



*National Institute for
Health Research*

Embedding Health Research



National Institute for Health Research
Annual Report 2009/10

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Foreword



Five years ago, the Government of the day consulted on a proposal to create a National Institute for Health Research (NIHR) in England. The ideas put forward stemmed from wide-ranging analysis and debate. They drew on our country's acknowledged strengths in applied health research and provided an ambitious and radical solution to the challenges we faced.

Those plans attracted considerable support, not least from the major political parties. They did so because they clearly addressed the needs and aspirations of the wide cross-section of people for whom health research matters. There was consensus that the NIHR was the way forward. Five years on, the achievements and progress described in this report provide firm and convincing evidence that the NIHR has delivered and continues to deliver what it set out to do.

The NIHR manages the largest single element of the public funding the UK devotes to health and social care research in a way that promotes excellence and provides our healthcare system with the evidence on which better services, better care and better outcomes depend. It nurtures the researchers who contribute so much to our science base. It helps to strengthen our economy.

In all this, the NIHR is a world leader. Its success in meeting the needs of its stakeholders, and the way in which it fuses a national research system with our National Health Service, has gained widespread recognition.

The coalition Government has set out its plans and ambitions for the health service in the White Paper *Equity and excellence: Liberating the NHS*. We are clear – and the White Paper makes it clear – that research is an essential part of our aim to achieve health outcomes as good as anywhere in the world.

As each chapter of this annual report illustrates, the NIHR is generating the knowledge and evidence on which continually improving outcomes depend. From Biomedical Research Centres and Units and the Clinical Research Network to its research programmes and the systematic review infrastructure, the Institute is contributing day by day to just that end.

For its part, the Government is committed to a future in which research continues as a core function of the NHS. It is committed to collaboration between those doing research and those who gain from research in all sectors of the economy. Moreover, in a healthcare system in which patients and the public come first, the Government is committed to supporting the emphasis that the NIHR puts on patient and public involvement in research.

This annual report is both an education and an inspiration. I am glad of this opportunity to endorse it.

A handwritten signature in black ink, appearing to read 'Earl Howe'.

Earl Howe
Parliamentary Under Secretary of State for Quality – Lords

The National Institute for Health Research

The National Institute for Health Research (NIHR) provides the framework through which the Department of Health can position, maintain and manage the research, research staff and research infrastructure of the NHS in England as a national research facility.

Vision

To improve the health and wealth of the nation through research.

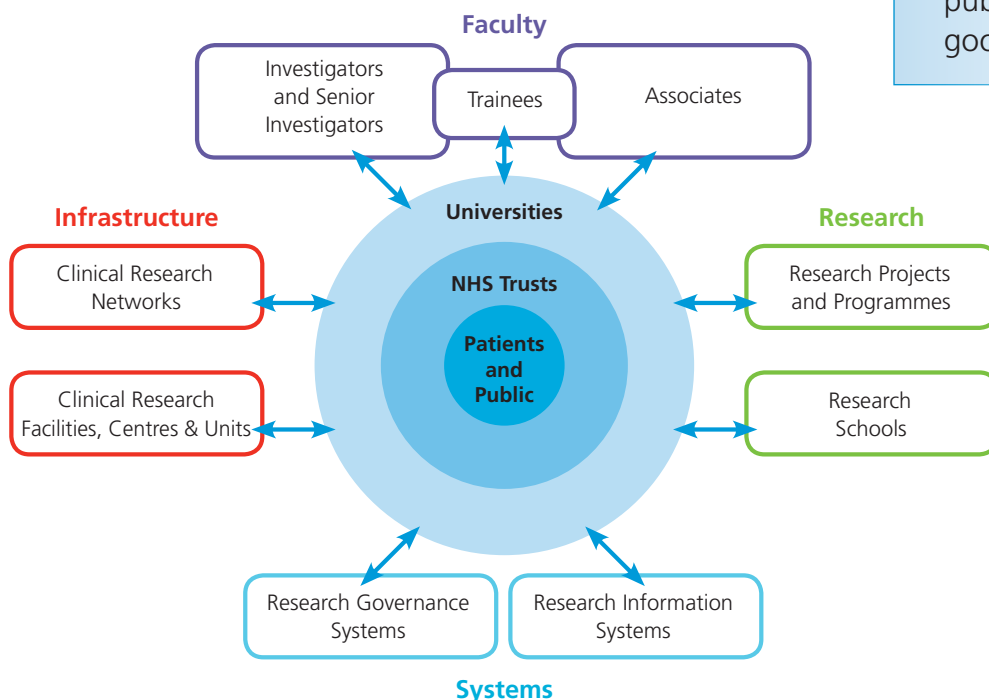
Mission

To maintain a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research, focused on the needs of patients and the public.

Goals

- Establish the NHS as an internationally recognised centre of research excellence.
- Attract, develop and retain the best research professionals to conduct people-based research.
- Commission research focused on improving health and social care.
- Strengthen and streamline systems for research management and governance.
- Act as sound custodians of public money for the public good.

The health research system of the NHS and the NIHR key work strands



Introduction

The National Institute for Health Research (NIHR) has a single clear remit – to improve the health and wealth of the nation through research. This year’s annual report shows many examples of how we are doing this.

Often referred to as the research arm of the NHS, the NIHR sits at an important crossroads between patients and the public, NHS clinicians and managers, the academic research community and the pharmaceutical, biotechnology, medical devices and diagnostics industries. It provides the infrastructure and systems to support both NIHR-funded research and research funded by partners such as the Medical Research Council, research charities and industry.

Focusing on patients and the public

To make sure that NHS hospital doctors, GPs, nurses, other health professionals and managers base their decisions on the best, latest, peer-reviewed evidence, NIHR research is firmly focused on the needs of patients and the public.

The evolution of modern medical treatments has relied heavily on scientific innovation and discoveries born in the laboratory. However, before new medicines can be used in hospitals and doctors’ surgeries, they must be tested in clinical trials to make sure that they are safe and effective.

The scientists and researchers who discover and pioneer radical new treatments deserve our thanks and praise. But so too do all those unnamed patients and members of the public who willingly take part in clinical trials, donate their blood, tissues and organs, or give their views to improve the quality of treatment and care, now and in the future. The huge advances in medicine and healthcare that we enjoy today would not have been possible without applied research and the selflessness of these volunteers. In Section 1 and throughout this report, there are many inspiring stories showing what motivates people to take part in research.

Supporting the research community

To ensure that research is of the highest quality, the NIHR supports a vibrant community of researchers, from newly appointed trainees on the first rung of their career to the country’s most senior and outstanding research leaders. Section 2 shows how we are supporting the research community as well as developing new systems to simplify research procedures, while meeting the highest ethical and regulatory standards to maintain patient and public confidence.

Working with industry

The NIHR also plays a key role in attracting global and UK-based life sciences companies to conduct clinical research in the UK to benefit patients and the public and attract investment into the economy. Section 3 highlights the initiatives that the NIHR is undertaking to support industry-sponsored trials, which are making England one of the best places in the world to conduct research.

Policy matters

Research is vital, not just to improve NHS treatment and care, but also to make sure that healthcare policy is based on sound evidence and that public money is spent in the most effective way possible. Section 4 demonstrates the ways in which NIHR-funded research is helping to inform health policy.

Improving the efficiency of the NHS

Research commissioned by the NIHR aims not only to identify the most effective treatments but also the most efficient ways of providing NHS services and tackling the most pressing challenges in healthcare today. This includes answering questions such as how to manage people with fluctuating blood pressure, how to save more lives following injuries and accidents and how best to isolate patients with hospital-acquired infections. The solutions to all these and more have been achieved by NIHR-funded research, highlighted in Section 5.

This report provides a snapshot of the NIHR's achievements in 2009/10 and demonstrates that research really is the foundation stone of a strong, efficient, cost-effective health system that works for patients, healthcare professionals, industry and policy makers.

Summary of progress



April 2009

NIHR HTA-funded study wins BMJ Research Paper of the Year award

Research funded by the NIHR Health Technology Assessment (HTA) programme into the treatment of Bell's palsy wins the prestigious BMJ Group Award for Research Paper of the Year.

NIHR regional conferences: committed to better research in the NHS

The NIHR launches a series of ten regional research conferences in partnership with each Strategic Health Authority.

May 2009

NIHR systematic reviews inform Government advice on pandemic influenza A (H1N1)

At the start of the pandemic, the Department of Health's recommendations on the prevention and treatment of pandemic influenza A (H1N1) are informed by information and advice from the NIHR Centre for Reviews and Dissemination and the UK Cochrane Centre.

NIHR Senior Investigators elected as Fellows of the Academy of Medical Sciences

Four NIHR Senior Investigators are elected to the Academy Fellowship, in recognition of their excellence in medical science.

June 2009

Tripartite model Clinical Investigation Agreement gives patients faster access to innovative treatments

The Contract Research Organisation model Clinical Investigation Agreement (CRO mCIA) is established. This will help medical technology industry-funded research that is managed by CROs to start more quickly, enabling NHS patients to gain faster access to innovative treatments.

Breakthrough science at the NIHR Manchester Biomedical Research Centre

Researchers based in the NIHR Manchester Biomedical Research

Centre (BRC) announce a breakthrough in genetic science: a rare childhood genetic disorder that can trigger a common autoimmune disorder, systemic lupus erythematosus. The BRC was also involved in the discovery of a genetic defect causing polycystic ovary syndrome in women.

High ranking for NIHR HTA journal

The influence and impact factor of *Health Technology Assessment*, the NIHR HTA journal, is ranked in the top 10 per cent of medical and health-related journals, by the *Journal of Citation Reports*.

July 2009

The NIHR Public Health Research programme launches its commissioned workstream

The first topics advertised concern safe alternatives to injecting drugs and home-visiting services for older people.

Accelerating personalised mental health care

The NIHR BRC for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London receives a £3 million infrastructure grant to create a new BRC Nucleus data collection and analysis facility. The BRC Nucleus will form the largest single case register and biobank for mental health in Europe, offering an unparalleled resource for researchers at the Institute of Psychiatry.

August 2009

NIHR Research Support Services (RSS) announces new framework for local NHS research management

This new RSS initiative aims to improve the quality, speed and efficiency of research and research processes in the NHS by harmonising and streamlining local NHS research management and governance.



NIHR King's PSSQ Research Centre secures €3 million EU grant

The NIHR King's Patient Safety and Service Quality (PSSQ) Research Centre takes the lead on a major new international research project on quality and safety in European hospitals.

September 2009

NIHR tackles pandemic influenza A (H1N1)

The NIHR commissions 14 fast-track projects on behalf of the Department of Health for urgent national H1N1 pandemic flu research to inform the Government's response to the virus over the course of the pandemic.

NIHR Comprehensive BRC showcases pioneering research

The Comprehensive BRC (CBRC) at University College London Hospitals NHS Foundation Trust and University College London hosts an open event featuring presentations on major research topics by some of the CBRC's most promising young Principal Investigators.

Third NIHR Trainee Conference held

The third NIHR Trainee Conference takes place in Manchester. Some 210 people attend with good representation of the various types of trainees.

NIHR Master Classes in Mental Health Research

The NIHR funds a week-long series of Master Classes in Mental Health Research at the Institute of Psychiatry in London, specifically designed for clinical researchers occupying NIHR-supported training posts.

Launch of proportionate ethical review pilot scheme

A pilot scheme reviewing applications to Research Ethics Committees (RECs) begins in London. After evaluation, the National Research Ethics Service (NRES) aims to extend the scheme to RECs outside London and incorporate it into the NRES standard operating procedures during 2010.

October 2009

First call for proposals for the NIHR Health Services Research (HSR) programme

The NIHR HSR programme launches its first call for proposals, providing the academic community with the opportunity to identify research questions aimed at addressing gaps in knowledge.

NIHR Manchester BRC Fellow wins prestigious prize

Final-year medical student Mohammed Chowdhury wins first prize at the European Congress of the International Society for Vascular Surgery for his research to single out a particular group of individuals with carotid artery disease.

November 2009

NIHR BRU in Hearing officially opens

The Biomedical Research Unit (BRU) in Hearing brings together academics and clinicians to conduct novel research into the management of hearing loss and tinnitus.

NIHR funds supporter membership of BioMed Central

The NIHR agrees a membership arrangement with BioMed Central to support the publication of research articles in the publisher's open access journals.

Cutting-edge CT scanner to benefit patient research

The new cutting-edge CT (computerised tomography) heart scanner at Barts and The London Cardiovascular BRU will enable experts to explore the best ways to treat heart disease and other cardiac conditions.



Report shows that BRCs are changing the translational research landscape

A RAND Europe review of the impacts of BRCs in England shows that they have a positive effect on institutional relationships between the NHS, academia, industry and other players. They also help shape the health research system to pursue translational research and innovation to benefit patients.

Business Innovation Award for breakthrough nanomaterial

Professor Alexander Seifalian (UCL Centre for Stem Cells and Regenerative Medicine) receives a Business Innovation Award from the Nanotechnology Knowledge Transfer Network and UK Trade & Investment for his development of a revolutionary, polymer-coated stent for treating coronary heart disease. The research was funded by the NIHR.

Health researchers' guide is published

The changing regulatory and governance environment for health research across the UK: A guide for researchers provides an overview of initiatives to streamline the regulatory and governance environment. It is designed to reduce bureaucracy, support world-class research and benefit patients.

December 2009

New NIHR Office for Clinical Research Infrastructure established

The new NIHR Office for Clinical Research Infrastructure (NOCRI) will facilitate collaborations between NIHR-funded infrastructure and funders of research, including industry.

Queen's Anniversary Prize awarded to NIHR SSCR members

Two School for Social Care Research (SSCR) members – Professor Martin Knapp, Director of the SSCR, and Professor Caroline

Glendinning, Associate Director of SSCR – receive the Queen's Anniversary Prize for Further and Higher Education in recognition of their achievements in social care research and impact on the wellbeing of the nation.

NIHR INVOLVE report demonstrates positive results

The NIHR INVOLVE report, *Exploring Impact: Public involvement in NHS, public health and social care research*, provides evidence that public involvement makes a positive difference and influences whether research is used to bring about change.

January 2010

First project of NIHR PHR programme launches

The first funded project of the Public Health Research (PHR) programme aims to evaluate whether the Royal Horticultural Society's Campaign for School Gardening increases the intake of fruit and vegetables in primary school children.

Review suggests that Doppler ultrasound reduces risk in pregnancy

Publication of evidence from a new Cochrane systematic review suggests that using Doppler ultrasound in high-risk pregnancies to monitor fetal health may reduce caesarean sections and the number of babies who die.

NIHR awards contracts to centres of excellence for TARs

The NIHR awards ten contracts to centres of excellence for Technology Assessment Reviews (TARs). These provide reliable and rigorous evidence-based assessment of the



benefits, harms and costs of particular healthcare treatments for organisations involved in developing health policy, such as NICE. Three new centres of expertise join seven existing NIHR TAR centres.

NIHR-funded research develops accurate blood test for peanut allergy
Clinicians and scientists at University Hospital South Manchester, University of Manchester and Phadia AB in Uppsala, Sweden, develop a new and significantly more accurate blood test for peanut allergy, which predicts whether an allergic reaction to peanuts will develop with more than 95 per cent certainty.

February 2010

NIHR provides easier access to research for earthquake rescue teams

A selection of relevant systematic reviews and their conclusions from The Cochrane Library is made freely available by the UK Cochrane Centre (funded by the NIHR) and others in The Cochrane Collaboration to support aid agencies and decision makers dealing with the health consequences of earthquakes.

NIHR Cambridge Comprehensive BRC develops artificial pancreas

Scientists from the Cambridge CBRC publish findings in *The Lancet*, showing that an artificial pancreas can be used to regulate blood sugar in children with type 1 diabetes.

March 2010

Third wave of Senior Investigators appointed

Forty first-class clinical and applied health researchers are appointed as NIHR Senior Investigators, increasing the total number to over 200.

NIHR SDO programme awards £1.4 million to four new research projects

In response to the Department of Health's End-of-life Care Strategy, the NIHR Service Delivery and Organisation (SDO) programme funds four new research projects on services for people at the end of life, provided by professionals not specialising in palliative care. This is over and above the £1.2 million already invested by the Department in palliative care research.

