰ had been in the public domain for over two years.

84 [TRA01080100](#)

85 [GGC14420001](#)

86 [TRA01200019](#)

87 [GGC27590001](#)

88 [INQ02870001](#)

89 [HPS00170001-02](#)

90 [INQ02890001](#)

Professor Reilly's position

Professor Jacqui Reilly, Head of Group for Healthcare Associated Infection at HPS, was posed the following question:

“Can we take it that it was thought that nationally across Scotland, Health Boards needed the guidance of HPS to learn lessons from the Stoke Mandeville and other outbreak reports?”

She replied:

“No, the Stoke Mandeville report received a high profile in the national press and the report was in the public domain so all the NHS boards had access to it and could read it, as could HPS”.⁹¹

From this reply it would appear that, despite acknowledgement by HPS of the similarity between its role in Scotland and that of the Health Protection Agency in England,⁹² HPS did not consider it appropriate to follow the recommendations of the Stoke Mandeville report that:

“16 The Health Protection Agency should ensure that the system for disseminating relevant information to the NHS about the emergence of new strains of micro organisms is robust. This will require collaboration with the reference laboratories and the NHS.

17. The Health Protection Agency should ensure that it provides regular, up-to-date advice to health professionals, in an electronic form, on the management of *C. difficile*”.⁹³

HPS did not issue any form of guidance on CDI based upon the Stoke Mandeville report or the Maidstone and Tunbridge Wells report prior to the publication of the HPS checklist in September 2008. Instead, according to Professor Reilly, the task of reviewing a report like the Stoke Mandeville report was left to Health Boards, and it was for Boards to consider whether there were any implications for their own practice.⁹⁴

The checklist

In her evidence Professor Reilly explained the creation of the HPS checklist⁹⁵ in the following terms:

“The HPS CDI checklist was developed as a support tool to check control measures were in place in the light of the evidence arising from both of these high profile outbreaks of CDI. It was discussed in the HPS internal CDI programme in early 2008. HPS had initial discussions with Sandra McNamee from GG&C about this in the context of the VOL outbreak, we sent her a draft version on 18 June 2008 to use at VOL. A consultation version was sent out to all NHS boards on 19 June 2008 (and comments were received from boards and HFS) which were collated on 22 August 2008. It was published on HPS website on 29 August 2008. We were unaware of whether any other board needed it at that time”.

As Professor Reilly acknowledges in that quotation, the creation of the checklist was prompted by the Stoke Mandeville and Maidstone and Tunbridge Wells outbreaks. This is confirmed by Dr Anne Eastaway, Consultant Microbiologist with HPS, who explained that:

“HPS had also been working on a checklist which had been drawn up based on the findings of the Stoke Mandeville and other outbreak reports. The checklist draws together actions that need to be taken across an NHS organisation such as an NHS board or hospital”.⁹⁶

As Professor Reilly explained, the production of the checklist was “accelerated”⁹⁷ following the discovery of the CDI problem at the VOLH. The checklist was used in June 2008 to assist in remedial action being taken when addressing the CDI problem at the VOLH.

The checklist highlights 32 issues seen as important to preventing and controlling CDI, including:

91 [TRA01100103](#)

92 [INQ04900008](#)

93 [INQ02890094-95](#)

94 [TRA01090155-156](#)

95 [TRA01100103](#); [HPS01590002](#)

96 [WTS02030011](#)

97 [TRA01090149](#)

- Data collection at ward level and data review
- Specific CDI issues are reviewed at senior management meetings, for example, outbreak/increased incidence reports and non-adherence to best practice
- CDI is acknowledged on the NHS Board's risk register
- Senior management supports and facilitates provision of infection prevention and control education programmes
- Antibiotic policy is followed with drug kardexes being checked
- Patients with CDI are in a single, clutter-free room
- There is evidence of medical review
- Equipment in use is fit for purpose⁹⁸

The Inquiry concludes from this evidence that HPS *did* consider the Stoke Mandeville and Maidstone and Tunbridge Wells reports⁹⁹ and *did* eventually issue guidance in the form of the checklist in the light of these reports. As mentioned earlier in this Chapter, the Stoke Mandeville report was published in July 2006 and the Maidstone and Tunbridge Wells report was published in October 2007. If the publication of the Stoke Mandeville report is taken as a starting point, it took two years for the checklist to be produced.

Guidance provided by Health Protection Scotland in May 2008

HPS also provided guidance to Boards, and to Infection Control Managers in particular, by letter dated 14 May 2008.¹⁰⁰ That letter was prompted by the discovery of CDI patients in Clyde with the 027 strain when there was a developing awareness of the CDI problem at the VOLH. It contained some of the advice subsequently contained in the checklist, and describes the 027 strain as “hypervirulent”.¹⁰¹ Notably, the letter draws upon draft guidance issued by the Department of Health in England. And while it does concentrate on the 027 strain, it also emphasises that the management of CDI is important regardless of ribotype.

No guidance on the 027 strain

It remains unclear to the Inquiry why no guidance on the *C. difficile* 027 strain was issued to Boards until May 2008, when the CDI problem involving the 027 strain in the VOLH was beginning to emerge. Knowledge of the issue at national level, at least in the specialist community, is not in question. The HPS weekly newsletter issued on 19 September 2006 has already been mentioned. That weekly report does record that no case of the 027 strain had yet been detected in Scotland (although Professor Reilly confirmed that the first was identified in 2006,¹⁰² which appears to have been an isolated case). In addition, while the weekly report notes conflicting evidence on the virulence of that strain in comparison with others, the HAI Task Force Delivery Plan project initiation document of July 2007 harbours no doubts over that, referring to “a new emerging hypervirulent strain (PCR ribotype 027), which causes more severe disease...”¹⁰³

The time taken to produce national guidance

A certain delay is understandable as far as the issue of national guidance is concerned. The Inquiry recognises that producing documents such as the NHS QIS Standards, eventually published in March 2008, and the HPS Guidance of Prevention and Control of CDAD, published in October 2008, requires time.

The Inquiry sees no reason, however, why advice to Boards to review their own facilities, systems and practices in the light of the Stoke Mandeville report could not have been issued within weeks of its publication. The advice in the form of the checklist would not have been difficult to produce much sooner. The issue of such advice was the responsibility of Scottish Government, but as Dr Kevin Woods, Director General for Health, Scottish Government, pointed out, it had not been alerted to the issue.

As noted earlier in this Chapter, the HAI Task Force Project Initiation Document produced in July 2007 had identified the need for extensive review, drawing to an extent on the

98 [HPS01590002-08](#)

99 [INQ02890001](#); [INQ02870001](#)

100 [HPS00730001](#)

101 [HPS00730003](#)

102 [TRA01100018](#)

103 [HPS00250001](#)

Stoke Mandeville report.¹⁰⁴ HPS was named in this document as the lead organisation.

Loss of opportunity to reinforce infection control messages

One result of the approach adopted by HPS is the significant lapse of time before the issue of the checklist. A second result is the loss of opportunity to use the detailed findings and recommendations of the earlier reports to encourage a Board such as NHSGGC to conduct a detailed audit of its own policies, practices and facilities, particularly at local level, in the light of those detailed findings and recommendations. The vital question here appears to the Inquiry **not** to be whether there were already policies and guidance in place, but whether use could have been made of the Stoke Mandeville and Maidstone and Tunbridge Wells reports to encourage implementation of those policies and guidance and review of their application.

Earlier circulation of the kind of advice contained in the checklist would have been highly desirable for that reason. It is to be noted that in England, in response to the outbreaks at Stoke Mandeville and before the publication of the report itself, a joint letter dated 21 December 2005 from the Chief Medical Officer and the Chief Nursing Officer was sent to all NHS Trust Chief Executives. The purpose of the letter was to draw attention to the prevalence of the potentially hypervirulent strain type 027 and to remind NHS Trusts of the importance of the need to minimise the risk of infection caused by *C. difficile*.¹⁰⁵

Had such advice been issued and received appropriate attention, it could only have led to a more timely and comprehensive overhaul of practice, if not policy, across Scotland. It would also have alerted Health Boards to the dangers of the 027 strain and put them in a better position to manage an outbreak of that strain when it arose, as was virtually inevitable.

Had it only been a question of publicising the prevalence of the new strain and the

increased risks associated with it, it would perhaps be easier to understand why this was not done until the 027 strain became a live issue in Scotland. But even on that particular issue, the Inquiry notes the evidence of Dr Woods that in retrospect perhaps not enough was done to alert Health Boards to the 027 strain and its implications.¹⁰⁶ The Inquiry endorses that view. In any event, the issues highlighted in the Stoke Mandeville and Maidstone and Tunbridge Wells reports went far beyond the 027 strain and CDI itself, and covered broader issues of patient safety and infection prevention and control.

18.6 The Scottish Government response

No action

In his evidence Dr Woods stated that “the Scottish Government did not take any action to draw the Stoke Mandeville case to the attention of Health Boards”.¹⁰⁷ He pointed out that in mid 2006 there were no recorded cases of *C. difficile* strain 027 in Scotland. He expected that there would be a general awareness of it and that it would be of interest to the infection control community.¹⁰⁸

No advice on further action

When asked if enough was done at national level to alert Health Boards to the newly emerging 027 strain, Dr Woods said that “in retrospect maybe not enough was done..”.¹⁰⁹ Importantly, Dr Woods went on to observe that Scottish Government had not as at June 2008 received any advice that further action was required. HPS had not, so far as he was aware, circulated information on the 027 strain beyond the specialist community.¹¹⁰

18.7 The Northern Health and Social Care Trust, Northern Ireland

The Northern Health and Social Care Trust

The Northern Health and Social Care Trust was established in 2007 as one of five such trusts providing health and social care

104 [HPS00250001](#)
105 [INQ05580001](#)

106 [TRA00980068](#)
107 [TRA00970114](#)
108 [TRA00970114-115](#)
109 [TRA00980067-68](#)
110 [TRA00980068](#)

services to the public in Northern Ireland. It covered the largest geographical area of the five, and included County Antrim and parts of Counties Tyrone and Londonderry. It provided hospital and community services to a population of about 440,000 living in these areas, and contained nine hospitals and 13 homes for older people.¹¹¹

The Regulation and Quality Improvement Authority for Northern Ireland (RQIA), published a review in August 2008 of the circumstances contributing to the incidence of CDI in the Northern Health and Social Care Trust in 2007 and early 2008.¹¹² After the publication of the RQIA report a Public Inquiry into the outbreak of *C. difficile* in the Trust hospitals was established in March 2009 (the Northern Ireland Public Inquiry), and its report was published on 21 March 2011.¹¹³

Remit of the Regulation and Quality Improvement Authority for Northern Ireland and findings

The RQIA had a broad remit that included reviewing the circumstances contributing to the rates of CDI in the Northern Trust in 2007 and 2008.

