ORIGINAL PAPER

Towards standard setting for patient-reported outcomes in the NHS homeopathic hospitals

Elizabeth A Thompson^{1,*}, Robert T Mathie², Elizabeth S Baitson², Susan J Barron¹, Saul R Berkovitz³, Martien Brands⁴, Peter Fisher³, Tom M Kirby³, Robert W Leckridge⁵, Stewart W Mercer⁶, Hugh J Nielsen⁴, David HK Ratsey⁷, David Reilly⁵, Helmut Roniger⁷ and Thomas E Whitmarsh⁵

Introduction: We report findings from a pilot data collection study within a programme of quality assurance, improvement and development across all five homeopathic hospitals in the UK National Health Service (NHS).

Aims: (1) To pilot the collection of clinical data in the homeopathic hospital outpatient setting, recording patient-reported outcome since first appointment; (2) to sample the range of medical complaints that secondary-care doctors treat using homeopathy, and thus identify the nature and complexity of complaints most frequently treated nationally; (3) to present a cross section of outcome scores by appointment number, including that for the most frequently treated medical complaints; (4) to explore approaches to standard setting for homeopathic practice outcome in patients treated at the homeopathic hospitals.

Methods: A total of 51 medical practitioners took part in data collection over a 4-week period. Consecutive patient appointments were recorded under the headings: (1) date of first appointment in the current series; (2) appointment number; (3) age of patient; (4) sex of patient; (5) main medical complaint being treated; (6) whether other main medical complaint(s); (7) patient-reported change in health, using Outcome Related to Impact on Daily Living (ORIDL) and its derivative, the *ORIDL Profile Score* (ORIDL-PS; range, -4 to +4, where a score ≤ -2 or $\geq +2$ indicates an effect on the quality of a patient's daily life); (8) receipt of other complementary medicine for their main medical complaint.

Results: The distribution of patient age was bimodal: main peak, 49 years; secondary peak, 6 years. Male:female ratio was 1:3.5. Data were recorded on a total of 1797 individual patients: 195 first appointments, 1602 follow-ups (FUs). Size of clinical service and proportion of patients who attended more than six visits varied between hospitals. A total of 235 different medical complaints were reported. The 30 most commonly treated complaints were (in decreasing order of frequency): eczema; chronic fatigue syndrome (CFS); menopausal disorder; osteoarthritis; depression; breast cancer; rheumatoid arthritis; asthma; anxiety; irritable bowel syndrome; multiple sclerosis; psoriasis; allergy (unspecified); fibromyalgia; migraine; premenstrual syndrome; chronic rhinitis; headache; vitiligo; seasonal allergic rhinitis; chronic intractable pain; insomnia; ulcerative colitis; acne; psoriatic arthropathy; urticaria; ovarian cancer; attention-deficit

¹Bristol Homeopathic Hospital, UK

²British Homeopathic Association, UK

³Royal London Homoeopathic Hospital, UK

⁴Liverpool Regional Homoeopathic Hospital, UK

⁵Glasgow Homoeopathic Hospital, UK

⁶General Practice and Primary Care, Faculty of Medicine, University of Glasgow, UK

⁷Tunbridge Wells Homoeopathic Hospital, UK

^{*}Correspondence: Dr EA Thompson, Bristol Homeopathic Hospital, Cotham Hill, Bristol BS6 6PD, UK. Tel.: +44 0117 973 1231; Fax: +44 0117

hyperactivity disorder (ADHD); epilepsy; sinusitis. The proportion of patients with important co-morbidity was higher in those seen after visit 6 (56.9%) compared with those seen up to and including that point (40.7%; P < 0.001). The proportion of FU patients reporting ORIDL-PS \geq +2 (improvement affecting daily living) increased overall with appointment number: 34.5% of patients at visit 2 and 59.3% of patients at visit 6, for example. Amongst the four most frequently treated complaints, the proportion of patients that reported ORIDL-PS \geq +2 at visit numbers greater than 6 varied between 59.3% (CFS) and 73.3% (menopausal disorder).

Conclusions: We have successfully piloted a process of national clinical data collection using patient-reported outcome in homeopathic hospital outpatients, identifying a wide range and complexity of medical complaints treated in that setting. After a series of homeopathy appointments, a high proportion of patients, often representing "effectiveness gaps" for conventional medical treatment, reported improvement in health affecting their daily living. These pilot findings are informing our developing programme of standard setting for homeopathic care in the hospital outpatient context. Homeopathy (2008) 97, 114–121.