New study to show how body clock controls disease

A partnership between the NIHR Manchester BRC, the University of Manchester and GlaxoSmithKline will

investigate how biological clocks control inflammation in lung diseases such as chronic obstructive pulmonary disease.

Launch of spring 2010 NIHR Leadership Support and Development Programme

This Programme offers successful applicants leadership support and development for 18 months. It now covers senior leaders, development leaders who have the potential to fill the top leadership roles, and advanced trainees who are beginning to lead their own research teams.

Assessing the value of public and patient involvement in health research

The NIHR Health Services Research and INVOLVE programmes announce a joint call to evaluate the effectiveness of public and patient involvement in health research.

SECTION 1

Putting patients and
the public at the
heart of NIHR-funded
research



The NIHR commissions and funds NHS and social care research that leads to new treatments, devices, diagnostics and best practice to provide better care for patients and the public. To make sure that the research we commission is truly in the public interest, we are leading the way in encouraging patients and the public to get involved in every area of our work.

The NIHR is committed to working with clinicians and managers in NHS Trusts to make sure that patients are aware of opportunities to take part in research relevant to them, and have the necessary information to make informed choices on whether to participate. To this end, when we commission new studies, research teams routinely have to show that they have sought input from patients, carers and the public.

Making patients the driving force

The NIHR encourages patients and the public to be actively involved in all NIHR-funded health and social care research, in order to:

- identify the important questions that health and social care research needs to answer
- give their views on research proposals alongside clinicians, methodologists, scientists, and public health and other professionals
- help assess proposals for funding
- take part in clinical trials and other health and social care research studies, not just as subjects but as active partners in the research process.

Public involvement leads to better research

Greater public involvement can lead to better research and clearer health outcomes, and can save money. A recent study by INVOLVE, *Exploring Impact: Public involvement in NHS, public health and social care research*, reported that public involvement in research helps increase recruitment to all types of research.

In clinical research it helped to ensure acceptability of trials, and participants felt them to be ethical, well designed and to have relevant outcome measures. It was also found to be of value in qualitative research where participants are asked to share their views and experiences.

“The impact of this study is immeasurable. It is a real shot in the arm for public involvement in research, which more than justifies the NIHR’s commitment. Patients and the public now have the chance to be part of real research-based change to improve the health and wellbeing of the nation.”

Professor Peter Beresford, himself a user of mental health services, chaired the advisory group overseeing the *Exploring Impact Report*. He is Director of the Centre for Citizen Participation, Brunel University, and chair of Shaping Our Lives, an independent user-controlled think tank and network for people who use social care, health and mental health services



INVOLVE

The NIHR's INVOLVE programme supports greater public involvement in NHS, public health and social care research. INVOLVE works with researchers towards creating the research community of the future, which will be broader, more inclusive and more representative of the population as a whole.

Constitutionally sound

The NIHR's efforts to include patients and the public in research is in keeping with the NHS Constitution, which states that research is a core part of the NHS and enables the health service to improve the current and future health of the people it serves.

The NHS Constitution pledges to do everything possible to ensure that patients from every part of England are aware of research that is relevant to them and that procedures are in place to ensure that they are notified of opportunities to join in relevant, ethically approved research and can choose whether to do so.

- The NHS commits to continuous improvement in the quality of services that patients and the public receive by identifying and sharing best practice in quality of care and treatments.
- Patients and the public have the right to expect NHS organisations to monitor, and make efforts to improve, the quality of healthcare they commission or provide.
- Quality of care is personal to each individual patient – patients and the public have the right to high-quality care that is safe, effective and right for them.



Clinical research networks

To make it easier for patients and health professionals to participate in relevant clinical trials, the NIHR has set up the Clinical Research Network (CRN) across England. Since it was established, it has made a significant difference to the number of people recruited onto clinical trials and to the validity of their results. In some cases, patients themselves have proposed and are leading research projects in partnership with academic researchers and NHS practitioners.

Network success

In 2009/10, the NIHR CRN:

- supported the practical delivery of 2,500 clinical studies in the NHS, including 389 funded by the life-sciences industry
- supported the recruitment of more than 400,000 patients into clinical trials
- significantly reduced the time taken from submission of an application to permission to proceed with a clinical trial
- trained more than 5,000 people in good clinical practice and other research-relevant skills, to ensure that the NHS can offer researchers on the ground the expertise to deliver clinical trials effectively
- set up 26 Specialty Groups to address national and local barriers to patient recruitment
- worked locally to ensure that resources are appropriately directed to increase the number of patients recruited into high-profile multi-centred clinical trials
- increased the number of medical technology studies receiving CRN assistance.

Clinical Research Network

The NIHR CRN aims to:

- make sure that patients and healthcare professionals from all parts of the country are able to participate in and benefit from clinical research
- integrate health research and patient care
- improve the quality, speed and coordination of clinical research
- increase collaboration with industry partners to make sure that the NHS can meet the health research needs of industry.

A number of specific topic networks coordinate clinical trials for cancer, stroke, mental health, diabetes, medicines for children, dementias and neurodegenerative diseases. Meanwhile, the Comprehensive Clinical Research Network coordinates clinical trials in disease areas outside these conditions, while the Primary Care Research Network focuses on disease prevention, health promotion, screening, early diagnosis, and the clinical management of long-term conditions in the community.

Transforming stroke rehabilitation

Patients in the West Midlands have been helping health professionals tailor rehabilitation more closely to individual needs by evaluating a new test, known as the Birmingham University Cognitive Screen (BUCS) to screen patients for cognitive problems after a stroke.

The BUCS trial, funded by the Stroke Association, is designed to standardise assessment of stroke patients' practical abilities to help them recover more quickly. Patients are asked to perform 22 tasks to assess specific strengths and weaknesses in skills involving attention, memory, language, number, and action control and planning.

Until the West Midlands Stroke Local Research Network (LRN) became involved, BUCS was a small trial at a single site at Moseley Hall Hospital, as the BUCS team had no experience in constructing a multi-centre trial. The LRN provided a package of skills and resources that was critical in increasing recruitment.

The LRN involved occupational therapists, used local knowledge to engage 12 sites across the region and provided research assistants to secure ethical approval, recruit patients, obtain consent and determine their mental capacity. This turned what was a relatively modest trial into a major success, the results of which are now having a strong positive impact on stroke treatment in the area.

Stroke survivor Brin Helliwell, who took the BUCS assessment, says, **"It was a real test of my cognitive abilities. It has all sorts of possible applications and could be an invaluable motivational tool, especially for young stroke survivors."**

Dr Wai-Ling Bickerton, Research Fellow, Behavioural Brain Sciences Centre, University of Birmingham and principal researcher for the BUCS study, adds **"While traditional assessments highlight what people can't do, this assessment clarifies what they can do. Patients like it and it means we can immediately advise them on what treatment will help them improve"**.

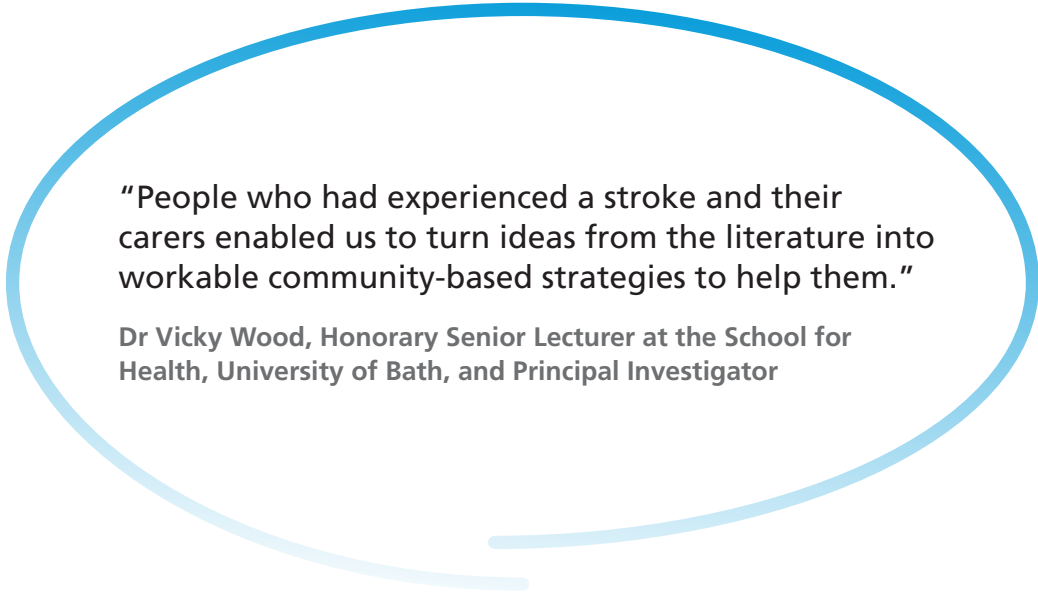
FACT

Strokes affect 150,000 people in the UK each year and are the leading cause of severe disability. Rehabilitation is vital to get people back on their feet and to help them live a full life. NIHR LRN involvement in the BUCS trial will help treatment to be better targeted to help patients regain their cognitive abilities following a stroke, with significant benefits for them and their families, and better use of NHS resources.

Research benefits for patients

Still focusing on stroke, another study – this time funded by the NIHR Research for Patient Benefit (RfPB) programme – invited stroke survivors and carers to give feedback and comments on a literature review of ways to provide optimum rehabilitation and community stroke services.

The review provided new insights into what stroke survivors need to live fulfilling lives, and is now aiding the development of new ways to provide rehabilitation for people who have suffered a stroke and their carers.



“People who had experienced a stroke and their carers enabled us to turn ideas from the literature into workable community-based strategies to help them.”

Dr Vicky Wood, Honorary Senior Lecturer at the School for Health, University of Bath, and Principal Investigator

Research for Patient Benefit

The RfPB programme is a national response-mode funding stream for research into everyday practice in the health service. Applications are assessed and processed by regional committees to ensure that research proposals increase the effectiveness of NHS services, provide value for money and benefit patients. In 2009/10, RfPB awarded over £21 million to 99 research projects. A total of 305 projects have been funded in ten competitions since 2006.

Translating research into better public health

The NIHR's focus on commissioning and delivering applied research that benefits patients and the public directly, and involving the public in designing and assessing outcomes, means that patients and the public have a strong local and national voice in shaping the NIHR's work and translating the results into better public health. Patient involvement is crucial for NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs), for example helping to turn research findings into new interventions to help improve health throughout the country.

Champions for achieving better health

In Sheffield, the South Yorkshire CLAHRC is evaluating a patient-led project to help reduce the risk of heart disease in the city's Asian community.

The Champions for Achieving Better Health in Sheffield (CABS) project offers Asian taxi drivers information and screening tests, such as blood pressure and cholesterol. The idea is that they then spread healthy lifestyle messages to their families, community, fellow cabbies and customers.

The South Yorkshire CLAHRC is working with Sheffield Hallam University and the NHS to analyse the project's cost-effectiveness and draw out key lessons, which could be applied elsewhere in England, to help reduce the risk of heart disease, diabetes and other common diseases. They are now evaluating the project to see if it can be rolled out across the country.

Sheffield cab driver Tahir Ali, 42, took part in the CABS project. He says, **"As a Health Awareness Champion, I try to spread the health message to everyone I meet. A friend from the local shop was overweight and I encouraged him to join the gym. Now he's half the man he was. Every time I see him he says, 'That's the man who saved my life.'"**

The CABS project is just one instance of the imaginative ways in which CLAHRCs are working to translate research findings into better public health. Other examples of how CLAHRCs are having an impact include:

- the publication of *Guidance on Action to be Taken at Suicide Hotspots*, based on work by researchers in the South West Peninsula CLAHRC. As a result, Primary Care Trusts and other bodies are now installing Samaritans signs and crisis phones at well-known suicide hotspots
- DESMOND, an education programme for people with or at risk of type 2 diabetes, taken forward by the Leicestershire, Northamptonshire and Rutland CLAHRC, which is now being rolled out nationally. This work has led to the development of other diabetes lifestyle prevention programmes, such as 'Walking away from diabetes'. These can lower the risk of high-risk individuals developing type 2 diabetes by 30–60 per cent.

Collaborations for Leadership in Applied Health Research and Care

The NIHR funds nine CLAHRCs, collaborative partnerships between universities and surrounding NHS organisations. They focus on developing models for conducting and applying health research that can be transferred across the NHS to provide the highest quality of patient care. In 2009/10, expenditure on CLAHRCs increased to £18.5 million.

Evaluating public health

Patients and the public are an integral part of the public health studies the NIHR is funding. They aim to identify preventive interventions to improve individual lives as well as benefiting the wider community and society to help ensure that everyone has the same chance to stay healthy.

On the buses



Tabitha Manzuangani
(photograph courtesy of LSHTM)

Tabitha Manzuangani, 15, from Norwood School, south London questioned 64 fellow students aged 11–16 as part of a study into the health implications of free bus travel for children and young people. She says, **“My research suggests that free public transport is correlated with better mental health in students under 16. This is important as anxiety, inferiority complexes and other mental health problems can lead to problems such as drug abuse, gang violence and even physical illnesses, such as heart disease.”**

Tabitha’s findings are part of the ‘On the buses’ project led by Dr Judith Green and colleagues at the London School of Hygiene and Tropical Medicine (LSHTM) to evaluate the impact of free bus travel on young people. The team is looking at both the direct impact of free bus travel on walking levels, road traffic injuries and assaults, and the indirect impact by examining whether free bus passes improve young people’s access to education, training or activities (such as sports that may benefit their health). It will also weigh up potentially negative impacts, for example on older people.

Dr Green, Reader in Sociology of Health, Health Services Research Unit, LSHTM says, **“This is an important study which will add to our understanding of how non-NHS services, such as transport, can affect health and wellbeing. We hope its findings will be used to inform the debate and ensure that decisions about the future of the scheme are made on the basis of what is best for the health of younger and older citizens.”**

Public Health Research programme

The ‘On the buses’ research is one of eight projects funded in 2009/10 by the NIHR’s Public Health Research programme. The programme funds research to provide new knowledge on the benefits, costs, acceptability and wider effects of non-NHS interventions intended to improve the health of the public and reduce health inequalities.

Research for future generations

In many cases, patients and the public agree to take part in research because, although they may not see the benefits themselves, they want to contribute to better health for future generations. For example, in Newcastle many patients and members of the public have agreed to donate their brains after death to a 'Brain Bank'. The Brain Bank is part of the Institute for Ageing and Health (IAH) and the NIHR Newcastle Biomedical Research Centre (BRC) in Ageing, and is helping researchers in their quest to improve understanding of the different disease processes in the brain that may lead to dementia.

Brain bank

Patricia Parker, 66, from Whitley Bay has agreed to donate her brain to the Brain Bank. She says, "I hope that my decision to donate my brain to the Brain Bank when I die will help researchers find a cure for dementia. I live alone and think how awful it would be to be diagnosed with such a dreadful disease and know you are just going to sink away. The sooner they find a cure the better. By becoming involved in the Brain Bank, I feel I am contributing to that cure."

Professor Ian McKeith, leader of the Newcastle Dementia and Neurodegenerative Diseases (DemaNDs) Research Group, part of the IAH at the NIHR BRC in Ageing, adds, "The Newcastle Brain Tissue Resource, supported by the Newcastle BRC with NIHR funding, is allowing us to make accurate, quantitative measures of all the different age-linked changes that can take place in the brain. This in turn will help us to develop sophisticated new ways to diagnose dementia and devise treatments tailored to people's specific needs."

The Newcastle Brain Tissue Resource is a joint venture between Newcastle-upon-Tyne Hospitals NHS Foundation Trust, Newcastle University IAH and the NIHR BRC in Ageing. The NIHR meets its service support costs and pays for NHS technical staff time.

The Resource has recently attracted backing from Brains for Dementia Research, funded by a joint award from the Alzheimer's Society and the Alzheimer's Research Trust.

Biomedical Research Centres

The NIHR funds 12 BRCs, five comprehensive and seven specialist, in the priority areas of Ageing, Cancer, Genetic and Developmental Medicine, Mental Health, Microbial Diseases, Ophthalmology and Paediatric/Child Health, to drive innovation in the prevention, diagnosis and treatment of ill health and to translate advances in biomedical research into clinical practice. In 2009/10, expenditure in BRCs increased to £117 million.