The RQIA made the following findings:

- Lack of awareness of the possible impact of the introduction of a virulent strain of CDI¹¹⁴
- Structural reorganisation putting monitoring of infection prevention at risk¹¹⁵
- Transfer of patients facilitating spread of infection¹¹⁶
- Shortage of isolation beds¹¹⁷
- Inappropriate use of antibiotics¹¹⁸
- Lack of systems to monitor implementation of antibiotic policies¹¹⁹
- Absence of systems to monitor the distribution of information to patients and staff¹²⁰

111 [INQ04460021](#)

112 [INQ05280001](#)

113 [INQ04460001](#)

114 [INQ05280111](#)

115 [INQ05280067-68](#)

116 [INQ05280112](#)

117 [INQ05280117](#)

118 [INQ05280120](#)

119 [INQ05280120](#)

120 [INQ05280128-129](#)

- Delay in recognition that there was an outbreak¹²¹

The Northern Ireland Public Inquiry remit and findings

The Northern Ireland Public Inquiry's remit was a narrow one and it was not required to repeat the work of the RQIA. Its purpose was:

1. To establish how many deaths occurred in Northern Health and Social Care Trust hospitals during the outbreak, for which *C. difficile* was the underlying cause of death, or was a condition contributing to death.
2. To examine and report on the experiences of patients and others who were affected directly by the outbreak, and to make recommendations accordingly.¹²²

The report of the Northern Ireland Public Inquiry includes a considerable body of evidence from patients and families of:

- Failure of effective communication with patients and relatives about the diagnosis and nature of the disease.
- Inadequate communication over personal protective equipment.
- Lack of communication over laundry.
- Lack of communication with relatives over death certification.
- Poor quality of nursing notes.
- General lack of care plans and needs assessments.

This evidence, although not expressed in terms of specific findings, was clearly largely accepted by the Inquiry in view of its recommendations.¹²³

The Northern Trust reports

Clearly, due to the timing of the publication of their reports, the Northern Ireland Inquiries fall into a different category from the Stoke Mandeville and Maidstone and Tunbridge Wells Inquiries. The period under investigation, 16 June 2007 to 31 August 2008, to a large extent overlaps with the

121 [INQ05280130](#)

122 [INQ04460005](#)

123 [INQ04460050-76](#)

period examined in this Inquiry. Furthermore, publication of the RQIA report took place after the period under examination by this Inquiry, and publication of the report of the Northern Ireland Public Inquiry took place when this Inquiry was in progress.

From the findings in the RQIA report in particular, as well as the report of the Northern Ireland Public Inquiry, it is apparent that the lessons available from Stoke Mandeville and from Maidstone and Tunbridge Wells had not been learned in the Northern Trust.

18.8 Ninewells Hospital, Dundee

The outbreak

Between 31 July and 6 November 2009 seven patients who had been in ward 31 of Ninewells Hospital, Dundee were found to be infected with the 027 strain of *C. difficile*. This infection caused the death of two patients, and contributed to the death of three further patients between 21 October and 6 November 2009.

At an early stage in its investigations this Inquiry intimated that it would explore what happened in the Ninewells outbreak. The Inquiry could not examine or comment upon individual cases of CDI. It was limited to considering the documentary evidence supplied by Tayside Health Board, in particular the report of the Outbreak Control Team and a number of contemporaneous records and minutes.

Outbreak report

The report of the Ninewells Outbreak Control Team¹²⁴ provides background information on the ward in question. Ward 31 was a 22-bedded medicine for the elderly ward, comprising three six-bedded bays and four side rooms. Patients were usually admitted from acute medical admissions for assessment and discharge either home or to other health or social care settings.¹²⁵ The report notes a general downward trend in CDI over the previous two years in Tayside.¹²⁶

The Outbreak Control Team report also provides a description of the outbreak itself. At the beginning of August a patient in ward 31, who was already known to be *C. difficile* toxin positive, experienced a relapse of symptoms of CDI. The patient was moved to a single room on 6 August and remained there. The strain of *C. difficile* was identified in September as 027.

No further case of CDI was detected in patients in the ward until 16 October. But on 14 October the Infection Control Nurse reported to the Infection Control Doctor that there had been three CDI patients, including the one previously identified in ward 31, in the preceding 30 days. Neither of the other two patients was by then still in ward 31, but testing indicated one of them had the 027 strain.

No other patient with diarrhoea was identified on the ward at that stage. The decision was taken to alert ward and clinical staff to the further 027 cases and to review the situation should another patient develop CDI. From 14 October infection control presence on the ward was increased and four additional infection control education sessions were delivered. Daily observations of infection control practice were carried out and records were kept.

Over the weekend of 17 and 18 October two further patients tested positive for *C. difficile*, and both cases were subsequently identified as 027 strain. They were managed according to the protocol in force and no further admissions were taken on the ward over the weekend. An outbreak was declared on 19 October and the ward was closed to further admissions from that afternoon.¹²⁷

An Outbreak Control Team was formed and met on the afternoon of 20 October, and it was agreed that the ward should remain closed. Full terminal cleaning of the ward took place on 24 and 25 October. A visit by HPS on 29 October did not highlight any omissions, and verbal feedback was provided to the Outbreak Control Team.¹²⁸ Arrangements were

124 [TAY00010001](#)

125 [TAY00010005](#)

126 [TAY00010003](#)

127 [TAY00010009](#)

128 [TAY00010012](#)

made to bring an additional side room back into use and to reduce the number of beds in each bay from six to four. Following the HPS visit, two mattresses failed an integrity test. Although there were no visible signs of damage, the *C. difficile* O27 strain was isolated from one of these mattresses.¹²⁹

The Outbreak Control Team report did not identify a single cause for the outbreak, but it listed potential contributory factors, including environmental issues, use of Proton Pump Inhibitors, and the characteristics of the O27 strain.¹³⁰

A number of actions for future practice emerged from the Outbreak Control Team report. Actions identified included the need to continue to press for compliance with restricted antibiotics, optimal compliance with hand hygiene and the importance of communication with staff, patients and the media.¹³¹

Following completion of the Outbreak Control Team report,¹³² a “lessons learnt” report was presented to the Executive Management Team of Tayside Health Board at its meeting on 22 February 2010.¹³³ The Outbreak Control Team report had been publicly released on 18 February.¹³⁴

The Ninewells Hospital outbreak – the different environment

The Ninewells outbreak occurred in an environment significantly altered by developments since, and in light of, the emergence of the VOLH outbreaks. This rules out direct comparisons between the outbreaks. Nevertheless, the documents examined by the Inquiry, in particular the Outbreak Control Team report, appear to present the following information:

- The outbreak trigger level was identified as soon as it was reached, and steps were therefore taken at an early stage to prevent further spread of infection, including requests for expert assistance from HPS

- The Outbreak Control Team was formed as soon as the outbreak was identified and met regularly, with almost daily updates circulated¹³⁵
- There was detailed monitoring of infection rates¹³⁶
- A close working relationship was in place between the Infection Control Nurse, the Infection Control Doctor and ward staff¹³⁷

18.9 Comparison between the VOLH, Stoke Mandeville, and Maidstone and Tunbridge Wells

The importance of learning lessons

In the foreword to the Stoke Mandeville report the Chairman made the following observations:

“I said in the immediate aftermath of the Bristol report (into children’s cardiac surgical services at Bristol Royal Infirmary) that it was not possible to say with confidence that events such as those which took place at Bristol would not happen again. What happened at Stoke Mandeville demonstrates that they are still happening. Patients died when their deaths could have been avoided. It is a matter of the greatest regret that the lessons of Bristol have not been learned and incorporated into every corner of the NHS”.¹³⁸

The same can be said in this Inquiry Report about the lessons of Stoke Mandeville, and later those of Maidstone and Tunbridge Wells.

List of VOLH issues

The Inquiry has identified at least 20 issues that have come under scrutiny in its own

129 [TAY00010015](#)

130 [TAY00010015](#)

131 [TAY00010017](#)

132 [TAY00010001](#)

133 [TAY00650004](#)

134 [TAY00650002](#)

135 [TAY00040001](#); [TAY00050001](#); [TAY00060001](#); [TAY00070001](#); [TAY00080001](#); [TAY00090001](#); [TAY00100001](#); [TAY00110001](#); [TAY00120001](#); [TAY00130001](#); [TAY00140001](#); [TAY00150001](#); [TAY00160001](#); [TAY00170001](#); [TAY00180001](#); [TAY00190001](#); [TAY00200001](#); [TAY00210001](#); [TAY00220001](#); [TAY00230001](#); [TAY00240001](#); [TAY00250001](#); [TAY00260001](#); [TAY00270001](#); [TAY00280001](#); [TAY00290001](#); [TAY00300001](#); [TAY00310001](#)

136 [TAY00010009](#); [TAY00010034](#)

137 [TAY00010007](#); [TAY00010009](#)

138 [INQ02890004](#)

investigations and are covered in this Report. On all of these there were lessons to be learned from the Stoke Mandeville and Tunbridge Wells reports.

- 1 State of repair of buildings and fabric
- 2 Hand washing facilities
- 3 Isolation of symptomatic patients
- 4 Communication with relatives
- 5 Laundry management
- 6 Provision of single rooms
- 7 Storage
- 8 Local surveillance
- 9 Fluid balance monitoring
- 10 Care planning
- 11 Stool charts
- 12 Training
- 13 Prescription of antibiotics
- 14 Recording of treatment and decisions
- 15 The impact of organisational change on patient safety
- 16 Clinical governance in infection control
- 17 Working relationships within the Infection Control Team
- 18 Management of a hitherto unknown and hypervirulent strain of infection
- 19 Staffing
- 20 Death certification

To a large extent these issues are reviewed in detail elsewhere in this Report, and to do so again here would be unnecessarily repetitive. Reference is made only to three selected examples.

Isolation of patients

Despite the “major lesson” of Stoke Mandeville – “that the immediate isolation of symptomatic patients was crucial to the control of outbreaks of *C. difficile*”¹³⁹ – there is clear evidence that this was not being applied in the VOLH. The Infection Control Manual,

issued in October 2004 and still in force in 2008, provided that for *C. difficile* patients “a risk assessment should be carried out by the ICT (Infection Control Team) to determine if the patient requires isolation nursing”.¹⁴⁰ Yet the practice at the VOLH was not to isolate patients until confirmation that they tested positive for *C. difficile* toxin. As discussed elsewhere in this Report, in a number of instances isolation did not take place even at that stage.

Prescription of antibiotics

The subject of antibiotic prescription is discussed in Chapter 13. It is clear that the general issue of inappropriate prescribing had long been recognised, although action to tackle it had been slow to materialise.