Keywords: Clinical data collection; Homeopathic hospitals; Patient-reported outcomes

Introduction

The United Kingdom's homeopathic hospitals are located in Bristol, Glasgow, Liverpool, London and Tunbridge Wells. The five have been an intrinsic part of the country's National Health Service (NHS) since its inception in 1948, and are staffed by medically qualified practitioners who possess additional training and certification in homeopathy. The range of skills and services on offer at each hospital varies in a number of ways. For example, the Royal London Homoeopathic Hospital (RLHH) provides a wide range of other Complementary and Alternative Medicine (CAM) services, such as acupuncture, autogenic training and herbal medicine, comprising in total more than 50% of patient appointments. All units have outpatient services only, except Glasgow Homoeopathic Hospital (GHH), which has an additional in-patient service. Services at the other three hospitals are mostly focused on homeopathy only. At Bristol Homeopathic Hospital (BHH), there is a defined package of care, with detailed review at the fifth appointment; other units consider the number of appointments required per patient on a more individual basis. The Liverpool hospital (LHH) is unusual in being part of a Primary Care Trust (PCT), rather than a hospital trust. Continuation of the main PCT contract for patient referrals to Tunbridge Wells Homoeopathic Hospital (TWHH) is currently under review.

Each of the hospitals has previously reported clinical outcomes data from a wide range of medical complaints. ^{1–5} In each unit, positive outcome has been reported by about 70% of follow-up (FU) patients overall, indicating the need for research initiatives to establish the positive effects of the homeopathic intervention in particular diagnoses. ^{6,7} From the perspective of quality assurance and improvement, on the other hand, these patient surveys have each been carried out without an explicit aim of identifying what standard of clinical outcome might reasonably be expected in subjects with a given type and complexity of medical complaint. Moreover, the earlier studies have each

used different methods and outcome scoring techniques, without an overarching objective to consider unifying approaches to clinical data collection across all hospitals.

The present report is a first step in a programme of quality assurance, improvement and development across all five homeopathic hospitals. It has the ultimate aim of setting standards for homeopathic practice outcomes in patients with medical complaints commonly treated in the outpatient setting nationally. Here we report our findings from a pilot data collection study for this programme. It represents the first collaborative effort by the five individual hospitals.

Aims

- To pilot the collection of clinical data in the homeopathic hospital outpatient setting, using Outcome Related to Impact on Daily Living (ORIDL) as outcome measure; to record patient-assessed outcome (in main complaint, MC, and well-being, WB) since the first appointment in the current series at that hospital.
- 2. By obtaining a 4-week sample of clinical data at all five homeopathic hospitals in the UK, to identify the range of medical complaints that doctors treat using homeopathy in hospital outpatients, and thus identify the nature and complexity of complaints most frequently treated nationally.
- 3. To present a cross section of patient-reported outcome scores by appointment number, including that for the most frequently treated medical complaints.
- 4. To explore approaches towards standard setting for homeopathic practice outcome in the most frequently treated medical complaints in outpatients treated at the homeopathic hospitals.

Methods

The study design and methods were agreed by all the authors, many of whom are members of the Faculty of

Homeopathy's Clinical Audit Sub-Committee. A total of 51 medical practitioners contributed to the data collection – see Acknowledgements. Each hospital confirmed locally that the work did not require Research Ethics Committee approval.

Data collection took place during the four 5-day periods from 5th to 30th March 2007. No individual patient was expected to receive more than a single appointment within that brief timeframe. An *Access* database (or *Excel* spreadsheet – see below) enabled the recording of all consecutive homeopathy appointments, under the following headings:

- Date of first appointment for currently treated medical complaint (day, month, year).
- Appointment number (1[=first appointment] to 6; >6 [not specified]).
- Age of patient.
- Sex of patient.
- Main medical complaint being treated, using a 'drop-down' menu* of 263 medical conditions (ICD-10 nomenclature).†
- Whether other main medical complaint/s (yes/no).‡
- Patient-assessed change in the MC at FU, using ORIDL.
- Patient-assessed change in overall WB at FU, using ORIDL.
- Whether also receiving other CAM therapy for this complaint at this hospital (yes/no).

Data were collected at clinics offering homeopathy only, i.e. not acupuncture, autogenic training, etc. Lifestyle, dietary or other advice given at the clinics was not categorised as "other CAM therapy", but regarded as part of normal homeopathic therapy. "Main medical complaint" was the doctor's opinion as to the nature of the principal health concern at the time of initial referral (e.g. from the referral letter or his/her own notes).