Tailored screening to improve breast cancer detection



Professor Gareth Evans

Pamela Daniels (Photograph courtesy of MEN Syndication)

Thousands of women in the Manchester area are helping researchers in an ambitious study to improve breast cancer detection by calculating their individual breast cancer risk. Women who take up the offer of a mammogram under the NHS breast screening programme are being invited to join the five-year study, which, it is hoped, will lead to more personalised breast screening based on risk.

The researchers will combine the results of the women's mammograms with known genetic variations and other factors, such as diet, exercise, age, pregnancy and menopause, to compute the risk.

"The study's findings are expected to lead to a greater uptake of mammography, fewer missed appointments and improved diagnosis of breast cancers at a stage when there is a greater chance of cure. This in turn should lead to fewer women turning up with advanced cancers, and lower treatment costs for the NHS," says Gareth Evans, NIHR Senior Investigator and Professor of Medical Genetics at the Regional Genetic Service, St Mary's Hospital Manchester, who is leading the study with the aid of an NIHR Programme Grant for Applied Research.

Pamela Daniels, 53, of Ashton-under-Lyne is one of 60,000 women taking part in the study, which is funded by a £1.59 million NIHR Programme Grant for Applied Research with support from the Genesis Appeal, the only charity in the UK entirely dedicated to the prevention of breast cancer.

She says, **"I agreed to take part in the trial when I went for a routine mammogram because I thought it might help other women. I didn't expect it to help me directly. Although quite a few female relatives had had breast cancer, I was shocked when the researchers told me this put me at a higher risk of the disease. I now go for regular screening, as does my sister. I feel something really good has come out of taking part in this research and I would encourage anyone to take part in a research trial if they get the opportunity. It certainly may have saved my life."**

Professor Evans, who also chairs the NICE Familial Breast Cancer Clinical Guideline, adds, **"As a clinician scientist, the NIHR Programme Grant for Applied Research funding has been absolutely invaluable, enabling me to build a fabulous research team dedicated to improving care for women entering the NHS Breast Screening Programme. Without NIHR's funding we would not be in a position to offer risk information to women or to help use NHS resources more effectively by targeting screening to those most at risk, many with little or no family history of breast cancer."**

FACT

One in ten women in this country will develop breast cancer at some time in their life. Thanks to huge strides in treatment, many more of them are surviving. However, there are still knowledge gaps in diagnosis, screening and prevention. NIHR funding of the world's largest ever study to look at causes and risk factors will help to fill these gaps, saving more lives and reducing NHS costs.

Programme Grants for Applied Research

NIHR Programme Grants for Applied Research provide the NHS with the evidence needed to improve health outcomes in areas of priority or need, such as disease management, safety and quality.

In 2009/10 a total of £42 million was awarded to 23 Programme Grants, including:

- quality of care – from children with respiratory tract infection to maternal care
- general health issues such as obesity, smoking and back pain
- a range of mental health interventions for example for people, with dementia, bipolar disorder, psychosis or attention deficit hyperactive disorder.

The first five Programme Development Grants were also awarded, totalling £0.5 million.



Better and cheaper solutions

Media coverage of health and social care and the development of new medicines and treatments can often focus on the high cost of medical treatments and care services. Yet good news stories of treatments that save the NHS money often attract less airtime and fewer column inches.

The NIHR's quest to commission research that leads to better outcomes for patients can also lead to cheaper solutions for the NHS. For example, NIHR funding is helping Professor Monica Spiteri and a team from the Directorate of Respiratory Medicine, University Hospital of North Staffordshire to test a new hand-held monitor that patients can use at home to detect progression of a common chronic breathing disorder. The new device uses infrared light to give a snapshot of changes in sputum – which can provide an early indication of chronic obstructive pulmonary disease (COPD) getting worse.

“This would be a major leap forward in the management of COPD. It could give patients more independence, enabling them to take preventive medication earlier. This would avoid costly GP visits and hospital stays, which currently cost the NHS £2,337 per admission, as well as leading to new targets for treatment.”

Monica Spiteri, Professor in Respiratory Medicine, Research Institute for Science and Technology in Medicine, Keele University

FACT

COPD causes progressive airway blockage and breathlessness. Emergency hospital admissions for the disease cost the NHS £253 million in 2003/04 (the latest date for which figures are available). NIHR funding to test an infrared device that can flag up signs of the condition getting worse could lead to better treatment for patients and also help to reduce pressure on NHS emergency admissions and costs.


Research for Innovation

This NIHR programme provides small, discrete grants for new and radical health research proposals that could lead to a step change in the care and management of patients. Grants are awarded to novel proposals that traditional peer review panels may reject as risky. In 2009/10, the programme awarded £1.1 million to six new research projects.

Improving patient safety

The NIHR's research does not focus solely on medical interventions. The invaluable work carried out by the NIHR's two NHS Patient Safety and Service Quality Research Centres (PSSQs) is helping to ensure that everyone using NHS services feels safe wherever they are treated.

At the Imperial College London PSSQ, for example, Dr Rachel Davis examined patients' willingness to raise safety-related issues and quizzed doctors and nurses on safety precautions relating to infection control, medication and reported incidents, as part of her PhD. The project is now assessing how patients can contribute to the safety and quality of their care and to develop and test ways to help them do this.



“Involving patients in monitoring the quality and safety of their treatment could help increase their satisfaction, improve their relationship with healthcare professionals, improve the quality of their care and reduce costs arising from medical errors.”

Dr Rachel Davis, PSSQ, Imperial College London

Meanwhile, researchers from the NIHR's PSSQ at King's College Hospital are working to discover what steps staff can take when a patient on a general ward suddenly deteriorates, to enable their level of care to be stepped up quickly.

The team are interviewing ward staff at Guy's and St Thomas' Hospitals, including healthcare assistants and student nurses. They want to find out how their response to changes in vital signs indicating a potential deterioration in a patient's condition (such as blood pressure, temperature and pulse) can alert them to the need to intervene.

Use of an early-warning score and better communication strategies have markedly reduced the risk of patients suffering a cardiac arrest at the hospital in the past year. The NIHR PSSQ researchers aim to draw out the key elements of best practice that will work in other hospitals.

“30–50 per cent of patients who develop severe sepsis die and every hour where effective treatment is delayed increases that risk. A high-quality response by staff at an early stage is essential to reduce this and is fundamental for patient safety. The PSSQ team have gained a variety of insights, which could in future improve patient safety in hospitals all over the country and save thousands of lives.”

Dr Adrian Hopper, Consultant Physician and Geriatrician, and Associate Medical Director for Patient Safety, Guy's and St Thomas' NHS Foundation Trust

Patient Safety and Service Quality Research Centres

PSSQs bring together NHS professionals from a wide range of research disciplines to investigate ways to improve the safety, quality and effectiveness of the services the NHS provides to patients and the public. Funding for PSSQs in 2009/10 increased to £2.7 million.



Improving the quality of social care

NIHR research is not solely concerned with improving the evidence base for health services. Social care, which is inextricably linked to healthcare, is also important. The NIHR School for Social Care Research (SSCR), one of two flagship schools funded by the NIHR (the other being the NIHR School for Primary Care Research) is working to enhance the evidence base for adult social care practice in England. Its aim is to improve the quality of practice, not just for people who use care services but for carers and practitioners as well.

There is robust research evidence that investment in social care can result in significant cost savings for the NHS, reflecting the interdependence between social care and healthcare, as well as increasing individuals' independence, quality of life and wellbeing.

Moving on from psychosis

A group of service users helped to inspire a new project designed to help people with serious mental health problems to move forward in their lives. The Enigma project, funded by the SSCR, will look at how health and social care professionals can help people recovering from an episode of psychosis develop new social relationships and make the most of these and other contacts. A key aim is to develop new guidelines for health and social care professionals and self-help materials for people who use services.

Dr Martin Webber, Programme Leader, Institute of Psychiatry, King's College London says, **"People experiencing psychosis tend to have fewer friends and less contact with family members, and find it difficult to sustain a job or stable housing. Group discussions in an NIHR Mental Health Research Network Clinical Research Group revealed how much service users value the help of their workers in developing social relationships and other forms of what we call 'social capital'.**

"The Enigma project will examine how health and social care workers can best help people who are recovering from psychosis to gain access to more social capital."

The project's advisory group includes two service-user researchers as well as consultants, who will be involved at all stages. In liaison with a wider reference group of service users and carers, they will also help to refine and disseminate the guidelines and self-help materials.

In 2009/10, the SSCR:

- launched its first public call for research proposals, resulting in the submission of 36 outline proposals, short-listed to ten, with five projects funded
- committed an initial £1.8 million to research projects
- commissioned 16 new methods reviews and two scoping reviews
- appointed 40 researchers as SSCR Fellows
- worked with 41 organisations in the consultation process, which submitted 121 research topics in the first few months (responses were received from users, carers, practitioners, social care organisations, researchers and the public)
- hosted its first annual conference
- held its first workshop on user involvement in adult social care research
- recruited three service users, three carers and three practitioners to set up a User, Carer, Practitioner Reference Group.

School for Social Care Research

The SSCR is a partnership between six leading academic centres of social care research in England:

- Personal Social Services Research Unit, London School of Economics and Political Science
- Personal Social Services Research Unit, University of Manchester
- Social Policy Research Unit, University of York
- Personal Social Services Research Unit, University of Kent
- Social Care Workforce Research Unit, King's College London
- Tizard Centre, University of Kent.

SECTION 2

Supporting the research community



Building a strong research community

In the past four years, the NIHR has created a research infrastructure that has successfully turned this country into a global clinical research centre second to none. However, world-class facilities alone are not enough. We need people with the ability to conduct world-leading research. The NIHR is privileged to work with some of the brightest minds in the country. The NIHR Faculty is at the heart of our determination to support them and to create a strong and vibrant research community.

The NIHR Faculty

The NIHR Faculty facilitates the exchange of ideas about research and innovation to advance health and social care research, now and in the future, by:

- funding training and career development, and implementing research capacity-building programmes
- offering mentoring and outreach, and supporting the development of present and future leaders
- running conferences and themed workshops to bring Faculty members together to share ideas and support learning, and
- sponsoring collaborative working through the NIHR Portal.

Faculty membership

The NIHR Faculty members are those who conduct or support people-based research and whose salary is funded at least in part by the NIHR. There are four categories of membership:

1. Senior Investigators lead the NIHR's most prestigious applied health and social care research. They are selected through annual competitions as 'best in their field' and provide research leadership and expert advice to the Faculty.
2. Investigators are actively engaged in research and include lead researchers, other senior researchers, and research assistants.
3. Associates support research led by others. They include clinical and clinical support staff, and scientific, laboratory, technical and research and development (R&D) staff.
4. Trainees are on one of the many NIHR training schemes and include Academic Clinical Fellows, Clinical Lecturers, Clinician Scientists and Research Fellows.

Supporting outstanding research leaders



Professor Til Wykes

The NIHR supports the country's most outstanding research leaders in clinical and applied health research through its prestigious Senior Investigator scheme.

Professor Til Wykes is one of over 200 Senior Investigators, chosen by rigorous peer review for her exceptional achievements as one of the best researchers in the mental health field. Like many of her colleagues, Professor Wykes wears more than one hat. She is Director of the NIHR Mental Health Research Network (MHRN). She also continues to work as a consultant clinical psychologist at London's Maudsley Hospital, and she is Professor of Clinical Psychology and Rehabilitation at the Institute of Psychiatry, King's College London.

Currently, Professor Wykes is leading a five-year NIHR Programme Grant for Applied Research (PGAR) study, which is set to improve inpatient psychiatric care at the South London and Maudsley NHS Foundation Trust. Staff and service users are involved in the study known as PERCEIVE (Patient involvement in improving the evidence base on inpatient mental health care). More than 1,000 service users and 1,000 acute ward staff members will have taken part in the study by the time it is completed in 2012.

"Inpatient psychiatric services are a major cost to the NHS. PERCEIVE is leading the way by prioritising service users' opinions in the development of inpatient care so that services are responsive to their needs, are more therapeutic and more likely to be effective. As well as measuring the effects of different ways of providing care on service users' perceptions, the team will calculate cost-effectiveness using a new measure of inpatient costs also developed with input from staff and patients", says Professor Wykes.

As director of the NIHR MHRN, Professor Wykes has done much to raise the profile and funding for mental health research in England. In 2009/10, the MHRN supported over 230 projects and recruited more than 32,000 participants – more than double the number taking part in mental health research previously. She says, **"This is a great achievement for the MHRN and a testament to our joint working with service users, carers and health service staff."**

She adds, **"Investment in mental health research is vital if we are to change our understanding of mental illness and prevent and treat it. The recognition of being a Senior Investigator as part of the NIHR Faculty is immensely rewarding and hopefully will provide me with support for continuing my activities in this area."**

FACT

One in four people in this country (over 12 million in all) experience a mental health problem each year, at a cost to the country of £100 billion. The NIHR's investment in mental health research has the potential to save the economy money and to improve social cohesion and family relationships.

Promoting leadership capability

In the past year, the NIHR has spearheaded a leadership programme for NIHR-funded researchers with the world-leading business school Ashridge. The programme initially targeted those in positions of the greatest responsibility. Now, it also has separate schemes for those aspiring to senior leadership roles (development leaders) and advanced trainees beginning to lead their own research teams.

So far, nearly 100 members of the NIHR Faculty Investigators have joined the scheme, which helps to develop core leadership and management skills tailored to their specific needs. It is enabling them to balance managerial, academic, clinical and research commitments. This will arm them with the necessary skills to drive forward evidence-based health research in a climate of continuing change.

“The NIHR Leadership Development Programme has been a step change in the way clinical research is supported. It has provided the research leaders with a unique opportunity to reflect on what leadership means and how it can best serve the aspirations of the whole NIHR initiative.”

Professor Ratko Djukanovic, Director of the NIHR Respiratory Biomedical Research Unit, Southampton University

“The NIHR’s Leadership Support and Development Programme gave me time to evaluate my own strengths and weaknesses and those of my Clinical Research Team. I especially valued mixing with others who understood the challenges of being a clinician and a researcher.”

Dr Candy McCabe, NIHR Career Development Fellow, Bath Centre for Pain Research

“The NIHR Leadership Development Programme has given timely insight, tools and training to many senior leaders in the pursuit of NIHR objectives and coordination of research teams, advancing the management of patients while securing our capacity for this vital work in the future.”

Professor Robert Sutton, Director of the NIHR Pancreatic Biomedical Research Unit, Liverpool University

Building research capacity

The NIHR aims to support researchers at all stages of their careers and in all research roles, not just those at the top. To this end, the NIHR provides a range of awards designed to build up the research skills of the NHS workforce to advance health and social care research now and in the future, and promote research as a viable career option for young researchers.

Developing doctors and dentists

The NIHR Integrated Academic Training Programme supports doctors and dentists wanting to combine research and professional training and is designed to ensure that trainees receive appropriate training and mentoring.

The NIHR Clinician Scientist Award Scheme, meanwhile, supports qualified doctors and dentists with the potential to be outstanding clinical academics. Other schemes focus on specific professional groups or are open to all those with the appropriate experience who wish to train in clinical and applied research.

In 2009/10, the In-Practice Fellowship funding stream provided support for 16 qualified GPs and dentists across England. The Fellowships allow GPs and dentists to pursue research alongside their clinical work and provide them with the skills to develop and lead their own research projects. The programme's success depends on co-operation between the Primary Care Trusts and academic institutes to ensure that Fellows can meet their clinical practice commitments and pursue their academic training.

Supporting the research leaders of the future

Dr Vishal Aggarwal is the first working general dental practitioner to receive an NIHR Clinician Scientist Award. This has enabled him to research a new approach to a painful condition affecting the face, mouth and jaws.

Current treatments for the condition, known as chronic orofacial pain (COFP), are often invasive, painful, harmful or, worse, ineffective. More importantly, Dr Aggarwal found they do nothing to tackle the anxiety and other psychological factors, which often herald the onset of COFP or the poor coping strategies that can make it last longer.

Dr Aggarwal is now working with a multi-disciplinary team of internationally recognised researchers to turn his findings into a behavioural intervention for COFP at the University of Manchester. The recent award of a prestigious Senior Lectureship in General Dental Practice at London's Queen Mary's University puts him on course to becoming one of England's leading research dentists and shows the enormous value of NIHR funding in enabling clinicians to develop a research career.