Dr Andrew Seaton, Consultant Physician in Infectious Diseases, NHSGGC, described the VOLH problem as a watershed moment and the point at which a much more strict approach towards antibiotic prescribing was adopted.¹⁴¹ That is no doubt correct. But clear evidence that broad spectrum antibiotics increased the risk of CDI had been in the public domain for a number of years. The Stoke Mandeville report states explicitly that “The restriction of the antibiotics to be prescribed is one of the established means of reducing the risk to patients of contracting *C. difficile*”, and a reduction in prescription of broad spectrum antibiotics had been put in place at Stoke Mandeville as early as 2003.¹⁴² The Maidstone and Tunbridge Wells report contains a recommendation that antibiotics “should be targeted, of the narrowest spectrum possible, and used for the shortest time possible”.¹⁴³ No one who had read those reports could be in doubt about the issue. It was only a “watershed moment” because action had not been taken sooner. Had the message been acted upon at the VOLH earlier, as it could have been, it is likely that the number of people contracting the infection would have been reduced.

140 [GGC00780254](#)

141 [TRA01150116-117](#)

142 [INQ02890026](#)

143 [INQ02870117](#)

139 [INQ02890030](#)

Maintenance and repair

A feature of the outbreaks at both Stoke Mandeville and Maidstone and Tunbridge Wells was the poor state of repair of the buildings, with the increased risk of infection that that entailed. The lack of maintenance at the VOLH, and the consequences of this are considered in Chapter 15 and the consequences of indecision over the hospital's future are raised in Chapter 8. This issue was identified in the local assessment at VOLH¹⁴⁴ but was not the primary focus of that assessment, no doubt because it was the one those involved had least power to alter. Had greater attention been paid at more senior level to the experience set out in those reports, it is likely that the increased risk to patient safety would have been better recognised and more effective steps taken to reduce this.

Relevant findings and recommendations

The Inquiry considers that the findings in the Stoke Mandeville and Maidstone and Tunbridge Wells reports contained important lessons on how the management of CDI could go wrong and how it should be managed. The recommendations in both reports provided valuable guidance which was available in the one case from July 2006, and in the other from October 2007, to be adapted and used elsewhere.

18.10 Conclusion

There was a failure at national and NHSGGC level to utilise the Stoke Mandeville and Maidstone and Tunbridge Wells reports as a basis for timely guidance and for audit and review. This meant that the application of lessons learned from Stoke Mandeville in particular, but also from Maidstone and Tunbridge Wells, was patchy, and was long delayed. Opportunities were lost at national and at Board level to improve the prevention and control of healthcare associated infection by drawing upon particular findings in those reports.

As discussed in Chapter 7 there was a two-year programme of work involved in the production of the Scottish *C. difficile* guidance linked to European guidance that was due to be published in 2008. The HPS approach was entirely appropriate. The production of the checklist based upon lessons to be learned from Stoke Mandeville in particular and subsequently Maidstone and Tunbridge Wells is a different matter. There was undue delay on the part of HPS in producing the kind of advice set out in the checklist. Earlier publication would have served to alert Health Boards to the dangers of the 027 strain and reinforced the importance of effective infection prevention and control measures and prudent prescribing. There was an opportunity missed.

Had NHSGGC considered the findings and recommendations of the Stoke Mandeville report in a more thorough and systematic way, and reviewed practices and implementation of policies in the light of these, many of the factors contributing to the VOLH CDI problem would have been eliminated or at least reduced by 2007. This would have been the case whether NHSGGC had acted on its own initiative or in response to guidance from HPS, NHS QIS or another central body. To a lesser degree the same is true of the Maidstone and Tunbridge Wells report.

The Inquiry draws additional support for its findings and recommendations in the report of the Northern Ireland Public Inquiry. This includes a recommendation that:

“organisational change should be recognised by the (Department of Health, Social Services and Public Safety) DHSSPS as carrying high risk for patient safety and quality of care, including the potential for a sub-optimal response to an outbreak of a healthcare associated infection. At such times of change, this risk should be addressed specifically and reported in the risk register of all trusts”.¹⁴⁵

144 [GGC20710003](#)

145 [INQ04460099](#)

The importance of this issue is given recognition in the Inquiry's own recommendation of due diligence and review in any major structural reorganisation.

Leaving that specific point aside, the Northern Ireland experience does exemplify what can happen if attention is not paid to lessons learned elsewhere. For the future it is therefore important that an effective system should be put in place to enable lessons learned elsewhere to be applied in Scotland in a timely manner.

18.11 Recommendations

Recommendation 74: Scottish Government (whether through HPS, HIS, the HAI Task Force or otherwise) should as a matter of standard practice ensure that reports published in the United Kingdom and in other relevant jurisdictions on infection prevention and control and patient safety are reviewed as soon as possible, and that, as a minimum, any necessary interim guidance is issued within three months.

Recommendation 75: Health Boards should review such reports to determine what lessons can be learned and what reviews, audits or other measures (interim or otherwise) should be put in place in the light of these lessons.

Chapter 19

Conclusion and
Recommendations

Conclusion

This was a lengthy and complicated Inquiry. It was necessary to examine a wide range of topics in order to comply with the terms of the remit. I was determined to carry out as comprehensive an investigation as possible so that a full account could be provided of why the CDI problem at the VOLH was so persistent and devastating. Patients and families had to relive painful experiences in providing statements and giving oral evidence and then had to wait for some considerable time for the publication of the Report. I consider that wait to be highly regrettable but I do firmly believe that the timescales identified throughout the Inquiry process were unrealistic. The extent of the work required to undertake a thorough examination of the many relevant issues cannot be overemphasised. In the event the Inquiry has unearthed serious personal and systemic failures. Patients who suffered from CDI at the VOLH were badly let down by people at different levels of NHSGGC who were supposed to care for them. The Scottish Ministers bear ultimate responsibility for NHSScotland and even at the level of the Scottish Government the systems were simply not adequate to tackle effectively an HAI like CDI. The major single lesson to be learned is that what happened at the VOLH to cause such personal suffering should never be allowed to happen again.

The Report and the recommendations are informed by all the relevant documentation gathered by the Inquiry, the evidence contained in written statements, and the evidence at the oral hearings, including the evidence of the experts who were commissioned to assist the Inquiry. The lessons to be learned are contained within the narrative of the Report and reflected in the recommendations.

Some of the recommendations are directed to aspects of basic nursing care, for example fluid monitoring, care planning, and the

prevention and management of pressure damage. I note from the important inspection work being carried out by Healthcare Improvement Scotland that these aspects of care still feature as sources of criticism, and I make no apology for including recommendations on these issues to reinforce how critical they are to good quality care. Such basic care is integral to compassionate care. The recommendations are not directed against individuals although they will have an impact on individual behaviour. Nevertheless, it is important for individuals such as nurses and doctors to realise that they have a professional responsibility to comply with what is laid down as proper practice by their professional bodies.

There may be some recommendations that have been overtaken by events. For example, as set out in Chapter 15, NHSGGC did introduce more effective reporting systems for CDI after June 2008, but again the message should be reinforced that systems must ensure that important information is relayed from ward to Board

I am convinced that the adoption of the recommendations proposed will result in a significantly improved focus on patient care, and in particular on the care of patients who contract a hospital infection such as CDI. CDI has been the focus of the Inquiry, but I am in no doubt that, although it was the failures in how CDI was managed at the VOLH that governed the work of the Inquiry, the recommendations should have a more far-reaching impact. Indeed the express intention of the Cabinet Secretary when announcing the setting up of the Inquiry was that lessons should be learned across Scotland. The recommendations are designed to encapsulate a concept of patient care that includes skilled and considerate medical and nursing care, transparency, candour, effective systems of infection prevention and control, and strong and dedicated leadership.

Recommendations

Chapter 6 National structures and systems

Recommendation 1: Scottish Government should ensure that the Healthcare Environment Inspectorate (HEI) has the power to close a ward to new admissions if the HEI concludes that there is a real risk to the safety of patients. In the event of such closure, an urgent action plan should be devised with the Infection Prevention and Control Team and management.

Chapter 7 National policies and guidance

Recommendation 2: Scottish Government should ensure that policies and guidance on healthcare associated infection are accompanied by an implementation strategy and that implementation is monitored.

Recommendation 3: Health Boards should ensure that infection prevention and control policies are reviewed promptly in response to any new policies or guidance issued by or on behalf of the Scottish Government, and in any event at specific review dates no more than two years apart.

Recommendation 4: Scottish Government should develop local Healthcare Associated Infection (HAI) Task Forces within each Health Board area.

Chapter 8 Changes in services at the Vale of Leven Hospital from 2002

Recommendation 5: Scottish Government should ensure that where any uncertainty over the future of any hospital or service exists, resolution of the uncertainty is not delayed any longer than is essential for planning and consultation to take place.

Recommendation 6: Scottish Government should ensure that where major changes in patient services are planned there should be clear and effective plans in place for continuity of safe patient care during the period of planning and change.

Chapter 9 The creation, leadership and management of the Clyde Directorate

Recommendation 7: In any major structural reorganisation in the NHS in Scotland a due diligence process including risk assessment

should be undertaken by the Board or Boards responsible for all patient services before the reorganisation takes place. Subsequent to that reorganisation regular reviews of the process should be conducted to assess its impact upon patient services, up to the point at which the new structure is fully operational. The review process should include an independent audit.

Recommendation 8: In any major structural reorganisation in the NHS in Scotland the Board or Boards responsible should ensure that an effective and stable management structure is in place for the success of the project and the maintenance of patient safety throughout the process.

Chapter 10 Clinical governance

Recommendation 9: Health Boards should ensure that infection prevention and control is explicitly considered at all clinical governance committee meetings from local level to Board level.

Chapter 11 The experiences of patients and relatives

Recommendation 10: Health Boards should ensure that patients diagnosed with CDI are given information by medical and nursing staff about their condition and prognosis. Patients should be told when there is a suspicion they have CDI, and when there is a definitive diagnosis. Where appropriate, relatives should also be involved.

Recommendation 11: Health Boards should ensure that patients, and relatives where appropriate, are made aware that CDI is a condition that can be life-threatening, particularly in the elderly. The consultant in charge of a patient's care should ensure that the patient and, where appropriate, relatives have reasonable access to fully informed medical staff.

Recommendation 12: Health Boards should ensure that when a patient has CDI patients and relatives are given clear and proper advice on the necessary infection control precautions, particularly hand washing and laundry. Should it be necessary to request relatives to take soiled laundry home, the laundry should be bagged appropriately and

clear instructions about washing should be given. Leaflets containing guidance should be provided, and these should be supplemented by discussion with patients and relatives.

Chapter 12 Nursing care

Recommendation 13: Health Boards should ensure that there is a clear and effective line of professional responsibility between the ward and the Board.