The ORIDL instrument (formerly referred to as the Glasgow Homoeopathic Hospital Outcome Score, GHHOS) has been developed to measure the outcome of care by asking about change, and relating this to impact on daily living. In this study it was the patient's reported assessment that was recorded. A score ≤ -2 or $\geq +2$ indicates the patient considered there had been a change in the quality of his/her daily living. In a preliminary validation of ORIDL there was significant agreement between patient outcomes assessed by the ORIDL and EQ-5D, the MYMOP, and the PEI-outcome instrument, suggesting that the ORIDL may be a valid and sensitive tool for measuring change in relation to impact on daily life. Detailed instructions on use of ORIDL were

provided to each participating doctor. These instructions are shown in Appendix A. Doctors recorded data during the patient appointment. All patient data were anonymous at source; individual doctor identity was not recorded. In each hospital, all data files were collected together to create a single hospital record (in *Excel* format). The file was then sent by e-mail to the study co-ordinator (RTM) and thence to the data analyst (ESB).

Methods of data analysis

The raw data from each hospital were reformatted into a standardised Excel spreadsheet, which allowed ease of use for filtering and locating any incomplete or erroneous data entries. Each column of data was filtered for missing values, which were addressed either by correction or exclusion. Terminology for non-listed medical complaints was reconciled using ICD-10 coding nomenclature. Through this procedure, 72 extra options were added to the original list, bringing the ultimate number of listed complaints to 335. All eczemas (allergic contact [9.2% of eczema patients], atopic [45.4%], seborrhoeic [3.7%], unspecified [41.7%]), except varicose eczema (four cases), were reconciled under the single heading "eczema". Likewise, "menopausal/perimenopausal disorder" and "menopausal flushing" were reconciled under the single heading "menopausal disorder". The ICD-10 term "CFS/ME" is referred to simply as "CFS".

The spreadsheet was then consolidated into a master file containing all data from all hospitals, and arranged into a number of different pivot table layouts for the various analytical approaches. Sub-set analysis was carried out on patients who had other main medical complaints (co-morbidity) or who were also being treated for their main complaint with other CAM therapy. For some illustrative purposes, the two ORIDL scores per patient were averaged (range, -4 to +4, increments of 0.5); we have termed this aggregate the *ORIDL Profile Score* (ORIDL-PS). Data from the total patient sample are presented here as national statistics across all five hospitals. Equivalent findings per hospital were also analysed separately and communicated directly to each hospital for local inspection and evaluation.

After the study was completed, practitioners were sent a brief questionnaire, designed to gauge their personal experience of using the database or spreadsheet and their opinions of the value they attributed to the data the study produced.

Results

The *Access* database was used at three of the hospitals, and the *Excel* version at the other two. Electronic format was used in all hospitals except one, where some practitioners used a hard-copy version of the spreadsheet, necessitating subsequent manual data transcription into *Excel*. There was a low incidence of missing essential data. Only two records were excluded altogether: one was due to missing "Complaint" data; the other was a second appointment for a single patient during the 4-week period of data collection (outside the scope of the study – see Methods). There were 53 missing or invalid dates of first appointment, of which 22 were corrected and 31

^{*}The *Excel* version contained a "pick-list" of the same medical complaints, whose entries could be copied and pasted into an Appointments page.

[†]If a patient presented with a complaint that was not in the drop-down menu, the new term was typed into the free-text field (or directly into the column "Main Complaint" in *Excel*). †Patients with complex individual predicaments, or who had more than one nameable Main Complaint, were recorded under a single "Main Complaint", together with an entry "Yes" in the field labelled "Whether other Main Complaint/s". This enabled calculation of the proportion of patients with important co-morbidity.

were stated as "missing data". These were only excluded when they were essential to a particular analysis (such as "average time to appointment"). There was one missing value in each of "Gender", "ORIDL-WB" and "Whether other main medical complaint", which were excluded and flagged in any analysis involving them specifically.

Patient demographics and medical complaints treated

Patient age profile overall showed a bimodal distribution, with a main peak at 49 years and a secondary peak at 6 years (Fig. 1). Male:female ratio was 1:3.5. There were 1797 patient visits overall (i.e. the total number of individual patients participating in the study), 195 being first appointments and 1602 FUs. The totals per hospital are shown in Table 1, which also shows the distributions of patient visits up to or greater than the sixth appointment. Size of clinical service and the proportion of patients who attended more than six visits varied considerably between units. The precise number of visits greater than 6 was not recorded. Overall, 45% of patients had attended more than six appointments; the highest frequency of appointments ≤6 was patients on their second visit (Fig. 2). The relationship between visit number and time since first homeopathic appointment per hospital is shown in Table 2, where inter-hospital differences in timing of FU appointments are evident, especially for appointments after the third.