Dr Vishal Aggarwal, Professor of General Dental Practice at Queen Mary's University adds, **"The NIHR's Clinician Scientist Scheme has helped me pioneer a career pathway which has both helped me personally and has huge potential to increase academic numbers in dentistry, as well as making sure research is relevant to patients and practitioners in primary care, where 90 per cent of dentistry takes place."**

Integrated Academic Training Programme

The Integrated Academic Training Programme, including the Clinician Scientist Award, supports doctors and dentists wanting to develop academic skills while completing their professional training. In 2009/10, the NIHR supported 1,105 dentists and doctors in specialty training through the Academic Clinical Fellowship (ACF) and Clinical Lectureship (CL) schemes. Overall spend was £51.1 million.

Supporting career development

The NIHR also runs Fellowship schemes open to professions involved in clinical and applied health research from doctoral research training to Senior Fellowship Awards. In 2009/10 applications increased from an excellent set of candidates, enabling the NIHR to more than double the number of Fellowships awarded to 47. Some £10.5 million was spent on these and other awards made under earlier schemes accounted in 2009/10.

Supporting nurses and health professionals

To improve patient care and enhance patient experience, nurses, midwives and other allied health professionals, as well as doctors and dentists, need the chance to develop research skills alongside their clinical practice. The NIHR's Clinical Academic Training Programme, funded mainly by the Chief Nursing Officer, provides the opportunity for them to do just that.

The Programme provides training at all stages from Masters to Senior Clinical Lecturer level. A similar scheme, funded by the Chief Scientific Officer, which provides early career research training for healthcare scientists, is also now in its second year.

Clinical Academic Training for nurses and allied health professionals

Clinical Academic Training supports clinical academic careers for nurses, midwives and allied health professionals, in collaboration with the Chief Nursing Officer for England, the Economic and Social Research Council and the Higher Education Funding Council for England. During 2009, 15 Clinical Doctoral Fellowships and 10 Clinical Lectureships were awarded.

Maternity care



Inga Dandoraviene and Lucia Rocca-Ihenacho

Lucia Rocca-Ihenacho, Senior Midwife Practitioner at Barts and The London NHS Trust, is one of two midwives benefiting from the Clinical Doctoral Research Fellowship scheme administered by the NIHR on behalf of the Chief Nursing Officer. She divides her time between her doctorate and clinical practice.

She says, "There is growing interest in finding possible solutions to the rising tide of childbirth interventions. Freestanding birth centres are one example of a 'model' of maternity care, which could help to reduce unnecessary intervention and improve service users' and staff experiences. My study aims to expand the knowledge and understanding of freestanding birth centres, which are geographically separated from hospitals."

She observes, "This study will complement 'The Barkantine Birth Centre Study: Assessing the impact of a new birth centre on choice and outcome of maternity care in an inner city area'. This consisted of a survey of women's views, an economic evaluation and analysis of routine data. The study, led by Professor Macfarlane from London's City University and funded by the NIHR Research for Patient Benefit Scheme, ended in March 2010.

"This Fellowship is a tremendous opportunity for me personally and I hope the availability of NIHR support will encourage other midwives like myself to combine a clinical and academic career."

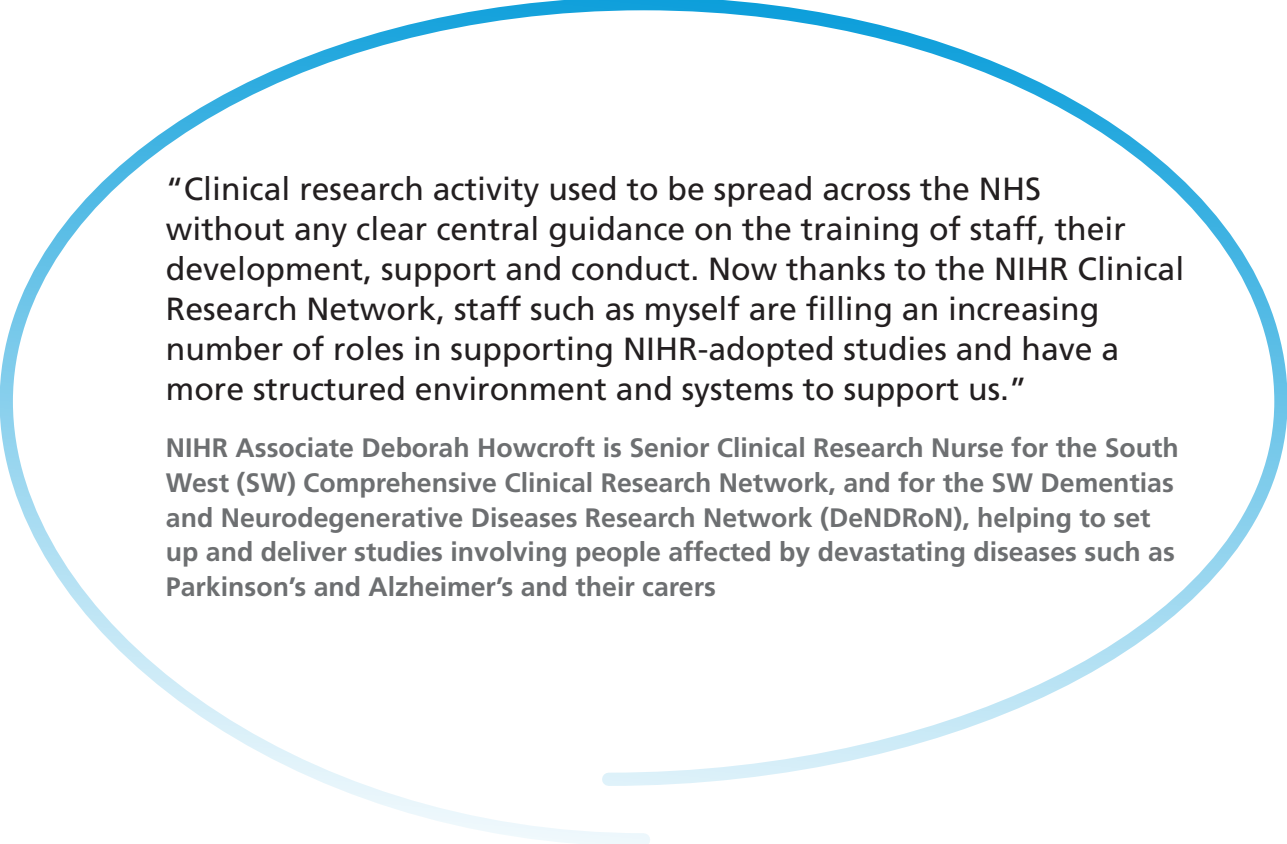
Inga Dandoraviene, who is expecting her first child, said, "I'm very excited to give birth at the birth centre and am keen to use the pool."

"The midwife discussed my progress not in numbers – how many hours to go or how many centimetres I was dilated – but by positively encouraging and listening to me. She was very supportive and understanding to me and my partner."

"The midwives were fantastic, really professional, I felt empowered by them. They had really good social skills."

Developing support staff

The NIHR does not just value the leaders of the research world. It also supports the often-unsung heroes and heroines, without whom research would be impossible: the staff who analyse tissue samples, enrol patients on trials and perform the myriad other tasks needed to support researchers in their work. These NIHR Associates, as they are known, may include consultants, nurses, other health professionals, scientific, laboratory and technical workers, or indeed any of the thousands of research staff across the country whose salaries the NIHR contributes towards, to enable them to support research.



“Clinical research activity used to be spread across the NHS without any clear central guidance on the training of staff, their development, support and conduct. Now thanks to the NIHR Clinical Research Network, staff such as myself are filling an increasing number of roles in supporting NIHR-adopted studies and have a more structured environment and systems to support us.”

NIHR Associate Deborah Howcroft is Senior Clinical Research Nurse for the South West (SW) Comprehensive Clinical Research Network, and for the SW Dementias and Neurodegenerative Diseases Research Network (DeNDRoN), helping to set up and deliver studies involving people affected by devastating diseases such as Parkinson’s and Alzheimer’s and their carers

Mentoring matters

To further their careers, researchers need the dedicated time and support to explore and determine their goals. The NIHR/Academy of Medical Sciences' unique Mentoring and Outreach Scheme, funded by the NIHR, enables clinical academic trainees to do this. The scheme offers advice on career planning, facilitates personal development and helps individuals build research networks and collaborations.

The Scheme offers group support, or one-on-one mentoring, depending on the level of trainee. This is just one of the many ways in which the NIHR is helping clinical academics to combine clinical practice with research as they progress along their career pathway.

Mentor

"The NIHR/Academy of Medical Sciences' Mentoring and Outreach Scheme is helping to maintain the flow of clinicians through the NIHR Integrated Academic Training Pathway, providing trainees with a portfolio of support, events and advice as they make key decisions."

Professor David Adams, Professor of Hepatology,
University of Birmingham

Mentee

"The NIHR's support of the Academy of Medical Sciences' Mentoring and Outreach Scheme means I can get independent advice and has helped me deal with the significant challenge of carrying on my research alongside my clinical practice."

Peter Hutchinson, Senior Academy Fellow and
Honorary Consultant Neurosurgeon, University of
Cambridge

Flexibility and sustainability

To stay active in research, NHS organisations have to be able to meet the costs, not just of researchers but also of their support workers. The NIHR allocates a dedicated sum to enable research-active NHS organisations to attract, develop and retain staff engaged in supporting high-quality clinical and applied health research. These funds meet some or all of the salary costs of researchers and their support workers where these are not already met by another funding source. Now in its third year, Flexibility and Sustainability Funding has proved invaluable in helping NHS organisations to sustain the workforce needed to support research funded by the NIHR and its partners.

"This funding has allowed us to retain experienced and skilled staff, enabling them to spend more time undertaking NIHR-related activities."

Petra Newbound, R&D Manager, Leeds Teaching Hospitals NHS Trust, host of West Yorkshire Comprehensive Local Research Network

"Researchers and clinical staff greatly value the Flexibility and Sustainability Fund and the opportunities that it provides."

Dr Tony Soteriou, Director of Research and Development, Avon and Wiltshire Mental Health Partnership NHS Trust

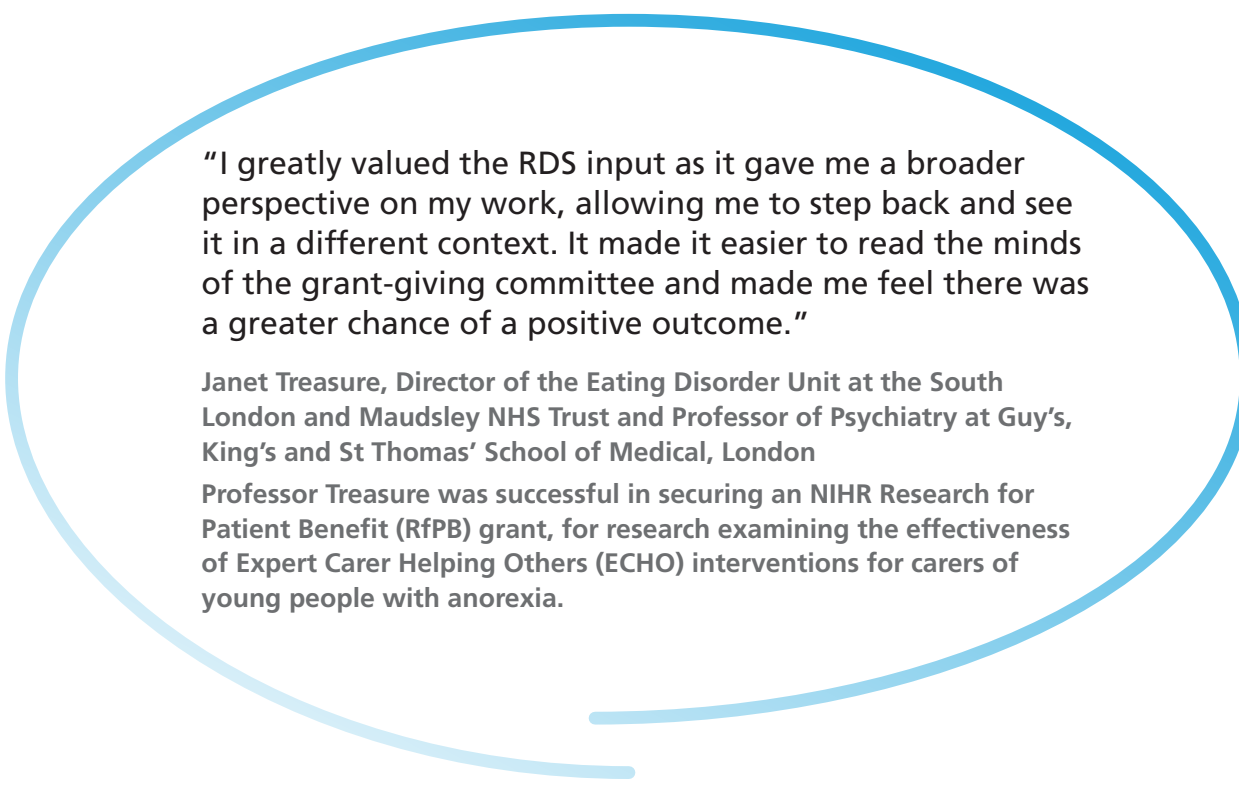
Improving the research environment

The NIHR aims to create a welcoming environment that positively encourages cutting-edge research and innovation in the NHS at every stage of the research process, from initial funding to final dissemination of the results. To this end, the NIHR has developed new systems to allow research projects to be peer reviewed and funded as quickly as possible, while meeting the highest ethical and regulatory standards to maintain patient and public confidence.

The NIHR's rapid response to the urgent need to assess the effectiveness of newly developed H1N1 flu vaccines in the face of a potential pandemic last winter is proof of the efficacy of the new systems it has put in place. It also shows how well they work when all partners involved collaborate (for more on the NIHR's pandemic influenza A (H1N1) response see page 61).

Better research by design

Researchers may need help and guidance to negotiate what may initially seem like a complex and impenetrable process for obtaining research funding. To help them the NIHR advises researchers through ten regional Research Design Services (RDS), set up to help researchers submit better proposals with a greater chance of securing funding.



"I greatly valued the RDS input as it gave me a broader perspective on my work, allowing me to step back and see it in a different context. It made it easier to read the minds of the grant-giving committee and made me feel there was a greater chance of a positive outcome."

Janet Treasure, Director of the Eating Disorder Unit at the South London and Maudsley NHS Trust and Professor of Psychiatry at Guy's, King's and St Thomas' School of Medical, London

Professor Treasure was successful in securing an NIHR Research for Patient Benefit (RfPB) grant, for research examining the effectiveness of Expert Carer Helping Others (ECHO) interventions for carers of young people with anorexia.

Research Design Service

The RDS helps researchers develop and design high-quality research proposals for submission to national, peer-reviewed funding competitions for applied health or social care research. They can offer guidance on sources of funding, research costing and engagement with research networks. They also help to ensure the involvement of patients and the public as lay members at an early stage, as well as encourage researchers to specify the potential benefits for patients, the public and the NHS.

In the first six months following their launch, the RDS provided more than 1,000 consultations and helped researchers to submit nearly 300 funding applications.

Busting bureaucracy

In the past, the process of getting health research off the ground was often hampered by red tape. One of the NIHR's specific remits is to eradicate such unnecessary bureaucracy, and its continued focus on this is now well on the way to achieving a health research structure that is simple, robust and less time-consuming.

For example, the NIHR's Coordinated System for Gaining NHS Permission (CSP), together with the Integrated Research Application System (IRAS) and Research Passport scheme, are now helping to speed up the research governance process, making it much easier and faster for researchers to get research underway.

"The web-based IRAS, which allows researchers to enter data just once instead of having to duplicate it for many sites, has really speeded things up. The Medicines and Healthcare products Regulatory Agency authorisation for a healthy volunteer phase I study now takes on average less than 13 days, which compares favourably with the US."

John Illingworth, Managing Director, Clinical Development and Support Services Ltd

There is a continuing programme of improvements to IRAS, led by the National Research Ethics Service (NRES), under the auspices of the UK Clinical Research Collaboration (UKCRC). Improvements in the last year included the addition of a new form for application to the Social Care Research Ethics Committee, established in June 2009, an e-learning package for applicants, and detailed changes to help applicants transfer information between IRAS and the EU's EudraCT system.