Recommendation 14: Health Boards should ensure that the nurse in charge of each ward audits compliance with the duty to keep clear and contemporaneous patient records. Health Boards should ensure that there is an effective system of audit of patient records, and that there is effective scrutiny of audits by the Board.

Recommendation 15: Health Boards should ensure that nursing staff caring for a patient with CDI keep accurate records of patient observations including temperature, pulse, respiration, oxygen saturation and blood pressure.

Recommendation 16: Health Boards should ensure that the nurse in charge of each ward reports suspected outbreaks of CDI (as defined in local guidance) to the Infection Control Team.

Recommendation 17: Health Boards should ensure that where there is risk of cross infection, the nurse in charge of a ward has ultimate responsibility for admission of patients to the ward or bay. Any such decision should be based on a full report of the patient's status and full discussion with site management, the bed manager, and a member of the Infection Control Team. The decision and the advice upon which the decision is based should be fully recorded contemporaneously.

Recommendation 18: Health Boards should ensure that there is an agreed system of care planning in use in every ward with the appropriate documentation available to nursing staff. Where appropriate they should introduce pro forma care plans to assist nurses with care planning. Health Boards should ensure that there is a system of audit of care planning in place.

Recommendation 19: Health Boards should ensure that where Infection Control Nurses provide instructions on the management of patients those instructions are recorded in the patient notes and are included in care planning for the patient.

Recommendation 20: Health Boards should ensure that where a patient has, or is suspected of having, *C. difficile* diarrhoea a proper record of the patient's stools is kept. Health Boards should ensure that there is an appropriate form of charting of stools available to enable nursing staff to provide the date, time, size and nature of the stool. Stool charts should be continued after a patient has become asymptomatic of diarrhoea in order to reduce the risk of cross infection. Health Boards should ensure that all nursing staff are properly trained in the completion of these charts, and that the nurse in charge of the ward audits compliance.

Recommendation 21: Health Boards should ensure that a member of nursing staff is available to deal with questions from relatives during visiting periods.

Recommendation 22: Health Boards should ensure that any discussion between a member of nursing staff and a relative about a patient which is relevant to the patient's continuing care is recorded in the patient's notes to ensure that those caring for the patient are aware of the information given.

Recommendation 23: Health Boards should ensure that a nurse appointed as Tissue Viability Nurse (TVN) is appropriately trained and possesses, or is working towards, a recognised specialist post-registration qualification. Health Boards should ensure that a trainee TVN is supervised by a qualified TVN.

Recommendation 24: Health Boards should ensure that where a TVN is involved in caring for a patient there is a clear record in the patient notes and care plan of the instructions given for management of the patient.

Recommendation 25: Health Boards should ensure that every patient is assessed for risk of pressure damage on admission to hospital using a recognised tool such as the Waterlow Score in accordance with best practice guidance. Where patients are identified as at risk they must be reassessed at the frequency identified by the risk scoring system employed. Compliance should be monitored by a system of audit.

Recommendation 26: Health Boards should ensure that where a patient has a wound or pressure damage there is clear documentation of the nature of the wound or damage in accordance with best practice guidance, including the cause, grade, size and colour of the wound or damage. The pressure damage or wound should be reassessed regularly according to the patient's condition. Compliance should be monitored by a system of audit.

Recommendation 27: Health Boards should ensure that where a patient requires positional changes nursing staff clearly record this on a turning chart or equivalent. Compliance should be monitored by a system of audit.

Recommendation 28: Health Boards should ensure that all patients have their nutritional status screened on admission to a ward using a recognised nutritional screening tool. Where nutritional problems are identified further assessment should be undertaken to determine an individual care plan. Appropriate and timely referrals should be made to dieticians for patients identified as being in need of specialist nutritional support.

Recommendation 29: Health Boards should ensure that there is appropriate equipment in each ward to weigh all patients. Patients should be weighed on admission and at least weekly thereafter and weights recorded. Faulty equipment should be repaired or replaced timeously and a contingency plan should be in place in the event of delays.

Recommendation 30: Health Boards should ensure that where patients require fluid monitoring as part of their clinical care,

nursing staff complete fluid balance charts as accurately as possible and sign them off at the end of each 24-hour period.

Recommendation 31: Health Boards should ensure that the staffing and skills mix is appropriate for each ward, and that it is reviewed in response to increases in the level of activity/patient acuity and dependency in the ward. Where the clinical profile of a group or ward of patients changes, (due to acuity and/or dependency) an agreed review framework and process should be in place to ensure that the appropriate skills base and resource requirements are easily provided.

Recommendation 32: Health Boards should ensure that there is a straightforward and timely escalation process for nurses to report concerns about the staffing numbers/skill mix.

Recommendation 33: Health Boards should ensure that where a complaint is made about nursing practice on a ward this complaint is investigated by an independent senior member of Nursing Management.

Chapter 13 Antibiotic prescribing

Recommendation 34: Health Boards should ensure that changes in policy and/or guidance on antimicrobial practice issued by or on behalf of Scottish Government are implemented without delay.

Recommendation 35: Scottish Government should monitor the implementation of policies and/or guidance on antibiotic prescribing issued in connection with healthcare associated infection and seek assurance within specified time limits that implementation has taken place.

Chapter 14 Medical care

Recommendation 36: Health Boards should ensure that the level of medical staffing planned and provided is sufficient to provide safe high quality care.

Recommendation 37: Health Boards should ensure that any patient with suspected CDI receives full clinical assessment by senior medical staff, that specific antibiotic therapy

for CDI is commenced timeously and that the response to antibiotics is monitored on at least a daily basis.

Recommendation 38: Health Boards should ensure that clear, accurate and legible patient records are kept by doctors, that records are seen as integral to good patient care, and that they are routinely audited by senior medical staff.

Recommendation 39: Health Boards should ensure that medical and nursing staff are aware that a DNAR decision is an important aspect of care. The decision should involve the patient where possible, nursing staff, the consultant in charge and, where appropriate, relatives. The decision should be fully documented, regularly reviewed and there should be regular auditing of compliance with the DNAR policy.

Recommendation 40: Health Boards should ensure that the key principles of prudent antibiotic prescribing are adhered to and that implementation of policy is rigorously monitored by management.

Recommendation 41: Health Boards should ensure that there is no unnecessary delay in processing laboratory specimens, in reporting positive results and in commencing specific antibiotic treatment. Infection control staff should carry out regular audits to ensure that there are no unnecessary delays in the management of infected patients once the diagnosis is confirmed.

Chapter 15 Infection prevention and control

Recommendation 42: Health Boards should ensure that all those working in a healthcare setting have mandatory infection prevention and control training that includes CDI on appointment and regularly thereafter. Staff records should be audited to ensure that such training has taken place.

Recommendation 43: Health Boards should ensure that Infection Control Nurses and Infection Control Doctors have regular training in infection prevention and control, of which a record should be kept.

Recommendation 44: Health Boards should ensure that performance appraisals of infection prevention and control staff take place at least annually. The appraisals of Infection Control Doctors who have other responsibilities should include specific reference to their Infection Control Doctor roles.

Recommendation 45: Health Boards should ensure that where a manager has responsibility for oversight of infection prevention and control, this is specified in the job description.

Recommendation 46: Health Boards should ensure that the Infection Control Manager has direct responsibility for the infection prevention and control service and its staff.

Recommendation 47: Health Boards should ensure that the Infection Control Manager reports direct to the Chief Executive, or at least to an executive board member.

Recommendation 48: Health Boards should ensure that the Infection Control Manager is responsible for reporting to the Board on the state of healthcare associated infection in the organisation.

Recommendation 49: Scottish Government should re-issue national guidance on the role of the Infection Control Manager, stipulating that the Infection Control Manager must be responsible for the management of the infection prevention and control service.

Recommendation 50: Health Boards should ensure that there is 24-hour cover for infection prevention and control seven days a week, and that contingency plans for leave and sickness absence are in place.

Recommendation 51: Health Boards should ensure that any Infection Control Team functions as a team, with clear lines of communication and regular meetings.

Recommendation 52: Health Boards should ensure that adherence to infection prevention and control policies, for example the *C. difficile* and Loose Stool Policies, is audited at least annually, and that serious non-adherence is reported to the Board.

Recommendation 53: Health Boards should ensure that surveillance systems are fit for purpose, are simple to use and monitor, and provide information on potential outbreaks in real time.

Recommendation 54: Health Boards should ensure that the users of surveillance systems are properly trained in their use and fully aware of how to use and respond to the data available.

Recommendation 55: Health Boards should ensure that numbers and rates of CDI are reported through each level of the organisation up to the level of the Chief Executive and the Board. Reporting should include positive reporting in addition to any exception reporting. The Chief Executive should sign off the figures to confirm that there is oversight of infection prevention and control at that level.

Recommendation 56: Health Boards should ensure that infection prevention and control groups meet at regular intervals and that there is appropriate reporting upwards through the management structure.

Recommendation 57: Health Boards should ensure that the minutes of all meetings and reports from each infection prevention and control committee are reported to the level above in the hierarchy and include the numbers and rates of CDI, audit reports, and training reports.

Recommendation 58: Health Boards should ensure that there is lay representation at Board infection prevention and control committee level in keeping with local policy on public involvement.

Recommendation 59: Health Boards should ensure that attendance by members of committees in the infection prevention and control structure is treated as a priority. Non-attendance should only be justified by illness or leave or if there is a risk of compromise to other clinical duties in which event deputies should attend where practicable.

Recommendation 60: Health Boards should ensure that programmes designed to improve staff knowledge of good infection prevention and control practice, such as the Cleanliness Champions Programme, are implemented without undue delay. Staff should be given protected time by managers to complete such programmes.

Recommendation 61: Health Boards should ensure that unannounced inspections of clinical areas are conducted by senior infection prevention and control staff accompanied by lay representation to examine infection prevention and control arrangements, including policy implementation and cleanliness.

Recommendation 62: Health Boards should ensure that senior managers accompanied by infection prevention and control staff visit clinical areas at least weekly to verify that proper attention is being paid to infection prevention and control.

Recommendation 63: Health Boards should ensure that there is effective isolation of any patient who is suspected of suffering from CDI, and that failure to isolate is reported to senior management.

Recommendation 64: Health Boards should ensure that cohorting is not used as a substitute for single room isolation and is only resorted to in exceptional circumstances and under strict conditions of dedicated nursing, with infected patients nursed in cohort bays with en-suite facilities.

Recommendation 65: Health Boards should ensure that appropriate steps are taken to isolate patients with potentially infectious diarrhoea.

Recommendation 66: Health Boards should ensure that the healthcare environment does not compromise effective infection prevention and control, and that poor maintenance practices, such as the acceptance of non-intact surfaces that could compromise effective infection prevention and control practice, are not tolerated.