A wide range of complaints was reported: 235 in total over all the hospitals. The top 30 complaints (those seen in more than 10 patients) are listed in Table 3: the four most frequently treated were eczema, chronic fatigue syndrome (CFS), menopausal disorder and osteoarthritis. ₹ Table 3 also gives details of the proportions of males:females and of ages <18:≥18 years. A slight majority of eczema patients were under 18 years, whereas a large majority of CFS patients were 18 years old or more. As would be expected, all patients with menopausal disorder or osteoarthritis were aged over 18. The only male-dominated complaints were seasonal allergic rhinitis and attention-deficit hyperactivity disorder (ADHD).

Overall, 47.8% of patients reported important co-morbidity; 13.2% of patients were receiving another CAM therapy at the same hospital for their main medical complaint. The proportion of patients with important co-morbidity was higher in those seen after visit 6 (56.9%) compared with those seen up to and including visit 6 (40.7%; P < 0.001, chi-square test). The complaints that were most frequently treated also varied with appointment number: after visit 6, the highest frequency was CFS, followed by osteoarthritis and then eczema.

Patient-reported outcomes: ORIDL

There was close correspondence between ORIDL-MC and ORIDL-WB scores (see Fig. 3a,b) over their entire

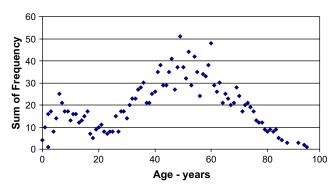


Fig. 1 Patient age profile.

range of values. The two variables were quite strongly correlated statistically ($r_S = 0.71$).

Number of appointments and ORIDL-PS

Table 4 illustrates the association between patientreported outcome (expressed, for this purpose, as ORIDL-PS) and appointment number for all medical complaints. For example, the proportion of patients per visit reporting positive change (ORIDL-PS > 0) increased from 73.2% at visit 2 to 87.2% at visit 6, and to 91.2% collectively for later visit numbers. There was a corresponding appointment-by-appointment decrease in the proportion of patients reporting no change (ORIDL-PS = 0). ORIDL- $PS \ge +2$ (health benefit affecting daily living) was reported by 34.5% of patients at appointment 2 and by 59.3% of patients at appointment 6; the proportion of ORIDL-PS $\geq +2$ increased further to 67.0% for visit numbers greater than 6. There was no obvious change in the reporting of health deterioration (ORIDL-PS < 0) over the course of treatments (average of about 3% of patients per visit number).

Towards standard setting

Data equivalent to those in Table 4 are presented for the four most frequently treated complaints: eczema (Table 5a), CFS (Table 5b), menopausal disorder (Table 5c), and osteoarthritis (Table 5d). The magnitude and visit-by-visit change of patient-reported improvement differed somewhat between them and in comparison with the data overall (cf. Table 4). For the top four complaints, the proportion of patients that reported ORIDL-PS \geq +2 at visit numbers greater than 6 varied between 59.3% (CFS) and 73.3% (menopausal disorder); the four proportions did not differ significantly (P = 0.11,

Table 1 No. of first and FU appointments per hospital, including no. of practitioners

11	NI 6	N	N/ f	T-4-1
Hospital	No. of	No. of FU	No. of	Total
(no. of	first	visits	FU visits	no. of
doctors)	visits	(appointments 2–6)	(appointment >6)	visits
BHH (12)	52	237		340
GHH (11)	30	166	169	365
LHH (6)	26	71	155	252
RLHH (18)	68	244	365	677
TWHH (4)	19	76	68	163
All HH (51)	195	794	808	1797

[§] Breast cancer, in sixth place, represents the homeopathic management of difficult symptoms such as hot flushes and the side-effects of chemotherapy.

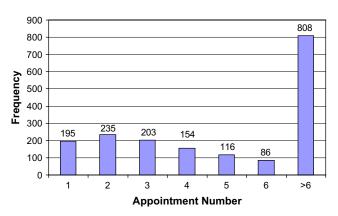


Fig. 2 Frequency of patient visits by appointment number.

chi-square). The proportions of patients attending more than six appointments varied considerably between medical complaints: eczema, 43%; CFS, 64%; menopause, 43%; osteoarthritis, 69%. The relatively low numbers per appointment per complaint precludes more extensive analysis.