The NRES also carried forward a programme of planned reforms, including piloting a proportionate review service, which is designed to ensure an appropriate level of review for low-risk studies presenting 'no material ethical issues'. It provides a responsive service for researchers while continuing to protect the interests of research participants.

Speeding up the research process

During 2009/10, the NIHR continued to refine mechanisms to speed up and facilitate the research process from concept to completion. This included:

- reviewing the NIHR CSP, to learn from experience since its launch in 2008
- updating guidance on Research Passports in line with the Vetting and Barring System, which came into operation in 2009
- developing the capacity of the NIHR Networks to support research teams in setting up studies so that they are less likely to fail, and
- launching a new programme of work to support and streamline local NHS research management. This will create a national framework of NIHR Research Support Services to facilitate the reconfiguration of NHS R&D Departments and improve the quality, speed and efficiency of research and research processes in NHS bodies.

Integrating information

To enable researchers to compare trends and cross-reference different types of data, the NIHR has been building an integrated information system to make inputting, retrieving and disseminating information faster and easier.

The NIHR Web Portal provides a secure platform where researchers can access shared workspaces, store information and collaborate on documents. This is especially useful for researchers working on projects and trials across multiple sites.

The NIHR Information Systems Programme is also piloting a unique online system, the Research and Development Management Information System (RDMIS), which should make carrying out research projects easier and more efficient. RDMIS will be available through the Portal where researchers will be able use it from initial concept to completion.

For example, the system could be used to help researchers develop proposals for research projects in collaboration with colleagues, find funding opportunities, apply for approvals, manage their study and publish and disseminate study findings. At each stage, RDMIS will support research teams, providing dedicated functionality and access to information.

Research and Development Management Information System

RDMIS will offer:

- a database enabling researchers to identify potential collaborators
- a funding search capability enabling researchers to find and respond to funding opportunities in their chosen field
- advanced document search and access to a huge repository of clinical research documents, findings and publications
- a streamlined and simplified path through approvals with the ability to track and monitor progress through the approvals process
- study-monitoring and reporting capability that can be tailored by users to provide them with the dashboards and reports that they need, and
- secure, role-based access to features and documents.

Conference time

In the past year, the NIHR has organised ten health research conferences, one with each Strategic Health Authority (SHA), to enable local NHS staff and academics to engage directly with the NIHR and their SHA. Each conference was tailored to the particular research needs of the SHA.

The aim was to enhance understanding of the opportunities available through the NIHR to undertake health and social care research, and demonstrate how its new and improved systems for managing research are reducing bureaucracy.

As well as plenary sessions, each conference had a 'market place' where delegates could talk directly to representatives from NIHR programmes, view online demonstrations of the new systems, and take part in a number of interactive seminars depending on their area of interest and specialty.

Delegates greatly appreciated the conferences, which enhanced their understanding of how the NIHR is integrating research within the NHS.

"Excellent – provided comprehensive perspective on research activity and opportunities."

"Overall a useful and well organised day – good for networking and increased my knowledge of the NIHR."

"Has made me more aware of what support and training is available. Also, I didn't realise how much they had achieved already."

SECTION 3

Attracting industry-funded research to the NHS



Pharmaceutical, biotechnology, medical devices and diagnostics companies invest billions of pounds in clinical research around the world. At the same time, patients who take part in trials stand to benefit from the latest drugs, medical interventions and innovative new devices, making it in their interest to take part in industry-sponsored trials.

The NIHR is working in many different ways to make it easier for industry-sponsored research to take place in this country, both to attract inward investment from global life sciences and collaborative companies, and to benefit patients. This includes contributing to cross-government initiatives, such as the Office for Life Sciences, to support and improve the research environment.

The NIHR provides a bridge between the NHS, academia and industry. On the one hand, it helps NHS clinicians and managers to understand how industry works, and the time and cost pressures faced by commercial companies. On the other, it enables industry players to understand the need to ensure patient safety and confidentiality in order to maintain public support for clinical research of all types. The regulatory and ethical framework in England is designed to ensure continuing public confidence and support for the work of the NIHR.

“The NIHR has brought change to the way clinical research is conducted in the UK. For companies that have chosen to use the Networks (CRNs), having a single point of contact, study feasibility assessment, support with patient recruitment, the revamped NHS approval system (CSP), a standard costing template; and guideline tariff for routine use has been a novel approach to a centralised system of research in the UK. This has worked particularly well in the North West Exemplar Programme.

Our members have been engaged in developing many initiatives, leading to better working relationships, and the NIHR will go from strength to strength in creating a better research environment via the implementation of Research Support Services (RSS). We hope this will go even further towards eliminating duplication in the review process, speeding up approval decisions and improving the reliability and quality of clinical research delivery in this country.”

Dr Richard Barker, Director General, Association of the British Pharmaceutical Industry

Delivering trials on time and on target

The NIHR Clinical Research Network (CRN) (page 15) has played a major role in helping commercially sponsored clinical trials and other studies meet recruitment targets, start up faster and proceed more smoothly. It provides robust feasibility assessment and support with study start-up processes, facilitates costing and contract negotiations with standard templates and has dedicated resources and trained staff to support the delivery of studies at NHS sites. To date, 305 companies have worked with the Networks, resulting in 463 studies being adopted and 14,148 patients being entered into commercial trials by the end of 2009/10.

Helping children with kidney disease

Close working with industry was an important factor in a successful research study showing that the drug losartan can lower urine protein levels in children with kidney disease and that it can do so with remarkably few side effects.

Losartan is used to treat adults with chronic kidney disease, but until now it was not known whether it was suitable for children. Many drugs given to children in hospitals are not tested on children and teenagers, so this trial was vital to provide better information on how to prescribe and use losartan to treat them.

The involvement of NIHR's Medicines for Children Research Network (MCRN) was pivotal in increasing the speed and delivery of this study in England. It was a global study that involved 50 centres in 19 different countries and was the first large randomised controlled trial for this type of drug.

Global study lead Dr Nick Webb says, "The way in which we were able to action ethical approvals and R&D approvals was much faster in the Trusts because of MCRN involvement. They provided a resource, in terms of staff support, that made a real difference.

"It's also important to highlight the impact MCRN researchers had on the study. This was a study that needed the support of parents and families, and the relationships they developed were crucial to its success. We achieved a high rate of retention, which was down to the strength of these relationships. It's one thing recruiting patients to a trial, but it's another keeping them." Dr Webb is Deputy Director of the Greater Manchester, Lancashire and South Cumbria MCRN and Consultant Paediatric Nephrologist at the Royal Manchester Children's Hospital.

For Dr Nick Deaney, Merck, Sharpe and Dohme Research Director, it was also a fruitful collaboration. "We got two clear benefits from working with MCRN. First, they directed us to Dr Webb, who became the global study lead and was heavily involved in the design and implementation of the study. Secondly, when we realised recruitment was more difficult than originally anticipated, they used the Network to recruit another site and helped us recruit to target. From our point of view, MCRN provided an invaluable contribution."

FACT

Children with chronic kidney problems are prone to protein in their urine (proteinuria), which causes no symptoms. However, if untreated this can lead to a deterioration of kidney function and may damage blood vessels, increasing the risk of heart disease and stroke in later life. The hugely successful international trial proved that losartan could significantly lower protein levels in children and improve their health.

Collaborating for cancer

A forward-looking partnership between the National Cancer Research Network (NCRN) and the pharmaceutical company AstraZeneca (AZ) could lead to faster access to new treatments for NHS cancer patients. Instead of having to abandon promising compounds in the drug development pipeline that fall outside the company's core research remit, AZ is allowing academic researchers to investigate them further. In return, the company gains a valuable external perspective and data that may point towards novel uses for various compounds.

"Market-changing ideas are rarely predicted, so if all research decisions are made solely on the basis of commercial viability, a breakthrough idea may be missed. For us, collaboration with the NCRN is about developing a programme of research studies – some with commercial potential, and some that may just lead us in an interesting new direction."

Chris Wilkes, Clinical Partnership Manager, AstraZeneca

"Academic investigators have a deep knowledge of theoretical opportunities, and commercial investigators have a wealth of knowledge about new drugs in development. By bringing all the right people together from both sides, exciting ideas can take shape. That means more options, for more patients, in more cancer areas. That has got to be a good thing."

Professor Rick Kaplan, Director of the National Cancer Research Network

"The NCRN/AZ partnership goes far beyond the usual level of collaboration. It acknowledges that no one group, either commercial or academic, has a monopoly on deciding the best direction for a new medicine. Through the workshops we have seen both sides challenge the other in extremely constructive ways."

Dr Richard Wilson, Centre for Cancer Research and Cell Biology, Queen's University Belfast

Exemplary results

The progress of the NIHR CRN North West Exemplar Programme visibly demonstrates how the NIHR's investment in improving systems and processes is enabling the NHS to set up industry studies more quickly and more efficiently.

Twenty industry-sponsored trials were chosen to be closely monitored through the improved approval and patient recruitment processes instigated by the NIHR. So far, 17 studies have started with a median set-up time of just 53 days. This is a dramatic improvement on the Association of the British Pharmaceutical Industry's benchmark figures and is on a par with Europe's best. An impressive seven studies went on to enrol the first global patient, in multi-country trials.

The project will be evaluated in October 2010 and its findings used to disseminate good practice across other NHS regions and industry.

"Through the North West Exemplar Programme we have screened the first patient in Europe, just three and half months after the initial protocol was finalised."

**Jenny Heaton, Clinical Scientist,
Boehringer Ingelheim**

"The positive changes in research infrastructure mean we can now look at new centres in smaller hospitals that didn't have the capacity to work with us before."

**Sadya Khan, Senior Clinical Study
Manager, GlaxoSmithKline**

"We will never have large-volume studies here, but if we can offer fast set-up in expert centres, I believe that this country will have a viable offer in the global market and the ability to outperform the other big European countries."

Dr Tim Cave, Medical Director, Novartis

The North West Exemplar Programme

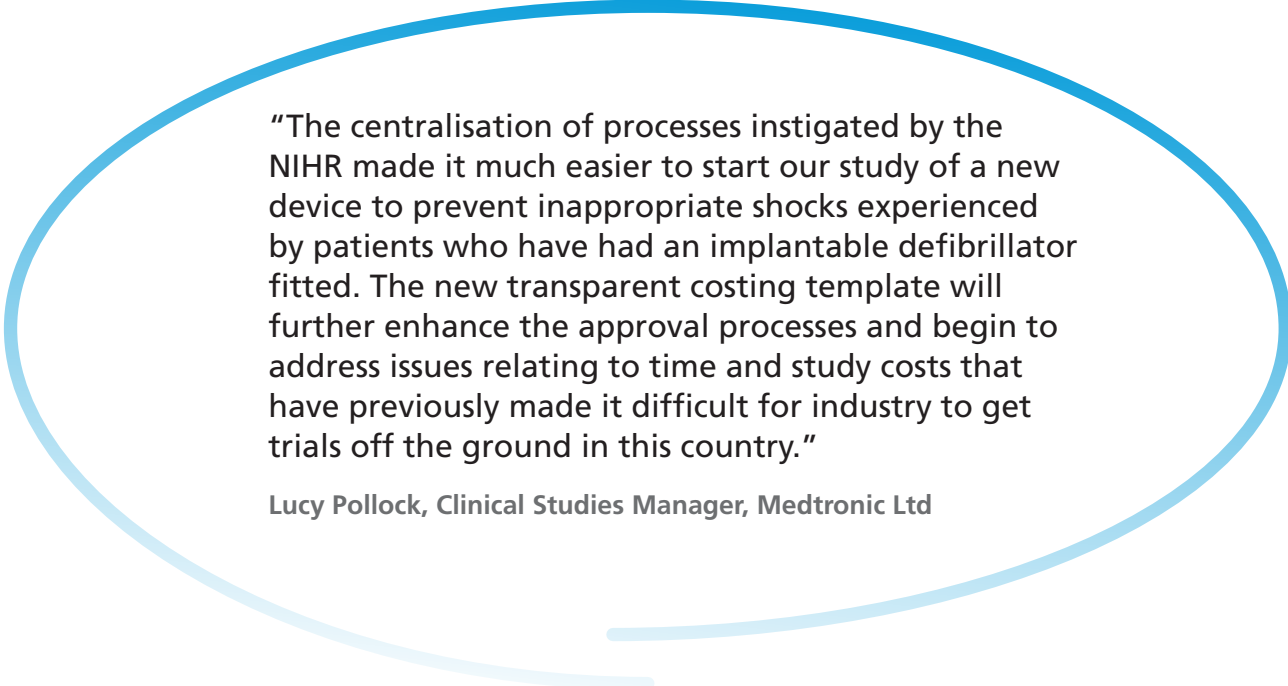
The North West Exemplar Programme is a joint initiative between the NIHR CRN, the North West Strategic Health Authority and the biopharmaceutical industry, sponsored by the NIHR NHS/Biopharmaceutical Industry R&D Leadership Forum. It aims to demonstrate that improved clinical trial performance is possible when the NIHR CRN works closely with partners in the pharmaceutical and biotechnology industries and across the NHS.

Boost for medical devices

However, the NIHR is not just concerned with biopharmaceutical companies; in the past year, it has bolstered its relationship with the medical technology sector to share information about improvements in the NHS clinical research environment and foster a medical technology ('med tech') research community.

Activities in 2009/10 included:

- meetings of the NIHR Medical Devices Clinical Research Working Group to optimise collaborations and communication between 11 key stakeholders
- hosting a successful stakeholder event with the Association of British Healthcare Industries, the HealthTech and Medicines Knowledge Transfer Network and the Department for Business, Innovation and Skills (BIS)
- the NIHR Comprehensive Clinical Research Network (CCRN) in particular, providing assistance with medical device company-sponsored clinical research studies
- feedback from a new working group on experience from submitting commercially sponsored medical device studies to the NIHR CCRN, including road testing a device-specific study costing template.



"The centralisation of processes instigated by the NIHR made it much easier to start our study of a new device to prevent inappropriate shocks experienced by patients who have had an implantable defibrillator fitted. The new transparent costing template will further enhance the approval processes and begin to address issues relating to time and study costs that have previously made it difficult for industry to get trials off the ground in this country."

Lucy Pollock, Clinical Studies Manager, Medtronic Ltd

Turning new ideas into high-tech products

The NIHR's Invention for Innovation (i4i) programme supports and accelerates the translation of bright ideas for new high-tech products into methods of prevention, diagnosis and treatment.

Towards prevention for bowel cancer

A study to enable the first assessment of an innovative, microwave-powered 'spatula' to remove intestinal polyps (a risk factor for bowel cancer) is one example of how the NIHR i4i funding is helping to support med tech studies to benefit patients and the NHS.

Although removing small polyps is relatively straightforward, larger ones can be technically more difficult with a higher risk of complications, such as bleeding. The device, called the Radiating Spatula, can help avoid the potential risks and speed up recovery.

The high performance and flexibility of the technology could lend itself to new scarless surgical techniques already being hailed as the next big advance in surgery.

Dr Chris Hancock, Creo Medical, says, **"This support from the NIHR enabled Creo Medical to develop the Radiating Spatula from a theoretical concept into a working prototype. As a direct result of the i4i award, we have just concluded a successful private investment deal to further develop and trial the product."**

FACT

With 30,800 diagnoses a year in England, bowel (colorectal) cancer is the third most common type of cancer and the second most common cause of cancer death. Intestinal polyps are small, mushroom-like growths, which can increase the risk of bowel cancer. NIHR support for a new device to remove polyps could help reduce the risk of this cancer with considerable cost savings for the NHS.

Invention for Innovation

The i4i programme offers funding streams to cover: feasibility studies; initial product development; commercial viability studies; and collaborative product development. In 2009/10, i4i awarded a total of £6 million to 43 research projects.

Turning research into treatments faster

The cross-fertilisation made possible by bringing together multi-disciplinary teams of scientists and clinicians from academia, the NHS and industry, at the NIHR's Biomedical Research Centres (BRCs) and Biomedical Research Units (BRUs), is having a strong and demonstrable impact on the speed with which basic research is turned into new treatments for patients.

Centre for success

The shared efforts of scientists and doctors in partnership with GlaxoSmithKline (GSK) at the NIHR Specialist BRC in Cancer (a partnership between the Royal Marsden NHS Foundation Trust and the Institute for Cancer Research) recently resulted in the discovery of a new combined treatment for women whose breast cancer has spread.