Recommendation 67: Health Boards should ensure that, where a local Link Nurse system is in place as part of the infection prevention and control system, the Link Nurses have specific training for that role. The role should be written into job descriptions and job plans. They should have clear objectives set annually and have protected time for Link Nurse duties.

Chapter 16 Death certification

Recommendation 68: Health Boards should ensure that where a death occurs in hospital the consultant in charge of the patient's care is involved in the completion of the death certificate wherever practicable, and that such involvement is clearly recorded in the patient records. Regular auditing of this process should take place.

Recommendation 69: Health Boards should ensure that if a patient dies with CDI either as a cause of death or as a condition contributing to the death, relatives are provided with a clear explanation of the role played by CDI in the patient's death.

Recommendation 70: Crown Office and the Procurator Fiscal Service (COPFS) should review its guidance on the reporting of deaths regularly and at least every two years.

Recommendation 71: Scottish Government should identify a national agency to undertake routine national monitoring of deaths related to CDI.

Chapter 17 Investigations from May 2008

Recommendation 72: Health Boards should ensure that a non-executive Board member or a representative from internal audit takes part in an Internal Investigation of the kind instigated by NHSGGC.

Recommendation 73: Health Boards should ensure that OCT reports provide sufficient details of the key factors in the spread of infection to allow a proper audit to be carried out, as recommended in the Watt Group Report.

Chapter 18 Experiences of *C. difficile* infection within and beyond Scotland

Recommendation 74: Scottish Government (whether through HPS, HIS, the HAI Task Force or otherwise) should as a matter of standard practice ensure that reports published in the United Kingdom and in other relevant jurisdictions on infection prevention and control and patient safety are reviewed as soon as possible, and that, as a minimum, any necessary interim guidance is issued within three months.

Recommendation 75: Health Boards should review such reports to determine what lessons can be learned and what reviews, audits or other measures (interim or otherwise) should be put in place in the light of these lessons.

Appendices

Appendix 1

Patients for whom individual expert reports were commissioned

Anne Agnew	Irene Harnett	Julia Monhan
Jean Beattie	Catherine Hitchinson	Patient A
John Boyle	William Hunter	Patient B
Alister Brand	Annie Johnson	Patient C
Mary Broadley	Alister Johnston	Patient D
Agnes Burgess	Jessie Jones	Jacqueline Patrick
Mary Burns	Margaret Kelly	Ellen Pirog
Rose Burns	Isabella Lettis	Elizabeth Rainey
Isobel Cameron	Allan Lynch	Rosa Rainey
Agnes Campbell	Agnes MacFarlane	Evelyn Scott-Adamson
Dureena Chandayly	Matthew Macfarlane	Walter Scullion
Coleman Conroy	Alexander McDonald	Annie Shaw
Charles Cook	Mary McDougall	Doris Smith
Margaret Dalton	Sarah McGinty	David Somerville
Edward Docherty	Thomas McGowan	Margaret Stevenson
Jeanie Dow	Martha McGregor	Catherine Stewart
George Drummond	Archibald McInally	Margaret Thompson
Janet Fitzsimmons	William McKenzie	James Thomson
Margaret Gaughan	Moira McWilliams	Elizabeth Valentine
Ellen Gildea	Mary Millen	Muriel Waddell
Anne Gray	Christina Miller	Catherine Wrethman
Mary Hamilton	John Miller	

Appendix 2

The Inquiry Team

Chairman of the Vale of Leven Hospital Inquiry – the Right Honourable Lord MacLean

Lord MacLean was admitted to the Faculty of Advocates in 1964 and became a Queen's Counsel (QC) in 1977. He was appointed a Senator of the College of Justice in 1990. In April 2001 he was appointed to the Inner House of the Court of Session and was also sworn as a member of Her Majesty's Privy Council. He retired as a judge in 2005.

His previous appointments and appearances relevant to the Chairmanship of this Inquiry include:

Membership of the Stewart Committee on Alternatives to Prosecution for Minor Offences (1977 – 1983);

Senior Counsel in the Piper Alpha Inquiry (1989 – 1990) where he represented those who survived the Disaster and the relatives of those who died in it;

Membership of the Parole Board for Scotland (1998 – 2000, 2003);

Chairman of the Committee on Serious Violent and Sexual Offenders (1999 – 2000);

One of the Judges who presided at the Lockerbie Trial at Camp Zeist (2000 – 2001);

Membership of the Judicial Appointments Board for Scotland (2002 – 2005);

Chairman of the Sentencing Commission for Scotland (2003 – 2005);

Chairman of the Billy Wright Inquiry in Northern Ireland (2004 – 2010).

Assessor to the Inquiry – Mrs Mary Waddell OBE

Mrs Mary Waddell is a Registered General Nurse and clinical teacher. Following completion of her general nurse training, Mrs Waddell held staff nurse posts in theatres and neurological nursing prior to completing midwifery training and two years in central Africa.

On return, a career in intensive care nursing followed with ten years being Sister in Charge of an intensive care unit in the Mater Hospital, Belfast. Mrs Waddell held a Nursing Officer post and then became Director of Nursing at the Mater.

In 1990, Mrs Waddell was appointed Director of Nursing at the Eastern Health and Social Services Board, a post she held until retirement. Mrs Waddell has wide clinical experience in key branches of nursing and commissioning at Trust, Board and Regional level. She has led a number of projects that significantly impacted on patient care at local and national level (wound management, continence, workforce planning, emergency planning and complaints).

Mrs Waddell was Nurse Advisor to the Regional Medical Services Committee, a group that had responsibility for commissioning all regional specialist services. She has provided advice, guidance and reports at Board level to allow them to meet their statutory responsibilities. Mrs Waddell had a key responsibility for standard setting and ensuring quality standards were met by Trusts. She chaired regional professional and educational groups.

Mary Waddell was awarded an OBE for services to Nursing in the 2002 New Year's Honours list.

Assessor to the Inquiry – Dr Geoff Ridgway OBE

Dr Geoff Ridgway was until recently a consultant to the Health Protection Branch and the Estates and Facilities Branch at the Department of Health, London. He was appointed OBE for services to Microbiology in the New Year’s Honours list December 2008.

Dr Ridgway qualified BSc Special Zoology in 1966 and went on to study Medicine at the Royal Free Hospital School of Medicine, qualifying MB BS in 1971. He specialised in Medical Microbiology, obtaining MD by thesis in 1977, at which time he was appointed Consultant in Clinical Microbiology at

University College London Hospitals; a post held until retirement in March 2004. He is a Fellow of both the Royal College of Pathologists and the Royal College of Physicians. He holds an Honorary Diploma in Hospital Infection Control, and was an Honorary Senior Lecturer at University College and at the School of Hygiene and Tropical Medicine, University of London.

His career encompassed the diagnosis and management of infectious diseases, with a special interest in genito-urinary bacterial infections. Other research interests included Hospital Infection Control and sterilization and disinfection technology.

Senior Counsel	Colin MacAulay
Junior Counsel	Lauren Sutherland
Solicitor	Nigel Orr
Deputy Solicitor	Andrea Summers Felicity Cullen – until May 2011
Secretary	Julie-Anne Jamieson
Deputy Secretary	Mark Dorrian
Document Manager	Alan Owenson
Witness Liaison Manager/ Analysis & Evidence Manager	Lynne Allan
Legal Assistant	Leeon Fleming
Office Manager	Ann Pullar Nicola Scammell – until July 2012 Lorna Innes – until March 2011
Witness Statement Team Leader	Peter Ritchie
Witness Statement Taker	Andrew Gibson
Specialist Support Officer	Nicola Keys
Specialist Support Officer	Emma Filshie
Administrative Support Officer	Agata Myszka

Appendix 3

Core Participants and their legal representation

Core Participant	Recognised legal representative	Senior Counsel and Junior Counsel
Greater Glasgow Health Board (also known as NHS Greater Glasgow and Clyde)	Robbie Wightman, Solicitor, NHS Central Legal Office	Alastair Kinroy QC Brian Gill, Advocate
Health Facilities Scotland	Stefano Rinaldi, Solicitor, NHS Central Legal Office	Simon Bowie QC Alasdair Burnet, Advocate
Health Protection Scotland	Stefano Rinaldi, Solicitor, NHS Central Legal Office	Simon Bowie QC Alasdair Burnet, Advocate
Medical and Dental Defence Union of Scotland	Laura Donald, Solicitor Advocate, BTO, Edinburgh	Dame Elish Angiolini QC
Royal College of Nursing	Chris Dickson, Solicitor Advocate, Anderson Strathern, Edinburgh	N/A
Scottish Ministers	Murray Sinclair, Solicitor to the Scottish Government, Scottish Government Legal Directorate	Alan Dewar QC Kay Springham, Advocate
Tayside Health Board (until December 2010)	Lorna McPhail, Solicitor, NHS Central Legal Office	Alastair Kinroy QC Catherine Devaney, Advocate
Patients and Relatives Jean Beattie Gareth Bourhill Brenda Bowes Sheila Chandler Anne Chisholm Marion Copland Brian Gaughan George Hamilton Margaret Harnett Joanne Harvey David Logan Allan Lynch Agnes MacFarlane Alexander McDonald Anne McDonald Anne McGarrity Michelle McGinty Enid McMurdo Carol Moore Maria Shaw Anna Squires Linsey MacFarlane (replacing Agnes MacFarlane) Marjory Cambridge (replacing Brian Gaughan)	Patrick McGuire, Solicitor Advocate, Thompsons, Glasgow	Jim Peoples QC Gordon Lamont, Advocate

Appendix 4

Expert witnesses instructed by the Inquiry

Ms Elizabeth Colgan

Elizabeth Colgan, RGN, RMN, ANDIP is Head of Programme of the Infection Prevention/ Hygiene Team in the Regulation and Quality Improvement Authority, Northern Ireland. She was commissioned by the Inquiry to provide written reports on the nursing care of seven focus patients who had contracted *C. difficile*, and to provide a separate overview report of her findings. Ms Colgan has extensive nursing experience and is involved in the inspection of hospitals and community facilities in relation to infection control and environmental cleanliness. She is also involved in the development and review of policies and procedures in relation to infection control and environmental cleanliness. She has recently led a series of inspections which focus on the care provided for the older person in the acute hospital setting, and has been given the responsibility for leading the development of a new programme of hospital inspection across Northern Ireland.

Ms Elaine Connolly

Elaine Connolly RGN, BSc is a Senior Inspector for the Independent Health Care Team in the Regulation and Quality Improvement Authority, Northern Ireland. She was commissioned by the Inquiry to provide written reports on the nursing care of five focus patients who had contracted *C. difficile*, and to provide a separate overview report of her findings. Ms Connolly is a qualified nurse, has been a registered manager of Nursing Homes and has had extensive experience in the senior management of the inspection of independent healthcare settings.