Participating doctors' views

Completed questionnaires were received from 19 practitioners. All but one found the database/spreadsheet easy to use and the instructions helpful; only one participant had not used such software previously. A number of constructive suggestions were offered for improvement in the next phase of the programme. More than half the practitioners formally used the ORIDL question sequence, and all but two felt it was straightforward to score a patient's stated outcome. All participants found it worth having recorded data in this way. All but three derived useful factual information about their own hospital's practice data; two of those practitioners had not yet seen their hospital's data report. The following are examples of quotes from participating clinicians:

The database was easy to use, except the entry of first appointment dates.

I think we need to include other conventional interventions since last visit.

Not all of the patients understood the outcome questions. Older patients had difficulties understanding, which created time pressures. It was usually easy to score, but not always.

Discussion

A systematic approach to the collection of outpatient data in the homeopathic hospital setting was successfully

piloted, using ORIDL to record patient-reported change in MC and WB since the first homeopathic appointment. Information has been obtained on patient demographics and on the most frequently treated complaints. The findings illustrate the range and complexity of chronic disease managed within the homeopathic hospitals. The most frequently treated conditions reflect previously published data, with eczema and asthma in the top ten along with arthritides, menopausal symptoms and CFS. Research suggests that patients seek out CAM approaches for a number of reasons, including a fear of drug side-effects and the desire to be more independent in their healthcare; patients are often appreciative of their conventional care but also aware of its limitations.^{8,9} Indeed, the medical complaints treated in the homeopathic hospitals often reflect areas of clinical practice where available conventional treatments are not fully effective - termed "effectiveness gaps". 10 The holistic approach of homeopathy enables the care of patients - even those with the most complex individual medical predicaments – in a single treatment setting.

The pace and duration of patient care varied considerably between hospitals. This was reflected particularly in the differing proportions of patients who received more than six appointments. One hospital (BHH) saw proportionately fewer patients after visit number 6 than any of the other units. It is also clear that the scope and complexity of medical complaints changed with longer packages of care. In the next stage of our initiative, we aim to understand more about those patients who need to remain in the system for more than six appointments. Importantly, the pilot has informed the process by which such collective effort may proceed through the adoption of common aims and methods.

Our use of a patient-reported outcome measure (PROM) reflects current initiatives by the UK Government in the assessment of quality of patient care. 11 For this pilot study, the ORIDL-PS provided a useful single index of change, reflecting MC plus WB scores across all medical complaints and patient appointments. As found previously,⁵ there was a moderately close relationship overall between MC and WB, and this is perhaps not surprising given the consecutive nature of acquiring those separate outcomes. Good statistical correlation was not a prerequisite for combining the two values into a single score. Whether used separately or combined, the ORIDL scoring system tracks change in relation to daily living. We therefore consider ORIDL-PS $\geq +2$ as suggestive of significant health improvement, just as ORIDL-MC and ORIDL-WB are designed separately to do so. In contrast to the

Table 2 Time (months) to appointment (mean \pm s.d.)

Hospital	Appointment							
	2	3	4	5	6	>6		
BHH	2.5 ± 1.5	6.4 ± 3.1	13.4 ± 14.0	18.2 ± 8.3	22.2 ± 6.1	51.9 ± 44.6		
GHH	$\textbf{3.3} \pm \textbf{3.7}$	7.1 ± 5.8	$\textbf{13.2} \pm \textbf{10.2}$	$\textbf{15.4} \pm \textbf{8.1}$	$\textbf{20.3} \pm \textbf{8.1}$	67.9 ± 46.8		
LHH	$\textbf{4.5} \pm \textbf{2.8}$	$\textbf{8.3} \pm \textbf{4.2}$	$\textbf{16.5} \pm \textbf{7.8}$	14.8 ± 4.5	$\textbf{22.5} \pm \textbf{9.2}$	60.2 ± 40.2		
RLHH	$\textbf{3.5} \pm \textbf{2.3}$	$\textbf{7.9} \pm \textbf{3.3}$	9.3 ± 3.7	14.0 ± 5.5	22.8 ± 18.1	73.9 ± 60.9		
TWHH	$\textbf{3.0} \pm \textbf{2.3}$	$\textbf{5.5} \pm \textbf{2.7}$	$\textbf{8.3} \pm \textbf{4.1}$	$\textbf{10.7} \pm \textbf{3.8}$	$\textbf{18.6} \pm \textbf{10.6}$	49.3 ± 46.5		
All HH	<i>3.2</i> ± <i>2.6</i>	7.1 \pm 4.0	$\textit{11.9} \pm \textit{9.9}$	15.5 ± 7.2	21.5 ± 12.9	66.6 ± 53.1		

Table 3 All medical complaints with total frequency >10 patients (*all appointments*), including proportions of males:females, ages <18:≥18 years, and first:FU appointments