Painstaking work by scientists in the lab at the BRC revealed that when a particular gene is switched on in certain kinds of tumours, they become less responsive to hormone treatment, but that lapatinib, a compound marketed by GSK, could potentially reverse resistance and restore the tumour's sensitivity to treatment.

From lab to clinic...

Armed with this information, consultant medical oncologist Professor Stephen Johnston led an international clinical trial of over 1,200 women whose cancers had progressed, in 200 centres around the world. This showed that a combination of lapatinib and the hormonal drug letrozole lifted the resistance and put a brake on cancer progression.

Unlike many cancer therapies, the new combination is taken as a tablet and the researchers found it has fewer side effects than conventional anti-cancer drugs.

... and back to the lab

The researchers, in partnership with GSK, also collected tissue samples from 1,000 women who took part in the study. The search is now on in the laboratory to find biomarkers – molecular signposts – that could show which women are most likely to benefit from the new therapy.

“This research marks a major step forward in the treatment of breast cancer that could help 10–15 per cent of women. Eventually it may help even more, including women with early aggressive breast cancers. The BRC made this research possible by directly funding the research of the senior clinical staff and researchers in the Academic Department of Biochemistry, as well as supporting some lab costs not covered elsewhere. Being in the BRC meant we were able to deliver a package of lab studies, early-phase clinical trials, a big phase III trial and biomarker studies.”

Professor Stephen Johnston, Consultant Medical Oncologist and Director of Clinical Research and Development, NIHR Specialist Cancer Biomedical Research Centre

Using scans to improve treatment for thalassaemia



Professor Dudley Pennell

Amit Ghelani

Exciting research carried out at the NIHR Cardiovascular BRU at the Royal Brompton Hospital could dramatically improve the life expectancy of people with the blood disorder, thalassaemia.

The researchers, led by NIHR Senior Investigator Professor Dudley Pennell, discovered that T2* cardiac magnetic resonance, a non-invasive heart scan, gives a much clearer picture of iron overload (which can occur as a result of the regular blood transfusions needed by patients with thalassaemia) than conventional tests, as well as detecting heart-related complications more accurately. The new scan can pinpoint at-risk patients, enabling them to be treated with drugs to remove the excess iron.

Professor Pennell says, **“The close working relationship between the Royal Brompton and Imperial College, and the enhanced collaboration with industry – namely Novartis, ApoPharma and Siemens – has been greatly supported by the consolidation of expertise and facilities within the BRU.”** Professor Pennell is Director of the NIHR Cardiovascular BRU and Professor of Cardiology at the National Heart and Lung Institute, Imperial College London.

Amit Ghelani, 24, who took part in the trial, says, **“I was quite poorly when I started on the trial, after being referred by my consultant. It was good to be involved because it meant I received regular scans and got the best care available for my condition.**

“It’s important for people with thalassaemia to keep an eye on their hearts but blood tests can only tell you so much. This trial involved an in-depth look at the heart’s function, which meant the doctors could see how well the drugs were working. I would urge anyone with a similar condition to get involved with similar trials if they possibly can.”

“This is precisely the sort of practical research aimed at helping patients the NIHR is keen to fund. It will help people, not just in England, but around the world.”

Professor Dame Sally C. Davies, Director General of Research and Development at the Department of Health

FACT

Thalassaemia is the term for a group of inherited blood disorders that affect the body's ability to create red blood cells. One of the biggest problems with beta thalassaemia, the most common and severe form in this country, is a build-up of iron in the body as a result of frequent blood transfusions. Heart complications, such as heart failure caused by iron overload, are a major cause of death in people with thalassaemia, and until recently most people with the disease died before the age of 35. The research supported by the NIHR has the potential to save 30,000 lives a year worldwide.

Biomedical Research Units

The NIHR funds 16 BRUs in priority specialist areas – cardiovascular, deafness and hearing problems, gastrointestinal, musculoskeletal, nutrition and respiratory, to translate advances in biomedical research into NHS practice. In 2009/10, expenditure in BRUs increased to £21.8 million.



Driving forward experimental cancer medicine

The NIHR, through the Experimental Cancer Medicine Centres (ECMCs) which it funds in partnership with Cancer Research UK, is also playing a leading role in speeding up the process of cancer drug development and the search for cancer biomarkers – molecules present in blood or tissue – that can be used to diagnose cancer, predict the aggressiveness of the disease, or show whether a drug will be effective in a specific patient and at what dose.

Targeting tumour cells

Researchers at ECMCs in Manchester, Southampton and St George's Hospital, London, recently completed the world's first phase II trial of a revolutionary treatment, known as fractionated radio immunotherapy, for patients with a type of non-Hodgkin's lymphoma, a cancer of the lymphatic system.

The treatment involves attaching a radioactive molecule to an antibody that specifically targets cancer cells and kills them. More accurate targeting of tumour cells means patients experience fewer side effects and the treatment can be administered over just four hospital visits.

Retired ambulance driver Mel Jones, 66, from Fleetwood, Lancashire, was the first patient in Europe to be treated with the drug. He says, **"I was over the moon when the doctor told me that my hair would not fall out during the treatment. I had at last grown a ponytail after years of having to wear it short in the ambulance service. What's more, I only had to stay in hospital for one night and have a couple of injections six to eight weeks apart as an outpatient. I'm so happy to be part of a trial that could help not just me but thousands of people with cancer."**

Professor Tim Illidge, an international leader in radio immunotherapy, led the study. It was funded by Cancer Research UK and pharmaceutical company Schering, utilising the expertise and resources of the Manchester ECMC. This is one of numerous studies being conducted at ECMCs that are helping to position England as a world leader in the battle against cancer.

Professor Illidge comments, **"The Manchester Experimental Cancer Medicine Centre acted as a teaching centre and hub to get other sites up and running so that patients from all over England could take part. The trial has been a very successful collaboration with industry and we really delivered through the infrastructure provided by the ECMC network."**

Experimental Cancer Medicine Centres

The NIHR funds 15 ECMCs across England in close partnership with the leading cancer charity Cancer Research UK.

"Improving the infrastructure by bringing in more nurses, lab technicians and data managers has increased the number of patients entering experimental trials and allowed us to develop more biomarker tests and clever imaging techniques by removing bottlenecks. They are all part of the personalised medicine jigsaw – the future in cancer."

Dr Sally Burtles, Director of Centres, Cancer Research UK

Advancing experimental medicine

Another way in which the NIHR is speeding up the translation of scientific advances into benefits for patients and industry is by funding Clinical Research Facilities (CRFs) for Experimental Medicine. CRFs are purpose-built, cutting-edge facilities, with specialist clinical, research and support staff, in locations where universities and NHS Trusts work together on dedicated programmes of patient-orientated experimental medicine research.

Advancing treatments

A small industry-sponsored study supported by the MCRN, which was carried out at two CRFs for Experimental Medicine, is helping to advance potential treatments and cures for the genetic disorder Duchenne muscular dystrophy, which causes progressive muscle failure.

The study, carried out in London and Newcastle, tested the safety of AVI BioPharma's drug, phosphorodiamidate morpholino oligomer (PMO), with a view to discovering the optimum dose when given as a treatment known as exon skipping. The treatment involves using a 'molecular patch', administered by 12 weekly intravenous injections, which acts a bit like a sticking plaster over a tiny part of the gene causing muscular dystrophy.

The study sought to explore the efficacy of the PMO to replace a missing protein called dystrophin in muscle – the hallmark deficiency in boys with the condition. Scientists hope that this type of therapy could put a brake on or even reverse muscular dystrophy symptoms. Follow-up studies are now planned to investigate whether the drug has any clinical benefit.

Deborah Stead, mother of nine-year-old Lewis, who took part in the research, said, **"My son Lewis has muscular dystrophy, so he isn't as strong as other boys his age and tires easily. All his muscles are involved, but his legs are especially badly affected and without steroids he wouldn't be able to walk. I hope these trials will lead to a treatment that will slow down the progression of muscular dystrophy and give our family, and others affected by muscular dystrophy, a lifeline."**

Principal Investigator Professor Kate Bushby, of the Newcastle Biomedicine CRF, Institute of Human Genetics, Newcastle University, explains, **"Although we still face many challenges, if this kind of gene-based treatment proves clinically successful, it will be a breakthrough of enormous impact for boys with Duchenne muscular dystrophy. This study would have been impossible without the facilities and support available at the CRFs."**

Clinical Research Facilities for Experimental Medicine

The NIHR is funding five NIHR CRFs, four Millennial CRFs in partnership with the Wellcome Trust and nine CRFs in partnership with various funders (the Wellcome Trust, the Wolfson Foundation, the Medical Research Council, the British Heart Foundation and Cancer Research UK) under the umbrella of the UK Clinical Research Collaboration (UKCRC).

Experimental Medicine Resources website

The UKCRC Experimental Medicine Resources website, managed by the NIHR Office for Clinical Research Infrastructure (NOCRI), provides a central information resource about the UK's capability and expertise in experimental medicine and early-phase clinical trials. It provides an optimum entry point for investigators from both industry and academia seeking information about new opportunities to conduct experimental medical studies. Users of the site can search for over 65 facilities by location, health or disease research topic, plus the expertise and equipment available.

Strengthening relationships with our partners

The NIHR Office for Clinical Research Infrastructure (NOCRI) was set up in December 2009. It aims to:

- support greater cohesion of the NIHR infrastructure in the NHS
- strengthen and foster mutually beneficial relationships with industry, research charities and others seeking to conduct research in this country
- help researchers identify suitable facilities and investigators
- build enduring relationships between the NIHR, NHS, NHS/university partnerships and the biotechnology, med tech and pharmaceutical industries
- promote and enhance the nation's reputation as a world-class centre for applied clinical research.

"The initiatives that the NIHR has put in place over recent years have done a lot to improve the environment for health research. Yet many parts of industry still don't know the opportunities and advantages that working with the NIHR infrastructure provides. NOCRI will provide them with signposts and support.

We now have a fantastic range of expert and dedicated individuals, facilities and technologies in the NHS to support high-quality research. NOCRI is here to help industry navigate the rapidly developing clinical research environment, thereby benefiting from the support and expertise available. Ultimately, this will result in the development of improved diagnosis and treatment of patients.

The NOCRI team understand the needs of both academia and industry. We will be proactive in putting in place a whole range of mechanisms to make it easier to do high-quality health research in England."


Mark Samuels, Managing Director, NOCRI

Collaborative agreements

Medical university academics, investigators in the NHS and researchers in the pharmaceutical, biotechnology, med tech and diagnostics industries are increasingly interested in collaborative research. Initiatives such as the Office for Life Sciences Capability Clusters promote closer working between these three sectors. However, it is essential that such collaborations are backed by legal agreements setting out the rights and responsibilities of each partner.

Negotiating new and different agreements for each collaboration is both time consuming and costly. This is why the NIHR has instigated 'model agreements', which have proved highly effective in reducing the time and cost of initiating studies in other areas of clinical research.

In January 2010, the NIHR and the Medical Research Council convened a working group, chaired by NOCRI, to consider the case for developing model legal agreements to underpin collaborations in clinical research between industry, the NHS and universities. The working group, which includes representatives from all three sectors, the devolved nations, the Intellectual Property Office and funders, including the major medical research charities, strongly supports the development of a new suite of agreements that would support collaborative clinical research. This work is currently being taken forward.



"The drive towards translational research is gaining momentum and is going to be a major feature of biomedical research, for the next ten years at least. We need to ensure that we are working together for a common purpose. There are good examples of collaborations that have worked well and we need to learn lessons from these."

Dr Duncan Richards, Clinical Director, GlaxoSmithKline Academic Discovery Performance Unit, speaking at the British Pharmacological Society special session on translational pharmacology

SECTION 4

Strengthening health policy



Government policies on health and social care must be based on the most up-to-date, high-quality research available, which means rigorous peer review. Changes in policy can have wide-ranging implications for the NHS and social care services in the way patients and care users are treated, and how public money is spent. Understanding and acceptance of research evidence can also significantly influence public attitudes and behaviour, for example with regard to drink driving, smoking, healthy eating, nutrition and physical exercise. The NIHR works closely with key Department of Health, NHS and social care policy makers and policy-making bodies to help ensure that robust evidence is available to support national policy.

Systematic reviews – deciphering the mass of research evidence

NIHR's Systematic Review Infrastructure (SRI) provides a highly coordinated way of assimilating, deciphering and bringing together all of the latest research evidence available on any current topic.

The NIHR SRI comprises:

- the UK Cochrane Centre (UKCC) and Cochrane Review Groups
- the Centre for Reviews and Dissemination (CRD)
- Technology Assessment Review (TAR) teams.

The NIHR SRI commissions reviews that explicitly address key questions faced by front-line professionals, national NHS decision-making bodies and other policy customers. These include the National Institute for Health and Clinical Excellence (NICE), the UK National Screening Committee, the Chief Medical Officer and the National Clinical Directors, including those for cancer, diabetes, mental health, heart disease and stroke.

The researchers who do these reviews are experienced academics, health and social care experts, who are able to extract and illustrate common themes and evidence, which emerge from a variety of research papers. Systematic reviews compare, contrast and, where appropriate, combine results from studies carried out in the UK as well as abroad, with reviewers commissioning translations into English, if necessary, to ensure that evidence comes from a comprehensive range of research sources.

The thoroughness with which the NIHR conducts systematic reviews has made them invaluable, not just to health and social care policy makers in England but all around the world.

“The NIHR’s systematic reviews have become internationally respected sources of high-quality research evidence to inform decision making in health and care services, and health research.”

Sir Iain Chalmers, Coordinator, James Lind Initiative

The UK Cochrane Centre – leading evidence-based healthcare

The NIHR funds the UKCC, which works with a global network of research reviewers called The Cochrane Collaboration. The NIHR is the largest single funder of the Collaboration, an international, independent, not-for-profit organisation of over 27,000 contributors from more than 100 countries, dedicated to making up-to-date, accurate information about the effects of healthcare readily available throughout the world.

There are 51 Cochrane Review Groups worldwide, and the NIHR contributes infrastructure support for 20 of these in the UK, with the UKCC providing training and support. Reviews are added to The Cochrane Library, which currently contains the full text for over 4,000 Cochrane Reviews analysing the most up-to-date research on the effectiveness of numerous healthcare treatments, innovations and interventions, as well as methodology and diagnostic tests. The reviews are updated as new information becomes available, which is particularly important and valued in the rapidly changing healthcare environment.

“The Cochrane Collaboration is an enterprise that rivals the Human Genome Project in its potential implications for modern medicine.”

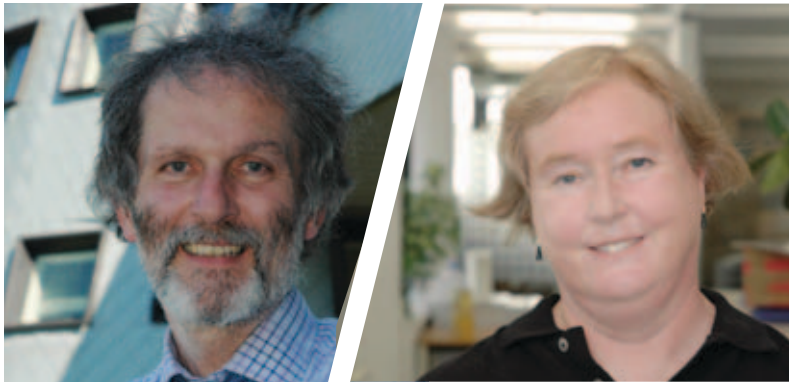
The Lancet 1995: 345: 840–2

FACT

One in 100 people suffer from schizophrenia, which places an enormous emotional and financial toll on them and their carers. The condition costs society an estimated £6.7 billion (2004/05 figures). The average annual cost to the economy of someone with schizophrenia in England is calculated to be around £55,000.

NIHR funding of the Cochrane Schizophrenia Research Group is helping to inform policy and ensure that people with the disease get the best possible care to relieve them, their carers and society of the heavy burden the disorder imposes.

Better treatment for people with schizophrenia



Professor Clive Adams

Janey Antoniou

Work by the NIHR-funded Cochrane Schizophrenia Group is making sure that NHS policy and practice are based on the most recent, reliable and robust research evidence. For example, NICE's recently updated schizophrenia guidelines drew on reviews compiled by the group and the World Health Organization's (WHO's) new guidance for schizophrenia draws extensively on information generated from the Group.