Dr Martin Connor

Dr Martin Connor MSc, MBChB, FRCPath, FFPH, DTM&H is a Consultant Microbiologist at Dumfries and Galloway Royal Infirmary. He was commissioned by the Inquiry to provide written microbiology reports on 18 focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. A Consultant Microbiologist since 1998, Dr Connor has extensive audit and management experience as well as experience of teaching medical students, junior doctors and nurses. Dr Connor to date has carried out a variety of research projects and produced a large number of publications.

Professor Brian Duerden

Professor Brian Duerden CBE, BSc (Hons, Med. Sci.), MD, FRCPath, FRCPEdin, was Inspector of Microbiology and Infection Control at the Department of Health until December 2010. He was responsible for clinical and public health microbiology services and was the clinical director for the HCAI programme. He is emeritus Professor of Medical Microbiology at Cardiff University and a Visiting Professor at Imperial College, London. Professor Duerden has provided the Vale of Leven Hospital Inquiry with expert microbiology advice with regard to the number of cases of *C. difficile* that occurred at the VOLH during 2007 and 2008. He has written a report reviewing the infection control arrangements at the VOLH during this period, and provided commentary on reports into the outbreak of *C. difficile* at the VOLH between December 2007 and June 2008 and a review of transcripts. Before moving to the Department of Health in 2004, Professor Duerden was Medical Director and Director of Service in the Public Health Laboratory Service and Director for Clinical Quality in the Health Protection Agency. His major interests are in anaerobic microbiology, healthcare associated infection and antibiotic resistance. He has published over 150 scientific papers, edited and contributed to several textbooks and served for 20 years as Editor in Chief of the Journal of Medical Microbiology. He was awarded CBE for services to medicine and charity in 2008.

Mr William Evans

William Evans RGN, PG Diploma, BSc is a Clinical Nurse Specialist in Infection Prevention and Control and Geographical Lead for the West Team based at St John's Hospital, Livingston. He was commissioned by the Inquiry to provide written reports on the nursing care of nine focus patients and one other patient who had contracted *C. difficile*, and to provide a separate overview report of his findings. Mr Evans is an experienced Registered Nurse with specialist experience in infection prevention and control. He also has previous operational management experience covering all aspects of care within elderly wards and day hospitals, with specific responsibility for the development of standards and audits.

Professor George Griffin

Professor George Griffin BSc, PhD, FRCP, FRCP(E), FRCPath, F.Med Sci, practises as a consultant physician in infectious diseases and general internal medicine at St George's, University of London. Working within the clinical infection unit he receives local, national and international referrals. He is also Professor of Infectious Diseases and Medicine and heads up the Academic Centre for Infection at St George's. Professor Griffin was commissioned by the Inquiry to carry out an analysis of the medical records of focus patients, as well as of a number of statistical patients, and to consider the role of *C. difficile* as a cause of death or a contributory factor to death. He provided a report on each of the 44 individual cases examined by him, and in addition produced an overview report of his findings in relation to death certification. Professor Griffin is the Chair of the Advisory Committee on Dangerous Pathogens (ACDP) and the special advisor to the government emergency committee called SAGE. He also chairs the committee for the Health and Safety Executive. Professor Griffin has extensive medical administration and teaching experience and has produced over 240 publications, given over 60 national and international guest lectures and held over 40 research grants.

Dr Mary Harrington

Dr Mary Harrington BA (Hons), MB, BS, MA (Oxon), MRCP, FRCP is a Consultant Geriatrician who has held consultant posts in London, Yorkshire and Manchester. She was commissioned by the Inquiry to provide written reports on the medical care of nine focus patients and one other patient who had contracted *C. difficile*, and to provide a separate overview report of her findings. Dr Harrington has extensive experience of acute and rehabilitation services for elderly patients, including orthogeriatrics, and as a community geriatrician. She served for over ten years on her hospital Mortality Review Committee, which scrutinises the care of all patients who die in the hospital. She was an expert panel member for Operation Jasmine, a police inquiry into care in nursing homes in South Wales, and is regularly instructed as an expert witness by coroners in England and Wales.

Ms Annette Jeanes

Ms Annette Jeanes RGN, SCM, ENB 100, 934, 998, Diploma in Nursing, Diploma in Infection Control, MSc is the Director of Infection Prevention and Control, University College London Hospitals Foundation Trust. She was commissioned by the Inquiry to provide written reports on the nursing care of ten focus patients who had contracted *C. difficile*, and to provide a separate overview report of her findings. Ms Jeanes has extensive experience as an expert witness and undertakes consultancy work. As well as being heavily involved in current infection control research, she has produced numerous publications and is a regular guest speaker at conferences and events with subjects ranging from cleaning to change management.

Dr Mike Jones

Dr Mike Jones BSc (Hons), MB, ChB, MD (Hons), FRCP (Edin), FRCP, FRCPS (G) is a Consultant in Acute Medicine at the University Hospital of North Durham. He is Director of Standards at the Royal College of Physicians of Edinburgh having previously been Vice President. He is National Clinical lead for ACUMEN e-learning project, and lead of the educational workstream of the national acute kidney injury project. He was commissioned by the Inquiry to provide written reports on the medical care of 13 focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr Jones has specialised in Acute General Medicine since 1998 and has extensive medical administration and teaching experience. He has produced some 80 articles, chapters, reports and presentations. He is also an External Examiner for International MRCP examinations, and was previously Clinical Specialty Advisor in General Medicine to the Chief Medical Officer for Scotland.

Professor Kevin Kerr

Professor Kevin Kerr BSc, MB, ChB, MD, FRCPATH, FRSPH is Consultant Microbiologist and Director of Infection Control at Harrogate and District NHS Foundation Trust, where he created the *C. difficile* Rapid Response Team. He was commissioned by the Inquiry to provide written microbiology reports on eight focus patients and one other patient who had contracted *C. difficile*, and to provide a separate overview report of his findings. He has published extensively and given a large number of presentations at national/international meetings in relation to infection control. He is Reviews Editor of the "Journal of Hospital Infection". He sits on the International Advisory Board of the Journal of Clinical Pathology and also the Association of Clinical Pathologists' Microbiology Committee. He is Honorary Clinical Professor of Microbiology at Hull York Medical School and an affiliate of the Centre for Immunology and Infection, University of York.

Dr Alan MacDonald

Dr Alan MacDonald BSc (Hons), MBChB, MSc MRCPATH, FRCPATH, is an Infection Prevention and Control Doctor/Consultant Microbiologist for NHS Ayrshire and Arran. He was commissioned by the Inquiry to provide written microbiology reports on six focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr MacDonald has extensive experience of microbiology in hospital settings, is a member of a number of professional bodies, and has produced several publications on infection control.

Dr Simon Mackenzie

Dr Simon Mackenzie is Divisional Medical Director, NHS Lothian, University Hospitals Division, and Consultant in Intensive Care in the Royal Infirmary, Edinburgh. He was commissioned by the Inquiry to provide a report on death certification where the patient has suffered from *C. difficile*. He was asked to provide details of policy, practice and guidance on death certification in 2007 to 2008 and to specific changes in policy, practice and guidance since then. Dr Mackenzie is Honorary Clinical Senior Lecturer at University of Edinburgh and an Examiner for the UK and European Diplomas in Intensive Care Medicine. He was also past-President of the Scottish Intensive Care Society and is a Specialist Adviser to the Scottish Medicines Consortium and the National Institute of Clinical Excellence.

Professor Anthony Palmer

Professor Anthony Palmer RGN, BSc, Diploma Nursing, PGCE, RNT was until recently Executive Director of Nursing and Deputy Chief Executive at Luton and Dunstable Hospital NHS Foundation Trust. He is currently an Independent Nursing Consultant and Expert Witness. Professor Palmer was commissioned by the Inquiry to provide written nursing reports on ten focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Professor Palmer is on the approved NHSLA List as a Nursing Expert and a member of the Expert Witness Institute with expertise in nursing care of the elderly. He is accredited with the Royal College of Nursing as a Nursing Expert and also a Clinical Advisor/Associate for the Care Quality Commission.

Mrs Lynne Phair

Lynne Phair MA, BSc (Hons), RMN, RGN, DPNS, IP is an Independent Consultant Nurse for Older People. From January 2010 to October 2010 she was a member of the Expert Medical Advisory Group to the *C. difficile* Public Inquiry, Northern Health and Social Care Trust, Northern Ireland. Mrs Phair has acted as an Expert Witness since 1993, and has provided expert nursing reports for a number of institutions including coroners, Police, Crown Prosecution Service, Court of Protection and the High Court. She has published over 50 books, chapters and articles since 1989. The Inquiry commissioned Mrs Phair to provide written reports on 11 focus patients and one other patient. She also provided an overview report setting out the principles of nursing older people and fundamental care and an evaluation as well as summary report of the care of an additional 35 patients with CDI in the early period of the Inquiry's investigation.

Mrs Christine Perry

Christine Perry RGN, MSc Nursing, is Director of Nursing and Director of Infection Prevention and Control at Weston Area Health NHS Trust. Mrs Perry has extensive nursing experience and became an Infection Control Nurse in 1995, being promoted to Senior Infection Control Nurse in 1998 and to Nurse Consultant in Infection Control in 2002. In 2004 she was one of the first Infection Control Nurses to be appointed as Director of Infection Prevention and Control. She was commissioned by the Inquiry to write a report on nursing structures at the VOLH, and was asked specifically to focus on staffing and management structures, infection control, hygiene/cleanliness, and communication. Mrs Perry is a former Chair of the Infection Control Nurses' Association and has been a member of national committees and advisory groups. She also provided the infection control nurse expertise to the Health Care Commission for its investigations into *C. difficile* at Stoke Mandeville Hospital and at Maidstone and Tunbridge Wells NHS Trust.

Professor Ian Poxton

Professor Ian Poxton BSc, PhD, DSc was Professor of Microbial Infection and Immunity at the University of Edinburgh until his retirement in December 2012, and is now Professor Emeritus. He provided a report outlining what *C. difficile* is and how it is acquired, the experience of, and data on, *C. difficile* outwith the UK, and future developments in the treatment and prevention of *C. difficile* infection. His major research interests are in bacterial pathogens. Professor Poxton has taught extensively as a postgraduate supervisor and published extensively on infection control and specifically on *C. difficile*. He is a member of a number of national and regional societies and committees.