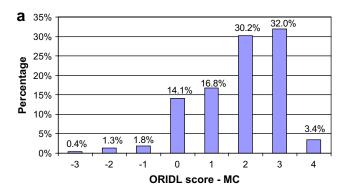
Complaint	Total frequency	No. of Male	No. of Female	Age < 18	Age ≥ 18	No. of first appointments	No. of FU appointments
Eczema	163	73	90	89	74	17	146
CFS	140	31	109	6	134	14	126
Menopausal disorder	110	0	110	0	110	7	103
Osteoarthritis – unspecified	106	14	92	0	106	5	101
Depression	83	18	65	4	79	12	71
Cancer – breast	69	0	69	0	69	8	61
Arthritis – rheumatoid	54	3	51	0	54	5	49
Asthma	50	20	30	27	23	1	49
Anxiety	46	10	36	5	41	5	41
Irritable bowel syndrome	45	7	38	4	41	11	34
Multiple sclerosis	40	4	36	0	40	2	38
Psoriasis	34	14	20	4	30	5	29
Migraine	28	2	26	4	24	5	23
Fibromyalgia	28	2	26	0	28	3	25
Allergy – unspecified	28	8	20	11	17	4	24
Premenstrual syndrome	27	0	27	1	26	2	25
Rhinitis – chronic	27	10	17	2	25	1	26
Headache	21	3	18	1	20	2	19
Vitiligo	19	9	10	9	10	1	18
Rhinitis – seasonal allergic	18	11	7	3	15	3	15
(hay fever)							
Pain – chronic intractable	17	3	14	0	17	4	13
Insomnia	17	6	11	3	14	1	16
Ulcerative colitis	16	8	8	0	16	2	14
Acne	16	3	13	2	14	3	13
Urticaria	13	1	12	2	11	1	12
Psoriatic arthropathy	12	4	8	0	12	1	11
Cancer – ovary	12	0	12	0	12	3	9
ADHD	12	10	2	11	1	2	10
Epilepsy	11	6	5	5	6	0	11
Sinusitis	11	2	9	0	11	0	11

assumptions made by some commentators, ¹² research suggests that observational studies and patient-reported outcomes of this type do not necessarily possess intrinsic positive bias. ^{13,14} Indeed, the fact that our study's findings revealed visit-dependent changes in outcome that differed per medical complaint (see below) tends to support objectivity in patient reporting.

Over all medical complaints, the proportion of patients per FU visit reporting at least some degree of health improvement increased from 73.2% at appointment 2 to 87.2% at appointment 6, for example. These figures are somewhat higher than those typically reported from the homeopathic hospitals individually, where 70% FU patients improved overall. 1-5 The explanations for the superior results in this five-hospital study are likely to be methodological, including the use of a new outcome measure in a cross-sectional sample of patients. Health benefit affecting daily living (ORIDL- $PS \ge +2$) was reported by 34.5% of patients at appointment 2 and by 59.3% at appointment 6. The observation that the proportions of ORIDL-PS \geq +2 tended to increase over the series of appointments reflects similar findings previously reported from GHH,⁵ and indicates the potential value of setting quality standards in terms of duration of homeopathic treatment. It would assist physicians in their judgment of when they might expect meaningful clinical improvement affecting a patient's quality of daily living.

There was some evidence that the magnitude and pace of patient-reported change was influenced by the nature of the main presenting complaint. For instance, CFS patients showed somewhat less improvement within the period of care overall than those with eczema, menopausal disorder or osteoarthritis. High proportions of CFS and osteoarthritis cases remained as outpatients for more than six appointments. Such condition-specific observations corroborate findings reported previously from the RLHH, where change in patients' use of conventional medication varied between diagnoses: 72% of patients with skin complaints, for example, reported having been able to stop or reduce conventional medicines, whereas cancer patients reported no change. It is also of interest that the outcomes typically reported by eczema patients in the current study are similar to a broadly comparable group admitted to dermatology departments in Norway, where 70% of subjects showed improvement in Dermatology Life Quality Index. 15

This 4-week national cross section of clinical outcomes data supports previous reports that referral to homeopathic hospital outpatients appears to be frequently associated with improvement in patients' health, and for a wide variety and complexity of medical complaints. Although these data are suggestive that patients typically gain improvements both in presenting complaint and wellbeing – and often with useful impact on their daily living – we cannot conclude that these are due to homeopathic care specifically. By definition, an observational study of this nature involves no reference group of patients to serve as controls. Moreover, we are unable to take into account other factors, such as regression to the mean, or improvement of symptoms that may have happened spontaneously over time



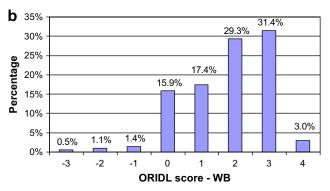


Fig. 3 (a) ORIDL-MC scores for all appointments. A total of 65.6% of patients reported ORIDL-MC \geq +2. (b) ORIDL-WB scores for all appointments. A total of 63.7% of patients reported ORIDL-WB \geq +2.