Professor Clive Adams, Coordinating Editor, Cochrane Schizophrenia Review Group says, **"The Cochrane Schizophrenia Reviews have had a demonstrable impact on national and international clinical guidance, on healthcare professionals, carers and consumers of care, mental health researchers and teachers and on the culture of health research and healthcare in general."**

The Group's findings are also invaluable to patients, as Janey Antoniou, a mental health service user who works at the mental health charity Rethink, explains: **"I work closely with the Cochrane Schizophrenia Group through my work at Rethink and so far have written over 40 patient information summaries, translating their systematic reviews into understandable user-friendly information for people with mental health problems."**

"Through this, my blog and our Facebook presence, we are helping to disseminate the findings of the Cochrane Schizophrenia Group in a way that is meaningful to users. We are currently working on ways to measure the impact of this."

Ms Antoniou regularly speaks at conferences on mental health issues and is a member of CCNet (Cochrane Consumer Network).

Other key impacts of the Cochrane Schizophrenia Group's work include:

- citations in *The Maudsley Prescribing Guidelines*, one of psychiatry's most widely used medication guides
- underpinning the NHS Choices Map of Medicine, used by doctors throughout the NHS to determine best treatment options.

Producing and disseminating the evidence

Healthcare policy makers simply do not have time to sift through every paper published. The influential work of the NIHR's Centre for Reviews and Dissemination (CRD), which helps to ensure that they have access to the latest research evidence and databases, has been lauded by *The Lancet* as one of the NIHR's most important contributions to the UK science base.

The CRD is an international centre of excellence in systematic review and evidence synthesis. It undertakes systematic reviews evaluating the research evidence on health and public health questions of national and international importance. The findings of CRD reviews are widely disseminated and have informed decision making in policy and practice, both in the UK and internationally. The CRD also undertakes methods research and produces internationally accepted guidelines for undertaking systematic reviews.

The CRD produces the Database of Abstracts of Reviews of Effects (DARE), the NHS Economic Evaluation Database (NHS EED) and the Health Technology Assessment (HTA) Database. These databases provide the best single source of quality-assessed evidence on the benefits, harms and costs of treatments and other interventions used in health and social care. As such, in a time of financial constraint, they are a key resource for evidence-informed decision making in the NHS and beyond.

In 2009, 400,552 identifiable users from around 206 countries and territories accessed the databases via the CRD website. Users accessed over four million records – a viewing rate of one abstract every eight seconds.

Changing service provision

Young people with eating disorders in the Bradford area will have better services thanks to collaboration between academic researchers from the NIHR CRD and NHS colleagues. The CRD is one of the partners in Translating Research into Practice in Leeds and Bradford (TRiP-LaB), the 'implementation theme' of the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for Leeds, York and Bradford. This project is providing a knowledge translation service to local decision makers, translating existing evidence into actionable messages to inform local commissioning.

In the past, some adolescents with eating disorders were admitted to hospitals outside the area at a cost ranging from £454 to £750 per bed day. The CRD evaluated the evidence base for this compared with other ways of providing services.

As a result, the Bradford and Airedale commissioners are proposing to invest in more services on a more cost-effective outpatient basis. The CRD's briefing document is also being used to inform strategic commissioning at a regional level by the Yorkshire and the Humber Strategic Commissioning Group.

Rod Grant, Senior Partnership Commissioning Manager, NHS Bradford and Airedale, says, **"The evidence briefing encouraged us to think differently about how we provide services and gave us the confidence to commission more services for young people with eating disorders and their families closer to home. This will save money by making best use of NHS funds to provide the most appropriate treatment."**

Working with NICE

NHS decision-making bodies, such as the NICE Appraisal Committee, the National Commissioning Group, the Royal Colleges and other professional bodies, need solid information about the potential benefits, harm and costs of particular healthcare treatments. To this end, the NIHR funds HTA Technology Assessment Reviews (TARs) to provide rigorous, independent, evidence-based assessments of new and existing medicines, treatments and procedures in the NHS in England and Wales.

In 2009/10, the NIHR expanded the number of centres conducting TARs from seven to ten. The three new TAR centres of expertise are:

- the BMJ Evidence Centre
- the Health Sciences Research Unit, University of Warwick
- Kleijnen Systematic Reviews Limited.

Each of the ten TAR teams is contracted to deliver an agreed number of high-quality assessment reports to strict deadlines to meet the needs of policy makers. All TARs undergo a rigorous process of peer and editorial review and are published in the NIHR *Health Technology Assessment* journal.

To date, the NIHR HTA Programme has commissioned over 200 TARs for use by NICE and over 100 for other policy makers to support evidence-informed policy and practice.

Responding quickly to need

A clear demonstration of how the NIHR works to support policy came in May 2009 when, following advice from WHO, the UK braced itself for pandemic influenza A (H1N1). There was an urgent need for evidence-based information to drive policy decisions. Thanks to the NIHR's coordinated and rapid response, DH policy makers had the information they needed swiftly to support their decision making.

The NIHR HTA Programme funded 14 studies to help inform the Government's response to the pandemic. This involved coordinating research in 314 NHS organisations across 640 research study sites, and setting up studies extremely rapidly. Fifty-seven per cent of NHS research sites were granted permission to start a clinical trial within two days of the Research Ethics Committee go-ahead. The results of the first NIHR-funded project appeared in *The Lancet* just six months after being commissioned.

One of these studies, led by the Health Protection Agency, showed that many more children and young people were infected in the first wave of the pandemic. A study by the University of Edinburgh showed that the H1N1 vaccine was especially effective in young children, older people and those with underlying medical conditions.

“The rapid availability of funding via the NIHR was essential for getting this study under way in time to inform national policy to this global emergency. It also enabled the UK to be the first country to conduct research revealing the true extent of the H1N1 pandemic influenza, in children and adults.”

Consultant epidemiologist Professor Elizabeth Miller, former Head of Immunisation Division, Communicable Disease Surveillance Centre, Health Protection Agency

“Understanding who benefits the most from the vaccination programme makes planning for future pandemics easier. Although this strain of swine flu did not prove as virulent as expected, this may not be the case in the future. Lessons about how to improve the efficiency of response to an H1N1 pandemic needs to be learned now so we can be well prepared.”

Dr Neil Kelly, a GP at one of 40 practices that helped to collect data for the University of Edinburgh research into the effectiveness of H1N1 vaccination

Health Technology Assessment programme

The NIHR HTA Programme reviews a broad range of methods to promote health, prevent and treat diseases, and improve rehabilitation and long-term care in six key areas: Diagnostic Technologies and Screening, Disease Prevention, Interventional Procedures, Pharmaceuticals, External Devices and Physical Therapies and Psychological and Community Therapies.

In 2009/10, the HTA Programme awarded funds to 60 new research projects with a combined research cost of over £66 million, and published 62 reports.

Vital cancer research

Cancer survival rates have doubled in the past 30 years but some cancers are still detected too late, which is why early diagnosis must be a priority. Improved cancer diagnostics are a major focus of the Cancer Reform Strategy, which aims to establish the country's cancer services as among the best in the world by 2012.

Predicting cancer

The Cancer Prediction in Exeter (CAPER) research team, established in 1997, set out to research a unique approach to the diagnosis of cancer in primary care. The innovative methodology pioneered by the team has been hailed as a major breakthrough in cancer diagnostics. Dr William Hamilton, a practising GP, who is also cancer lead at the NIHR School for Primary Care Research, leads the CAPER team.

The most recent CAPER study on diagnosing ovarian cancer, CAPER-O, was published in the *British Medical Journal* in 2009, to huge national and international acclaim from policy makers, doctors and ovarian cancer charities. Its publication also attracted wide publicity in the medical and popular media.

Mr Nigel Acheson, Consultant Gynaecological Oncologist at the Centre for Women's Health, Royal Devon and Exeter NHS Foundation Trust, is in no doubt of the enormous importance of the CAPER-O findings. He says, **"Dr Hamilton's research findings dispel the idea that ovarian cancer is a 'silent' killer and are helping to raise awareness of symptoms among doctors and women."**

Dr Hamilton says, **"The whole aim of our studies is to identify what symptoms really matter when a patient consults their doctor. We also want to put a figure on those symptoms. Once we can do that, it's much easier to design investigation services to test the right patient at the right time."**

At a policy level, the CAPER-O findings are helping to inform the ongoing review of diagnosis and management of ovarian cancer by NICE. Its findings are also a key source of evidence for the new Cancer Diagnostics Advisory Board, established by the Department of Health to enable GPs to test for cancer as quickly as possible when patients report suspicious symptoms.

Dr Hamilton's *BMJ* paper recently won the 2009 Royal College of General Practitioners Research Paper of the Year Award, the aim of which is to raise the profile of research in general practice and primary care.

Dr Fiona Godlee, Editor in Chief of the *BMJ*, said, **"We are delighted that another *BMJ* paper has won this award. This study is important for both clinicians and developers of guidelines in this field, and it is inspiring to see such high-quality research being undertaken in primary care. At the *BMJ* we believe strongly in the value of identifying best practice in healthcare and communicating this effectively for the benefit of patients. We are proud to have published this important piece of work."**

“The CAPER studies led by Dr Willie Hamilton provide important new insights into the symptoms of patients presenting to primary care who are subsequently diagnosed with cancer. These studies now cover colorectal, lung, prostate, brain and ovarian cancer. Each study has adopted a case-control approach, based either on detailed review of GP records or on electronic primary care datasets.

Before these studies were conducted, very little was known about cancer symptoms and symptom duration from a primary care perspective. The findings provide a rational basis for the development of decision support tools to assist GPs in deciding which patients should be investigated or referred to secondary care and which can be observed in primary care.”

Professor Sir Mike Richards, National Cancer Director,
Department of Health

FACT

Ovarian cancer strikes 6,800 women and claims 4,300 lives each year in this country. Survival rates are among the worst in Europe, partly as a result of delayed diagnosis. NIHR support for better ways for GPs and women themselves to spot ovarian cancer at an early stage is behind a major policy initiative to improve ovarian cancer diagnosis.

School for Primary Care Research

The NIHR School for Primary Care Research is a partnership between the Universities of Birmingham, Bristol, Keele, Manchester, Nottingham, Southampton, Oxford and University College London. The school is delivering high-quality research to inform the development of clinical practice in primary care.

Anticipating new developments

NHS policy makers, especially NICE, need to know well in advance about significant new and emerging health technologies that are likely to have an impact on the NHS. The NIHR National Horizon Scanning Centre (NHSC) performs the critical task of keeping an eye – worldwide – on the emergence of new health technologies. NHSC technology briefings provide NHS policy makers, with notice of new and emerging health technologies around two years prior to launch.

The NHSC's horizon scanning activity covers drugs, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitation and therapy, public health and health promotion interventions. The NHSC works closely with developers in the pharmaceutical and medical technology industries around the world.

Technology briefings outline what the technology is, its likely patient group, the current treatment alternatives, the level and amount of research evidence available and a prediction of its relevance both clinically and to the wider NHS.

In 2009, the NHSC:

- identified a total of 1,042 emerging technologies
- notified the NICE topic selection team on over 80 emerging new drugs or new indications for currently licensed drugs
- notified key policy makers of over 30 medical devices and diagnostic technologies.

SECTION 5

Changing NHS practice



For NHS and social services staff, delivering high-quality care depends on keeping abreast of the latest research evidence. This means that all those working in hospitals, surgeries and elsewhere must be aware of research findings and use them to hone their working practices for the benefit of those they care for.

The NHS Constitution clearly outlines the role NHS staff are expected to play in delivering high-quality care. This includes maintaining the highest standards of care and service, being responsible not only for the care they personally provide, but also for that provided by their team and the NHS as a whole. In addition, staff are expected to take up training and development opportunities and to engage actively in annual appraisals and personal development planning to stay up to date with best practice.

Delivering any and all of these commitments depends on NHS staff, at all levels, using the latest research evidence to support best practice in their specialty.

Now that the NIHR has successfully set up the infrastructure, commissioning, dissemination and support systems to enable this country to be a world leader in research for patients and the public, it is time for the NHS and social care staff to embed research findings into their everyday thinking and practice. To this end the NIHR is providing NHS clinicians and managers with strong, peer-reviewed evidence to support the delivery of more effective health and social care solutions.

There are countless stories of clinicians, managers and others on the ground in the NHS starting to see real pay-offs from NIHR-funded research.

“Five years ago we lacked structure and transparency. The NIHR forced us to reprioritise and to make a positive decision to invest in research. We put £12 million into research and development on top of the allocation from NIHR and our charitable trustees gave us £7 million. As a result, we were able to go to charity and industry and ask them to match this. This has been extremely successful and elevated us to being the most productive Biomedical Research Centre in the country with 12,000 different research projects funded. The NIHR has greatly enhanced our reputation as research provider and our reputation is now equivalent to the best in the world.”

Sir Robert Naylor, Chief Executive of University College London Hospitals (UCLH) NHS Foundation Trust

Improving diagnosis and treatment and cutting costs



Professor Peter Rothwell

June Dougan

One of the most striking examples of how NIHR-funded research is being integrated into everyday practice is the ground breaking research carried out by NIHR Senior Investigator Professor Peter Rothwell, which is changing clinicians' views on the diagnosis and treatment of high blood pressure.

In the past, occasional variations in blood pressure readings were dismissed as unimportant. However, Professor Rothwell and colleagues discovered that such 'episodic hypertension' is just as risky as persistent high blood pressure as a cause of stroke and other cardiovascular problems, and that some drugs used to treat high blood pressure actually increase its variability and therefore fail to prevent stroke. The research received wide coverage in high-profile national and international medical journals, including an unprecedented four simultaneous papers in *The Lancet*, as well as in the popular press.

June Dougan, 77, who lives in Oxford, is one patient who is benefiting from the change in thinking. She says, "After I had a mini-stroke I was invited onto the study, which found I have fluctuating blood pressure. I was quite shocked when they told me. Overall, the research showed that it is as dangerous to have fluctuating blood pressure like me, as continuous high blood pressure, and so checking for fluctuating blood pressure could save lives."

Professor Rothwell explains, "Stroke is the most common cause of disability in the UK, affecting 150,000 people each year, and accounting for 5 per cent of total NHS costs. Our findings improve our understanding of its causes, the identification of people at risk, and the effectiveness of prevention, and will reduce the £8.9 billion annual cost of stroke to the UK." Peter Rothwell is an NIHR Senior Investigator and Professor of Neurology at the Stroke Prevention Unit, John Radcliffe Hospital.

FACT

High blood pressure is the biggest modifiable risk factor for stroke. It also increases the risk of heart failure, angina and heart attack. NIHR funding has improved doctors' understanding of the dangers of fluctuating high blood pressure and is changing their practice. As well as saving lives and preventing disability, this could help make huge cost savings for the NHS. The NHS spends £2.8b billion directly on stroke treatment and care, while the cost to the wider economy is £1.8 billion. Meanwhile, the informal care cost is estimated to be £2.4 billion.

"This ground breaking research by Professor Rothwell, funded by the NIHR, has important implications for clinical practice, suggesting that clinicians should use drugs that both lower average blood pressure and decrease variability rather than, as at present, using some drugs that reduce blood pressure but actually increase variability. It will have a huge impact worldwide on the prevention of the often devastating brain injury caused by stroke."

Peter Sleight, former British Heart Foundation Professor of Cardiovascular Medicine, University of Oxford

Back to basics

Another way in which the NIHR research evidence is being incorporated into everyday practice is through the use of an innovative 'tool' to help GPs and physiotherapists teach patients how to manage back pain better.

The tool, which was developed by Dr Nadine Foster, one of the first recipients of an NIHR Career Scientist Award, comes as a nine-item paper questionnaire that physiotherapists can use in-clinic or as a six-item tool that GPs can access via their practice computer system.

Dr Foster's findings have been translated into five languages and are being validated for use in two other countries. They are also underpinning further research and quality improvement studies, including an NIHR Programme Grant for Applied Research on spinal pain and a Health Foundation funded project (IMPACT Back).

Patricia Earl, 46, who works as a teaching assistant, is just one of the many people to benefit from this research. She says, "I've suffered with a bad back on and off for 20 years. Going on the trial helped me learn strategies for dealing with the pain. I no longer let it stop me doing things, and knowing that I'm in control makes me feel much better. The toolkit is a great idea if it enables doctors or physiotherapists to help people like me to manage back pain themselves."