Dr James Reid

Dr James Reid BA, BM, BCh, MRCP holds a Postgraduate Certificate in Managing Health and Social Care, and is Consultant in Integrated Medicine at Leicester Royal Infirmary. He specialises in General Medicine and Geriatric Medicine with special interest in orthogeriatric liaison and rehabilitation and postural stability and falls in the elderly. He was commissioned by the Inquiry to provide written reports on the medical care of 11 focus patients and one other patient who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr Reid has extensive clinical management experience and has produced a number of publications. In 2007 he helped produce the operational policy for a 22 bed Isolation Ward in response to high levels of hospital acquired *C. difficile* infection at the University Hospitals Leicester NHS Trust. Since the ward was opened in-hospital mortality, stay duration following CDT diagnosis, and readmissions have all reduced.

Professor Chris Robertson

Professor Chris Robertson BSc, MSc, PhD is Professor of Public Health Epidemiology, Mathematics and Statistics at Strathclyde University, Glasgow. He was commissioned to provide a statistical analysis of data supplied by the Inquiry. The main aims of this analysis were to investigate the temporal and ward patterns of diagnoses and testing for *C. difficile*, and to investigate the temporal and ward patterns of deaths among *C. difficile* patients. Professor Robertson is an applied statistician with interests in the application of statistics over a wide variety of disciplines. His main current research interest is in statistical modelling of infectious diseases and in epidemiological studies.

Dr Ray Sheridan

Dr Ray Sheridan BSc (Hons), MRCP is a Consultant Physician in General Medicine and Medicine for the Elderly with special interests in falls and movement disorders. He also has teaching responsibilities for the Peninsula Medical School at the Royal Devon and Exeter Hospital. Dr Sheridan looks after a general and geriatric medicine ward where cases of infections such as *C. difficile* are cohorted. He is also responsible for weekly multidisciplinary *C. difficile* ward rounds jointly with Infection Control, Pharmacy and Microbiology. He was commissioned by the Inquiry to provide written reports on the medical care of 11 focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr Sheridan worked on the Regulation and Quality Improvement Authority Independent Review of the *C. difficile* outbreak in Northern Ireland. He has published a paper on assessing *C. difficile* severity and mortality risk factors.

Mr Alex Smith

Alex Smith CPFA is a chartered public finance accountant and is currently a non-executive member of a number of boards and committees in NHS 24, the Scottish Public Pensions Agency, Transport Scotland and the Scottish Government. Mr Smith was commissioned by the Inquiry to provide a report on a number of management issues, including the way in which the Clyde area hospitals were brought within the management responsibility of Greater Glasgow Health Board. His report covers such matters as management within the Clyde Directorate, clinical governance arrangements and general oversight of infection control within Greater Glasgow and Clyde, and policy and guidance issued by NHSScotland on healthcare acquired infection. Mr Smith has worked in the NHS in Scotland since 1974 and has held several senior finance and management roles.

Dr Sheldon Stone

Dr Sheldon Stone BSc, MBBS, MD, FRCP is a General Physician for Older People, Stroke Physician and Senior Lecturer at the Royal Free Hampstead NHS Trust. He provided the Inquiry with preliminary guidance and created a framework within which the Inquiry went on to extend its research and investigation. Dr Stone is a Staff Governor of the Royal Free NHS Foundation Trust and Founding Member of the Hand Hygiene Alliance. He was secretary of the Department of Health/Health Protection Agency Joint Working Group on the prevention and management of *Clostridium difficile* infection. He has led an evaluation of the contribution of the national Cleanyourhands campaign in England to the reduction of *C. difficile* infection.

Mrs Sharon Stower

Mrs Sharon Stower RGN, MA, MBA (Health), Dip HSM, Cert MHS is an Independent Nursing and Health Care Consultant who has carried out work for the Royal College of Nursing (RCN) and the NHS. She is listed on the RCN Expert Witness database. Mrs Stower was commissioned by the Inquiry to provide written reports on the nursing care of nine focus patients who had contracted *C. difficile*, and to provide a separate overview report of her findings. As an experienced Director of Nursing she has worked extensively in both public and independent health care sectors and has worked for the Health Care Commission as a Clinical Nurse Advisor/Expert.

Dr Louise Teare

Dr Louise Teare MB BS, MSc, MBA, NEBOSH holds a Diploma in Hospital Infection Control, a Cardiff Expert Witness Certificate, and an Advanced Leader Certificate from the British Association of Medical Managers. She is currently Consultant Medical Microbiologist, Infection Control Doctor and Director of Infection Prevention and Control for Mid Essex Hospitals Trust. Dr Teare was commissioned by the Inquiry to provide written microbiology reports on eight focus patients and one other patient who had contracted *C. difficile*, and to provide a separate overview report of her findings. Dr Teare has made a significant contribution to national agendas and policy making on microbiology and infection prevention and control matters. She was a member of the Healthcare Commission Investigation Team into outbreaks of *C. difficile* at Maidstone and Tunbridge Wells NHS Trust. Dr Teare is also a current member of the Public Health Topic Expert Group for the National Institute of Clinical Excellence, providing Public Health advice on healthcare associated infections.

Dr Rod Warren

Dr Rod Warren MB, BChir, MA, MRCPATH is lead consultant microbiologist at the Royal Shrewsbury Hospital. He was commissioned by the Inquiry to provide written microbiology reports on 19 focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. From his appointment as the first NHS full-time consultant microbiologist in Cambridge in 1977 Dr Warren has pursued applied research and published extensively, as well as being heavily involved in teaching and examining. He has a wealth of medical advisory experience in the NHS and is a member of a number of national and regional committees as well as committees in Shropshire. He is also a member of a number of professional associations and societies, including the Hospital Infection Society.

Dr Henry Woodford

Dr Henry Woodford BSc, MRCP, FRCP, CertClin Ed is a Consultant Physician in elderly medicine at North Tyneside Hospital. He was commissioned by the Inquiry to provide written reports on the medical care of 17 focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr Woodford is currently head of service for Elderly Medicine at his hospital and has recently been training programme director for geriatrics within the Northern deanery. He has written two textbooks – Essential Geriatrics (which is now in its second edition) and Acute Medicine in the Frail Elderly.

Dr Tim Wyatt

Dr Tim Wyatt BTech, PhD, CBIol, FIBiol, FRCPath, MIHM retired from full-time work in 2010 and is currently employed as a Consultant Clinical Microbiologist at the Northern Ireland Public Health Agency. Formerly, he was Consultant Clinical Microbiologist at Belfast HSC Trust, Clinical Lead for Molecular Sciences and Infection Control Doctor with responsibility for the Mater Hospital and North and West Belfast Trust and Belfast Community. He was commissioned by the Inquiry to provide written microbiology reports on four focus patients who had contracted *C. difficile*, and to provide a separate overview report of his findings. Dr Wyatt undertakes advisory activities for the Department of Health, Social Services and Public Safety and the Public Health Agency in Northern Ireland, Public Health England and the Department of Health in London. He has produced 32 publications including original research and contributions to several books.

Assistance was also provided at an early stage of the Inquiry by two further experts, Dr Colin Currie, Senior Lecturer/Hon. Consultant, Geriatric Medicine, Edinburgh University and NHS Lothian until 2010, and Professor Cillian Twomey, Consultant Physician in Geriatric Medicine, Cork University/St. Finbarr's Hospitals, Cork.

Appendix 5

Witnesses who gave oral or written evidence

Syed Ahmed	Fiona Coulter	Donald Gray
Javed Akhter	Brian Cowan	Christine Griffin
Musa Al-Shamma	Morven Cowie	George Griffin
Linda Bagrade	Susan Craig	George Hamilton
Bruce Barnett	Andrew Crawford	Roisin Hannaway
Jean Beattie	Fiona Creech	Anne Harkness
Jack Bisset	Rosslyn Crocket	James Harnett
Katrina Black	Elizabeth Culshaw	Margaret Harnett
Catherine Booth	Evonne Curran	Mary Harrington
Robert Boulton-Jones	Linda Currie	Janine Hart
Gareth Bourhill	Myra Currie	Joanne Harvey
Brenda Bowes	Graham Curry	Elizabeth Hawkins
Susan Brimelow	Conal Daly	Gordon Herd
Christine Brodie	Stephanie Dancer	Mary Hesketh
John Burgess	Lorna Dannenberg	Joan Higgins
Elaine Burt	Linda de Caestecker	Elizabeth Hunter
Patricia Bynon	François de Villiers	Pauline Jack
Robert Calderwood	Deb den Herder	Annette Jeanes
Marjory Cambridge	John Dickson	Ann Johnston
Anne Cameron	Frank Dixon	Fiona Johnston
Roberta Campbell	Thomas Divers	Lily Johnston
Hugh Carmichael	Geoffrey Douglas	Mike Jones
Lorraine Casey	Donald Drummond	Laura Kean
Carol Cavana	Marion Drummond	Rosamond Kelly
David Chandler	Brian Duerden	Margaret Kelso
Sheila Chandler	Anne Eastaway	Kevin Kerr
Anne Chisholm	Alison Edwardson	Afaq Khan
Peter Christie	William Evans	Claire Kilpatrick
Patricia Clarke	Isabel Ferguson	Paul Kingsmore
Alison Claxton	Margo Ferguson	Charles Kinloch
John Coia	Elizabeth Fettes	Ann Lang
Elizabeth Colgan	Lance Forbat	Isobel Law
Elaine Connolly	Lesley Fox	Sarah Leslie
Martin Connor	Laura Gargaro	David Logan
Patrick Conroy	Mark Garthwaite	Nancy Logan
Charles Cook	John Gebbie	Allan Lynch
Marion Copland	Ysobel Gourlay	Heather Lynch
Peter Copland	Jane Grant	Alan MacDonald

Jonathan MacDonald	Sandra McNamee	Graeme Simpson
Agnes MacFarlane	Margaret Melvin	Alex Smith
Catherine MacGillivray	John Menzies	Caroline Smith
Simon Mackenzie	Deborah Mills	Doris Smith
Deborah Mack	Helen Mooney	William Cairns Smith
Anne MacPherson	Carol Moore	Lorna Sneddon
Anne Madden	Mary Morgan	William Somerville
Katy Madden	Eunice Muir	Anna Squires
Nancy Malcolm	Jean Murray	Diane Stavert
John Mallon	Karen Murray	Margaret Stevenson
Marie Martin	Helen Neeson	Janet Stewart
Paul Martin	Scott Nicol	John Stewart
Jim McCarroll	Craig Nixon	Sharon Stower
Melanie McColgan	Helen O'Neill	Marie Swan
Tilda McCrimmon	Margaret Owen	Catriona Sweeney
Pauline McCrossan	Anthony Palmer	Judy Taylor
Douglas McCrudden	Christine Perry	Louise Teare
Alexander McDonald	Lynne Phair	Graeme Waddell
Anne McDonald	Gabby Philips	Pauline Waddell
Ciara McDonald	Ian Poxton	Margaret Walker
Eleanor McDonald	David Rainey	Thomas Walsh
Karen McDonald	Annette Rankin	Jan Warner
Anne McGarrity	Elizabeth Rawle	Rod Warren
Kim McGarrity	James Reid	Barbara Weinhardt
Charles McGinty	Robin Reid	Brian Wilson
Helen McGinty	Jacqui Reilly	Helen Wilson
Lisa McGinty	Eleanor Rennie	Susan Wilson
Michelle McGinty	Chris Robertson	Camilla Wiuff
Alexander McIntyre	Walter Scullion	Henry Woodford
Isobelle McIntyre	Jane Searle	Kevin Woods
Matt McLaughlin	Andrew Seaton	Tim Wyatt
Ally McLaws	Anne Shaw	Catherine Wrethman
Enid McMurdo	Maria Shaw	
Kathryn McNally	Ray Sheridan	

Appendix 6

Organisations which provided documentary evidence

Crown Office and Procurator Fiscal Service

Greater Glasgow Health Board (also known as NHS Greater Glasgow and Clyde)

Health Facilities Scotland

Health Protection Scotland

NHS Education for Scotland

NHS Quality Improvement Scotland

Nursing and Midwifery Council

Scottish Government

Strathclyde Police

Tayside Health Board

In addition, a number of individuals provided documentary evidence to the Inquiry.