(as in menopausal disorder), or where conventional treatments might have had an important impact during the package of care (as in asthma). A causal relationship between homeopathy and reported outcome therefore cannot be attributed from our data. In addition, it should be noted that these data do not reflect changes in patients who stopped attending: they might have improved to their satisfaction or found homeopathy unhelpful. In subsequent studies, full account will be taken of such non-attenders, together with those patients who use other CAM and/or conventional medicines.

The information we have obtained in this pilot study is being used to explore further the opportunity of standard setting for homeopathic care in the hospital outpatient context. Identifying the appointment by which ORIDL- $PS \ge +2$, for instance, is typically achieved for a given medical complaint within a package of care would allow us to set meaningful standards of outcome. This in turn would enable

Table 4 Percentages of patient-reported outcomes per appointment (all medical complaints)

Appointment no.				0 < ORIDL- PS ≤ 1.5, %	
2	235	3.8	23.0	38.7	34.5
3	203	2.0	17.7	28.1	52.2
4	154	1.9	9.1	31.8	57.1
5	116	4.3	12.1	19.8	63.8
6	86	3.5	9.3	27.9	59.3
>6	808	4.3	4.5	24.3	67.0

Table 5 Percentages of patient-reported outcomes per appointment

Appmt. no.	No. of patients	ORIDL- PS < 0, %	ORIDL- PS = 0, %	0 < ORIDL- PS ≤ 1.5, %	<i>ORIDL-</i> <i>PS</i> ≥ 2.0, %			
(a) Ecz	ema							
2	26	7.7	23.1	30.8	38.5			
3	15	0.0	26.7	26.7	46.7			
4	16	0.0	0.0	56.3	43.8			
5	18	0.0	11.1	16.7	72.2			
6	7	0.0	14.3	28.6	57.1			
>6	64	0.0	3.1	25.0	71.9			
(b) CFS	3							
2	15	0.0	40.0	40.0	20.0			
3	10	10.0	40.0	0.0	50.0			
4	8	12.5	0.0	25.0	62.5			
5	8	0.0	37.5	50.0	12.5			
6	4	0.0	25.0	50.0	25.0			
>6	81	4.9	9.9	25.9	59.3			
(c) Men	opausal c	disorder						
2	14	0.0	21.4	28.6	50.0			
3	16	0.0	12.5	18.8	68.8			
4	11	0.0	18.2	9.1	72.7			
5	10	10.0	10.0	40.0	40.0			
6	7	14.3	0.0	14.3	71.4			
>6	45	2.2	4.4	20.0	73.3			
(d) Osteoarthritis								
2	7	0.0	28.6	14.3	57.1			
3	7	0.0	28.6	42.9	28.6			
4	8	0.0	0.0	50.0	50.0			
5	5	20.0	0.0	20.0	60.0			
6	4	0.0	0.0	25.0	75.0			
>6	70	4.3	2.9	21.4	71.4			

us to focus potential outcome with patients and communicate this to referring medical practitioners or funders scrutinising service delivery. There is clearly a need to track individual patients longitudinally and to obtain more information on longer-term attenders, and these will be key features of the ongoing development programme. This process will also necessarily take into account severity of presenting symptoms and the presence of important comorbidity, as well as the particular nature of the holistic model of patient care. Data of such fundamental nature will also help to inform research, including condition-specific outcomes studies and randomised controlled trials.

Conflict of interest

None of the authors has any financial or personal relationships with other people or organisations that could have influenced this work inappropriately.

Acknowledgements

The work was part-funded by the British Homeopathic Association.

We wish to record our thanks to the following practitioners at the homeopathic hospitals who contributed to this clinical data collection:

BHH: Chris Calcott, Julie Geraghty, Moira Hamilton, Michael Handford, Jonathan Hardy, Gill How, Andrew Morrice, Willa Muir, Richard Savage, Elizabeth Thompson, Trevor Thompson, Roy Welford.

GHH: Leonora Coll, Elaine Hamilton, Martin Innes, Robert Leckridge, Jacqueline Mardon, Alan Mathieson, Iain McLellan, Bridie O'Dowd, Kamal Ohri, David Reilly, Tom Whitmarsh.