FACT

Back pain accounts for around 7 million GP consultations each year. Some 1.6 million people are referred on to specialists and 1.3 million people are treated by physiotherapists. The total direct costs of back pain were estimated at £1.6 billion in 1998, of which physiotherapy accounted for £251 million. According to the most recent estimates these costs have risen by approximately 30 per cent. NIHR-funded research could help reduce both the misery patients suffer and the direct and indirect costs to the NHS.

Bell's progress

The changes brought about by NIHR research are often simple but highly effective. For example, the Bell's Palsy study, led by Professor Frank Sullivan in Dundee, found that 83 per cent of people with Bell's Palsy, paralysis of the facial nerve, who were prescribed prednisolone, a relatively cheap steroid drug, completely recovered within three months. Furthermore, 95 per cent recovered after nine months. The researchers found that expensive antivirals, which are often prescribed, were no better than a placebo.

When David Bell, 35, woke up one morning unable to control the side of his face, close his eye or speak properly, he had never even heard of Bell's Palsy. He says: **"Taking part in this trial made me feel I'd contributed to something that could help other people with Bell's Palsy recover faster. This condition may not be life threatening but it affects your quality of life and is under-researched so I hope this study will lead to more trials and better treatments."**

The Scottish Bell's Palsy Study, which had more patients with the condition than all previous studies on this topic combined, was published in the prestigious US *New England Journal of Medicine*, was awarded the BMJ Group's Research Paper of the Year award, and was subsequently cited in two Cochrane Reviews. It was also incorporated into the NHS Map of Medicine, and NHS Clinical Knowledge Summaries produced by NICE. It was funded by the NIHR HTA programme.

Professor Frank Sullivan says, **"Thanks to NIHR funding and other support, we now have clear-cut evidence for the first time that early treatment with steroid tablets makes a full recovery from paralysis of the facial muscles more likely."**

FACT

Bell's Palsy affects one in 60 people at some time in life, most often between the ages of 30 and 45. It accounts for almost three-quarters of all acute facial palsies. A third of those who develop it are left with facial weakness, muscle tightness, facial pain or spasms. An NIHR-funded trial showed that a relatively simple, cheap treatment brings full recovery for most patients.

Saving lives following injury and accident

Serious injury is a major public health problem all over the world but especially in developing countries where road traffic crashes and homicide are increasing. Some 5.8 million people die each year from injuries – more than the number of deaths from HIV, TB and malaria combined – mainly as a result of blood loss.

The drug tranexamic acid (TXA), which reduces clot breakdown, is widely used in surgery to reduce blood loss and the need for transfusion. The CRASH-2 trial was jointly funded by the NIHR HTA Programme, Pfizer, the BUPA Foundation and the J P Moulton Charitable Foundation. It showed for the first time that TXA also reduces the chances of dying from injury by 15 per cent with no increase in risk in unwanted clotting. The researchers, led by Dr Ian Roberts an NIHR Senior Investigator and Professor of Epidemiology and Public Health at the London School of Hygiene and Tropical Medicine, estimate that this simple, safe, cheap and widely available drug could save up to 100,000 lives a year worldwide.

Dr Roberts says, “Everyone knows we have an NHS; not everyone knows that we have a National Institute for Health Research. It is really good news that there is an organisation that funds research for patient benefit and not just for profit. This research would not have been funded in many countries of the world. Thanks to the NHS and the NIHR we have been lucky to be able to do research that will save lives not just in this country but all over the world.”

“CRASH-2 is an important example of the complex relations between coagulation, fibrinolysis, inflammation and tissue after tissue injury ... The study shows that inhibition of fibrinolysis after administration of tranexamic acid after major trauma is an important mechanism to reduce mortality.”

Jerald H Levy, Department of Anaesthesiology, Emory University School of Medicine, Atlanta, writing in *the Lancet*, 15 June 2010

“The CRASH-2 trial has the potential to have enormous influence in an extremely neglected area of global health.”

Richard Horton, Editor, *The Lancet*

Bridging the gap

To help bridge the gap between pre-clinical studies in the lab and clinical trials on humans, the NIHR and the Medical Research Council (MRC) work closely together through the Efficacy and Mechanism Evaluation (EME) Programme to accelerate the progress of new interventions that could have a major impact on health 'from bench to bedside'.

Towards healthier babies

An example of the NIHR–MRC joint collaboration is a ground breaking study being carried out by Professor Jane Norman, Consultant Obstetrician and Gynaecologist at the University of Edinburgh Centre for Reproductive Biology, which is investigating how to reduce high birth weight of babies born to obese women.

The link between maternal obesity and high birth weight has been well documented. The cause of this link is unclear but the higher levels of insulin recorded in obese pregnant women may be a factor. Controlling the mothers' blood glucose levels and so decreasing their insulin resistance may help to reduce their babies' birth weights. The study will test whether metformin, a drug widely used to treat insulin resistance and which has been shown to be safe to use in pregnancy may help.

"As the prevalence of obesity among pregnant women continues to rise, an intervention to prevent the health risk being passed on to their children is urgently required," says Professor Norman.

FACT

Obese mothers-to-be are more likely to develop pregnancy complications such as pre-eclampsia, a disease of the placenta that causes high blood pressure. Meanwhile, their babies are more likely to be large, stillborn, suffer birth defects and get stuck in the birth canal. Large babies are also more likely themselves to be overweight at all stages in life and to have an increased risk of type 2 diabetes, heart disease and stroke in later life. Joint NIHR–MRC research is helping to find ways to tackle this urgent problem.

Efficacy and Mechanism Evaluation Programme

The EME Programme is funded by the MRC and managed by the NIHR. It aims to bridge the gap between efficacy (whether an intervention works) and mechanisms (how it works) to improve patient care. In 2009/10, the Programme awarded £5,324,886 to seven new research projects.

Improving the patient environment

It is not just treatments resulting from NIHR-funded research that are now benefiting NHS patients. Improved patient environments in which to deliver effective clinical care are also having an impact. Last year the NIHR–NHS Physical Environment Research Programme commissioned a number of innovative initiatives to improve the quality of the patient care environment.

A range of research projects has been funded in infection control, one of the biggest challenges facing hospitals today. For example, Professor Michael Kong and his team at Loughborough University are investigating the use of cold gas plasmas, in the form of a plasma brush and curtain, to combat persistent hospital-acquired infections such as MRSA, E Coli and C difficile. Initial results have been positive, with rapid decontamination occurring. This raises the potential of using plasmas to decontaminate surgical instruments and disinfect skin and living tissues.

Sustainability is another key research area. Health buildings need to be cooled, yet conventional mechanical cooling consumes a large amount of energy. Alan Short, Professor of Architecture at Cambridge University, has been commissioned to create a green design strategy for low ventilation and cooling of health buildings. He is investigating how buildings could be designed differently to help natural ventilation, while at the same time ensuring temperature control and infection control needs are taken into account.

Building design can be used to improve other environmental factors, too. Noise in hospitals can be physiologically and psychologically stressful, presenting a major problem for patients. To address this, the programme has funded Professor Jian Kang and a team at the University of Sheffield to explore acoustic effects in hospitals and to look at ways of minimising noise.

Fighting infection by design



A new type of isolation room could have a major impact on how hospitals manage healthcare-associated infections (HCAIs). The room has a specially ventilated lobby that acts as a buffer to stop infectious microorganisms entering or leaving. Through NIHR funding, BSRIA, an independent test laboratory in Bracknell, constructed and tested a full-sized physical model of an isolation room and, working with researchers from the University of

Leeds, used experiments and computer models to examine air flow and infection risk under hospital conditions.

“The performance of the room exceeded all expectations,” says William Booth, BSRIA Head of Physical Modelling and Site Investigations.

The research at BSRIA is a major landmark in understanding how isolation rooms work. As a result, key findings are now being incorporated into a major revision of NHS hospital building guidelines for isolation rooms.

Dr Catherine Noakes, who coordinated University of Leeds input on the project, says, **“NIHR funding has helped us to really understand how the physical design of an isolation room affects the risk of transmission of hospital-acquired infections.”**

There are at least 300,000 healthcare-associated infections in hospitals each year. Potentially fatal and a cause of great suffering and anxiety, they also cost the NHS around £1 billion a year. Funding by the NIHR's Physical Environment Research Programme could lead to design improvements in hospital buildings that can help reduce the substantial financial and human costs.

Improving NHS efficiency

Improvements in patient care do not just depend on new medicines; the efficiency of health services also plays a crucial role in the patient experience. NHS managers are drawing upon powerful evidence from research funded by the NIHR Service Delivery and Organisation (SDO) programme that shows what can be done to improve quality alongside productivity, and how innovation can drive and embed change.

Evidence-based approaches to the quality, innovation, productivity and prevention (QIPP) challenge are informing decision making by health practitioners, managers and policy makers with regard to improved quality of patient care and efficiency of health services. Models and concepts evaluated through research can enable NHS managers to address productivity and patient experience through new developments in staff roles and interaction with patients in different areas of service delivery.

Recent achievements include:

- a patient, staff and system-focused project on the impact of changing workforce patterns in emergency and urgent out-of-hours care on patient experience, staff practice and health system performance
- a project by Dr Ian Kessler at Oxford University, which shows the important role that healthcare assistants can play in complementing other health professionals to provide a high-quality service to patients, and
- a report led by Karen Spilsbury at the University of York, which evaluates the development and impact of assistant practitioners supporting the work of ward-based registered nurses in acute NHS trusts.

An ongoing programme of research is addressing further questions that will support NHS managers to address the QIPP agenda within a local context.

Service Delivery and Organisation

The SDO programme commissions research into the way health services are organised and delivered by the NHS in order to help health practitioners, managers and policy makers improve the quality of patient care and the efficiency of health services. In 2009/10 the programme awarded £9.6 million to 31 new research projects and had 278,356 participants involved in research projects.

“The NIHR’s focused and transparent approach ensures that organisations and clinical teams committed to high-quality research can access the support and infrastructure they need to be successful. The emphasis on patient and public benefit and the development of research networks has enabled busy clinical staff to participate in high-quality research. In Bradford this has led to a dramatic increase in trial recruitment, number of studies undertaken, grants awarded and publication in peer-reviewed journals.”

Miles Scott, Chief Executive, Bradford Teaching Hospitals NHS Foundation Trust

Financial summary

NIHR funding for 2009/10

Area	Spend (£m)
Infrastructure	
Biomedical Research Centres	117.5
Biomedical Research Units	21.8
Patient Safety and Service Quality Research Centres	2.7
Collaborations for Leadership in Applied Health Research and Care	18.5
Experimental Cancer Medicine Centres	5.4
Clinical Research Facilities	13.3
Clinical Research Networks	286.2
Flexibility and Sustainability	128.3
Research Design Service	12.0
Ad-hoc support and excess treatment costs	3.8
Other (including clinical academics)	5.7
Infrastructure total	615.2
Faculty	
Integrated Academic Trainees – including academic clinical fellowships, lectureships and clinician scientist awards for doctors and dentists	51.1
Fellowships (including legacy training awards)	10.5
Senior Investigators	3.6
Other (including management and academic units)	4.1
Faculty total	69.3
Research programmes	
Health Technology Assessment ¹	40.7
Programme Grants for Applied Research	29.0
Service Delivery and Organisation	6.6
Research for Patient Benefit	11.6
Investment for Innovation (New and Emerging Applications of Technology and Health Technology Devices)	8.8
Research for Innovation	0.4
NHS Physical Environment	0.4
Methodology	1.3
Schools for Primary and Social Care Research	5.0
Reviews (Cochrane, Centre for Reviews and Dissemination and Technology Assessment Reviews)	11.5
Horizon Scanning	1.3
INVOLVE	0.7
Patient Research Cohorts Initiative	1.1
Other (including legacy programmes and management not attributed to specific programmes ²)	23.9
Programmes total	142.3
Systems	
NHS Research Ethics System (NRES)	3.9
Local Research Ethics Committees	7.5
Busting bureaucracy information systems	9.4
Other (including Research Capability Programme)	3.2
Systems total	24
Total NIHR revenue spend	850.8
Other spend	
NIHR capital allocations	68.7
Total research spend	919.5

¹ Spend on HTA includes spend on Public Health Research programme and excludes £4.8 million contribution from Scotland and Wales to allow access by researchers in these countries to agreed elements of this programme.

² Including time-limited research programmes: genetics/gene therapy/knowledge parks/Biobank; mental health and forensic mental health; cancer, including prostate; patient safety.

Postscript by Professor Dame Sally C. Davies

Director General of Research and Development



What a great story this annual report tells. It clearly demonstrates, through a broad range of human interest case studies, the many and varied ways the National Institute for Health Research is making a real difference through the NHS to the lives and health of patients and the public.

Whether tackling nationwide public health issues, such as healthcare-associated infections that put the vulnerable at risk, or finding and developing new targeted cancer treatments that don't induce hair loss, the NIHR's work is invaluable.

We know that patients and the public receive the best and safest treatments and interventions when these are based on the most robust, peer-reviewed evidence produced by our health research professionals. This is what the NIHR does.

It seems extraordinary that the NIHR did not exist four years ago, because it is now so firmly established across the landscape of the NHS and in the academic institutions that specialise in health and social care research. What has been created in this short time is astounding.

Since April 2006, we have been very busy establishing the best possible structures and environment for research – from creating flagship schools for research and centres of expertise, to putting in place the many different types of research funding streams necessary to meet the needs of NHS patients and the public. Just as importantly, we created the mechanisms to assist the community of NIHR Investigators. This includes providing the secure working environment of the NIHR Portal, and new training schemes, advice services and leadership development programmes, as well as improving and streamlining the systems and processes used for ethics and NHS approvals and permissions.

We have also been working to attract global and UK-based life-sciences companies to conduct clinical research in the UK in order to benefit patients and the public and draw investment into the economy. Our Clinical Research Network has played a major role in helping commercially sponsored clinical trials and other studies meet recruitment targets, start up faster and proceed more smoothly. The Exemplar Programme visibly demonstrates that the NIHR's investment in improving systems and processes is enabling industry to set up trials more quickly and efficiently.

All this, yet there is still so much more to do. We need to give more patients the opportunity to take part in clinical trials wherever they live in the country. To this end, we are working with partner organisations to develop a user-friendly, web-based resource – the UK Clinical Trials Gateway – specifically for the public. It will hold details of all the clinical trials taking place in the UK and will be made available on the NHS Choices website later this year.

To deliver more decisive evidence at greater speed, researchers need easy access to a wide range of data sources. Our Research Capability Programme (RCP) was set up to increase the quality, availability, accessibility and choice of data routinely available to researchers. The Programme is currently piloting the Health Research Support Service (HRSS) to provide data sources for researchers. This will enable larger-scale clinical studies that could lead to new cures and more effective ways of managing ill health as well as enabling NHS resources and services to be directed where they are most needed. Of course, when using patient data in this way, patient confidentiality is an absolute imperative, and the HRSS is putting strong safeguards in place to ensure that data is properly used.

We need further work on reducing the bureaucracy and the length of time taken to approve and begin new trials, and to ensure that when they are approved they can start quickly and reach a successful outcome. This will encourage even more life-sciences companies to conduct their clinical trials and investigations in England, rather than in other countries. In addition, we need to ensure that NHS hospital doctors, GPs, nurses and other health professionals have access to the latest research evidence to guide their treatment decisions and their patients' choices.

I believe that, as a result of the hard work and support of an enormous number of people, the NIHR is well placed to meet these challenges. The coalition Government's White Paper, *Equity and excellence: Liberating the NHS*, provides strong support. The White Paper makes extensive reference to the importance of conducting research, and of using research evidence, as key elements of the NHS. It sets out the importance of research to the new NHS Commissioning Board, to commissioners, providers, clinicians and patients. The White Paper also makes timely reference to the importance of research in times of constrained resources: 'Research is even more important when resources are under pressure – it identifies new ways of preventing, diagnosing and treating disease. It is essential if we are to increase the quality and productivity of the NHS, and to support growth in the economy' (*Equity and excellence*, July 2010, p.24).

It has been an incredibly eventful and busy four years since the NIHR was created. I have enjoyed the journey and want to take this opportunity to thank everyone who has worked so hard and with such conviction to bring all this about.



Professor Dame Sally C. Davies

Director General of Research and Development
Department of Health