Appendix 7

Acronyms

ACIC	Acute Control of Infection Committee
AHP	Allied Healthcare Professional
AMT	Antimicrobial Management Team
ARSSAP	Antimicrobial Resistance Strategy and Scottish Action Plan
BICC	Board Infection Control Committee
CCP	Cleanliness Champions Programme
CCU	Critical Care Unit
CDAD	<i>Clostridium difficile</i> associated diarrhoea/disease
CDI	<i>Clostridium difficile</i> infection
CG	Clinical Governance
CLO	Central Legal Office
CMO	Chief Medical Officer
COPFS	Crown Office and Procurator Fiscal Service
CPA	Clinical Pathology Accreditation
CSA	Common Services Agency
CSBS	Clinical Standards Board for Scotland
DNAR	Do Not Attempt Resuscitation
GGHB	Greater Glasgow Health Board
GMC	General Medical Council
GP	General Practitioner
GROS	General Register Office for Scotland
HAI	Healthcare Associated Infection
HDU	High Dependency Unit
HEAT	Health Improvement, Efficiency, Access and Treatment
HEI	Healthcare Environment Inspectorate
HFS	Health Facilities Scotland
HIS	Healthcare Improvement Scotland
HPS	Health Protection Scotland
ICD	Infection Control Doctor
ICN	Infection Control Nurse
ICT	Infection Control Team
IRH	Inverclyde Royal Hospital
LIMS	Laboratory Information Management System
MAU	Medical Assessment Unit
MDDUS	Medical and Dental Defence Union of Scotland

MRSA	Meticillin resistant <i>Staphylococcus aureus</i>
MSSA	Meticillin sensitive <i>Staphylococcus aureus</i>
NES	NHS Education for Scotland
NHSGGC	NHS Greater Glasgow and Clyde
NMC	Nursing and Midwifery Council
NMUU	National Medicines Utilisation Unit
NAS	National Archives of Scotland
NRS	National Records of Scotland
NSS	NHS National Services Scotland
OCT	Outbreak Control Team
PACS	Picture Archiving Communications Systems
PCR	Polymerase Chain Reaction
PHPU	Public Health Protection Unit
PPE	Personal Protective Equipment
QIS	Quality Improvement Scotland
RAD	Rehabilitation and Assessment Directorate
RAH	Royal Alexandra Hospital
RCN	Royal College of Nursing
RQIA	Regulation and Quality Improvement Authority for Northern Ireland
SAPG	Scottish Antimicrobial Prescribing Group
SCN	Senior Charge Nurse
ScotMARAP	Scottish Management of Antimicrobial Resistance Action Plan
SE	Scottish Executive
SEHD	Scottish Executive Health Department
SG	Scottish Government
SHO	Senior House Officer
SMG	Strategic Management Group
SMT	Senior Management Team
SPC	Statistical Process Chart
SSSCDRL	Scottish Salmonella, Shigella and <i>Clostridium difficile</i> Reference Laboratory
TVN	Tissue Viability Nurse
UTI	Urinary Tract Infection
VOLH	Vale of Leven Hospital

Appendix 8

List of figures and tables

Chapter 3	Healthcare Associated Infection and <i>Clostridium difficile</i>
Figure 3.1	Current recommendations for testing faecal specimens
Chapter 4	The number of patients with CDI and those who died
Figure 4.1	Patients with CDI
Figure 4.2	Deaths related to CDI
Chapter 5	<i>C. difficile</i> infection rates and undeclared outbreaks
Table 5.1	All positive and negative CDI test results
Table 5.2	Positive CDI results by ward
Figure 5.1	New diagnoses of CDI by ward
Figure 5.2	Potential outbreaks
Figure 5.3	The number of days patients were symptomatic
Table 5.3	Patients symptomatic more than ten days
Figure 5.4	<i>C. difficile</i> toxin positive test results 1 January 2007 to 30 November 2007
Table 5.4	CDI patients on ward 14 in April 2007
Table 5.5	CDI patients on ward 14 in July 2007
Table 5.6	CDI patients on ward F in March and May 2007
Table 5.7	CDI patients on ward 3 in June 2007
Table 5.8	CDI patients on ward 6 from February to April 2007
Figure 5.5	<i>C. difficile</i> toxin positive test results 1 December 2007 to June 2008
Table 5.9	CDI patients on ward 6 in December 2007
Table 5.10	CDI patients on ward 6 in February 2008
Table 5.11	CDI patients on ward 6 in April and May 2008
Table 5.12	CDI patients on ward F in January and February 2008
Chapter 6	National structures and systems
Table 6.1	HEI Inspection methodology
Chapter 7	National policies and guidance
Figure 7.1	Australian/New Zealand 4360:1999 model
Table 7.1	The risk matrix

Chapter 8	Changes in services at the Vale of Leven Hospital from 2002
Figure 8.1	Impact on unscheduled medical admissions
Table 8.1	VOLH: Bed complement at 31 March 2002
Table 8.2	VOLH: Bed complement at March 2008
Table 8.3	VOLH: Bed complement at April 2012
Chapter 10	Clinical governance
Figure 10.1	Clinical Governance Structure
Figure 10.2	Flow of clinical governance information in Clyde 2007-2008
Table 10.1	Clyde Acute Senior Management Team action notes
Chapter 12	Nursing care
Table 12.1	Early period CDI patients and wards
Table 12.2	The Loose Stools Policy
Figure 12.1	Bristol Stool Chart
Table 12.3	Recommended/documentation of risk status
Table 12.4	Mrs Perry's review of staffing levels
Chapter 13	Antibiotic prescribing
Figure 13.1	Model antimicrobial prescribing practice pathway in acute hospitals
Figure 13.2	Greater Glasgow and Clyde Health Board <i>C. difficile</i> toxin positive cases
Chapter 14	Medical care
Table 14.1	Physicians commissioned by the Inquiry and their reports by ward
Table 14.2	Microbiologists commissioned by the Inquiry and their reports by ward
Table 14.3	NHS medical career grades
Table 14.4	Consultants employed at the VOLH and their specialisms
Table 14.5	Junior medical staffing numbers at VOLH
Figure 14.1	Co-amoxiclav use in Clyde hospitals
Table 14.6	Delays in process
Table 14.7	Delays in treatment
Table 14.8	Combined process and treatment delays

Chapter 15 Infection prevention and control

Figure 15.1	The infection control management structure at the VOLH in the period January 2007 to June 2008
Table 15.1	Number of beds and number of single rooms in each ward
Table 15.2	Isolation delays after positive result known
Figure 15.2	Patients cohorted in room 16 on ward F
Figure 15.3	NHSGGC infection control reporting structures
Figure 15.4	A T-card
Figure 15.5	A patient card
Figure 15.6	New cases of CDI from 2006 to 2008 on ward 6
Table 15.3	NHSGGC Infection Control report - number of infections at the VOLH
Figure 15.7	NHSGGC Infection Control report - <i>C. difficile</i> trend at the VOLH
Table 15.4	<i>C. difficile</i> toxin positive cases in ward 14 in April 2007
Table 15.5	Patients who tested <i>C. difficile</i> toxin positive on ward F in March 2007
Table 15.6	CDI patients on ward 6 in December 2007
Table 15.7	CDI patients on ward 3 in June 2007
Table 15.8	Patients who tested <i>C. difficile</i> toxin positive on ward 6 from February to April 2007
Table 15.9	<i>C. difficile</i> toxin positive results authorised by Microbiologists
Table 15.10	Nurses who completed CCP by ward prior to 1 June 2008
Table 15.11	Period during which Sisters and Deputy Sisters completed CCPs
Table 15.12	Time taken to complete CCP by Ward Managers
Table 15.13	VOLH terminal cleans December 2007 to June 2008
Table 15.14	Hand Hygiene Audit - Compliance of staff
Table 15.15	Overall compliance in hand hygiene audits
Table 15.16	Environmental audits
Table 15.17	Audit criteria
Figure 15.8	Infection control management structure 2009 onwards
Figure 15.9	Infection control committee structure 2009 onwards
Table 15.18	Infection control report - Timetable for CDI
Table 15.19	Training Tracker Modules taken at VOLH (2009-2011)
Table 15.20	Scoring system and re-audit cycle
Table 15.21	Infection Control Safe Patient Environment Audits 2010-2011

Appendix 9

Timeline of investigations prior to the Inquiry

10 JUNE 2008	NHSGGC Outbreak Control Team established
10 JUNE 2008	NHSGGC Internal Investigation commenced
18 JUNE 2008	Scottish Government Independent Review of <i>Clostridium difficile</i> Associated Disease at the Vale of Leven Hospital from December 2007 to June 2008 set up
AUGUST 2008	Independent Review report published
11 JULY 2008	NHSGGC Internal Investigation report published
OCTOBER 2008	NHSGGC Outbreak Control Team report published
24 NOVEMBER 2008	Joint Health and Safety Executive and Strathclyde Police investigation commenced
JANUARY 2009	Scottish Government Follow Up Report on implementation of the recommendations from the Independent Review published
6 JANUARY 2009	C.diff Justice Group public petition lodged at the Scottish Parliament
22 APRIL 2009	Scottish Government – Announcement by Cabinet Secretary that there will be a Public Inquiry
31 MAY 2009	Strathclyde Police interim report on deaths at VOLH submitted to Procurator Fiscal
24 JUNE 2009	Crown Counsel instructed that no criminal proceedings were to be taken
1 OCTOBER 2009	Vale of Leven Hospital Public Inquiry commenced