LHH: Martien Brands, Valerie Hayhurst, Eftihia Metallidou, Paul Nickson, Hugh Nielsen, Kathy Ryan.

RLHH: Federica Boecklin, Ann Bowden, Jennifer Boyle, Michael Cannell, Sara Eames, Michael Finnegan, Peter Fisher, Said Haider, Christian Hasford, Gill Hyams, Asha Jain, Sosie Kassab, Marysia Kratimenos, Jennifer Lenhart, Amita Raja, Helmut Roniger, Anton van Rhijn, Andrea Wiessner.

TWHH: Mabel Aghadiuno, Susanne Dreher-Brogan, David Ratsey, Helmut Roniger.

We record our thanks to Maria Higgins for co-ordinating data collection at GHH.

Appendix A

Outcome Related to Impact on Daily Living (ORIDL)

Ask every follow-up patient:

1. Compared to how you were before your initial appointment, what has been the *overall effect of your treatment at this hospital* on your *Main Complaint* (the one you came to get treated)?

If the patient says "none", "the same" or is unsure, record 0.

If the patient says "better" or "worse", record their perceived degree of improvement or deterioration based on the numerical scale below.

2. Compared to how you were before your initial appointment, what has been the *overall effect of your treatment at this hospital* on your *general Well-being*?

If the patient says "none", "no change" or is unsure, record 0.

If the patient says "better" or "worse", record their perceived degree of improvement or deterioration based on the numerical scale below.

- +4 Cured/back to normal
- +3 Major improvement
- +2 Moderate improvement, affecting daily living
- +1 Slight improvement, no effect on daily living 0 No change/unsure
- -1 Slight deterioration, no effect on daily living
- −2 Moderate deterioration, affecting daily living
- −3 Major deterioration
- -4 Disastrous deterioration

References

- 1 Sharples F, van Haselen R, Fisher P. NHS patients' perspective on complementary medicine. *Complement Ther Med* 2003; 11: 243–248.
- 2 Spence D, Thompson EA, Barron SJ. Homeopathic treatment for chronic disease: a 6-year university-hospital outpatient observational study. *J Altern Complement Med* 2005; 5: 793–798.
- 3 Clover A. Patient benefit survey: Tunbridge Wells Homoeopathic Hospital. *Br Homoeopath J* 2000; **89**: 68–72.
- 4 Richardson WR. Patient benefit survey: Liverpool Regional Department of Homoeopathic Medicine. *Br Homeopath J* 2001; **90**: 158–162.
- 5 Reilly D, Mercer SW, Bikker AP, Harrison T. Outcome related to impact on daily living: preliminary validation of the ORIDL instrument. BMC Health Serv Res 2007; 7: 139.
- 6 White A, Ernst E. The case for uncontrolled clinical trials: a starting point for the evidence base for CAM. *Complement Ther Med* 2001; 9: 111–115.
- 7 Walach H, Jonas WB, Lewith GT. The role of outcomes research in evaluating complementary and alternative medicine. *Altern Ther Health Med* 2002; **8**: 88–95.
- 8 Shaw A, Thompson EA, Sharp D. Complementary therapy use by patients and parents of children with asthma and the implications for NHS care: a qualitative study. *BMC Health Serv Res* 2006; **6**: 76.
- 9 Shaw A, Thompson EA, Sharp DJ. Expectations of patients and parents of children with asthma regarding access to complementary therapy information and services via the NHS: a qualitative study. *Health Expect* 2006; **9**: 343–358.
- 10 Fisher P, van Haselen R, Hardy K, et al. Effectiveness gaps: a new concept for evaluating health service and research needs applied to complementary and alternative medicine. J Altern Complement Med 2004; 10: 627–632.
- 11 Delamothe T. Editorial: What counts? *Br Med J* 2 February 2008; **336** 10.1136/bmj.39476.584005.47.
- 12 Chanda P, Furnham A. Does homeopathy work? Part 1: a review of studies on patient and practitioner reports. *FACT* 2008; **13**: 82–89.
- 13 Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs. N Engl J Med 2000; 342: 1887–1892.
- 14 Thompson TDB, Weiss M. Homeopathy what are the active ingredients? An exploratory study using the UK Medical Research Council's framework for the evaluation of complex interventions. BMC Complement Altern Med 2006; 6: 37.
- 15 Wahl AK, Mørk C, Lillehol BM, et al. Changes in quality of life in persons with eczema and psoriasis after treatment in departments of dermatology. Acta Derm Venereol 2006; 86: 198–201.