



# National Institute for Health Research

Annual Report 2010/11



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# National Institute for Health Research

Annual Report 2010/11

Prepared by the Research and Development Directorate

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# Foreword



**Dame Sally Davies** 

Health and social care research matters to each and every one of us. It underpins the quality of our health and care services and makes a vital contribution to health outcomes and our quality of life. All of us have the high expectation that we will be offered cutting-edge treatments and world class care when we, or our friends, or family, are ill or vulnerable. Delivering the best possible health and care relies on having the best possible research evidence.

The National Institute for Health Research (NIHR), launched in April 2006 by the Department of Health for England, was established to fulfil this ambition and to create the best possible environment in which research and innovation could flourish. This 2010/11 Annual Report on the NIHR highlights a year of landmark successes, the result of sustained Government investment in the research fabric of the nation, and in the research community of the NHS and partner academic institutions. Everyone involved should feel pride in the scale and breadth of the achievements.

Funding research for the benefit of patients and the public is at the heart of the NIHR, and the individual projects picked out in this Report demonstrate how the NIHR is providing evidence to improve treatments, interventions and care. From funding new DNA vaccine trials progressing the fight against leukaemia or assessing whether mild physical activity and stimulation for dementia patients helps prevent further brain degeneration, to studies into the health benefits of housing regeneration projects, NIHR investment has the potential to save and improve the health and lives of so many, both here and abroad.

More patients than ever before are taking advantage of the opportunity to take part in clinical trials and studies and, by doing so, gaining access to innovative technologies or treatments. It is so encouraging to see that the NHS is fulfilling its pledge in the *NHS Constitution*, published in 2009, to ensure that patients, from every part of England, are made aware of research that is of particular relevance to them with 97% of NHS Trusts now contributing patients to studies registered on the NIHR Clinical Research Network Portfolio.

A particularly exciting development of 2011, and one that will truly benefit trauma patients, has been the creation of the NIHR Centre for Surgical Reconstruction and Microbiology, a unique partnership with the Ministry of Defence, University Hospitals Birmingham and the University of Birmingham. The Centre, the only one of its kind outside the USA, will transfer groundbreaking new procedures and therapies developed in the battlefield to advance clinical practice in the NHS when treating accident and emergency patients. This brings with it the hope of saving many lives and reducing trauma and disabilities for wounded individuals.

With the new NIHR School for Public Health joining the prestigious flagship NIHR Schools for Primary Care and Social Care Research, and further investment in the NIHR's world-class Biomedical Research Centres and Units, the NIHR continues to deliver the best possible evidence upon which to base health and social care services and practice.

The Government's *Plan for Growth* (March 2011) highlights how health research has a key role in the national economy as well as in improving health and care. This Report shows that the NIHR continues its work attracting global and UK-based life sciences companies to locate and invest in this country. Take one example from the NIHR's impressive record on cancer research: the Experimental Cancer Medicine Centres. These are partnerships funded by Cancer Research UK and the NIHR, which are running collaborative studies with over 60 industry partners and are positioning England as a world leader in the battle against cancer.

The *Plan for Growth* is but one of a number of Government documents published during 2010-11, including the 2010 White Paper *Liberating the NHS* and the Government's response to the *NHS Future Forum*, that highlight the ongoing central support for research in the NHS, the NIHR and its aims. This support, alongside the investment committed in the 2010 Spending Review, demonstrates clear recognition of the importance of the NIHR, and the academic excellence, rigour and influence of our nation's research community, to the health and wealth of the nation.

Sally ( CC

Professor Dame Sally C. Davies Chief Medical Officer and Chief Scientific Adviser Department of Health

# Introduction

The National Institute for Health Research (NIHR) was established in April 2006 to provide 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.



Further information about the NIHR is available on the NIHR website: www.nihr.ac.uk

# Key achievements in 2010/11

#### The Crash-2 trial funded by the NIHR wins the BMJ research paper of the year award

The trial funded by the NIHR Health Technology Assessment programme showed that early administration of tranexamic acid, to patients with severe bleeding injuries, saves lives with no evidence of adverse effects from unwanted clotting. This low-cost medicine that has the potential of saving thousands of lives has been recommended for inclusion in the World Health Organization Model Lists of Essential Medicines.

#### The Barts and The London NIHR Cardiovascular Biological Research Unit (BRU) opened

Professor Dame Sally C. Davies officially opened the London NIHR Cardiovascular BRU at The London Chest Hospital. The BRU's focus is on translational research, and aims to establish novel therapies and treatments for patients with heart problems.

#### Cochrane Collaboration influential in a revision of the Lancet's publication criteria

The *Lancet* announced that it would ask authors of all research reports submitted after August 2010 to put their work into context of what has gone before, by either reporting their own up-to-date systematic review or citing a recent systematic review done by others following findings by the UK Cochrane Centre.

#### Health Service and Population Research Group awarded Queen's Anniversary Prize

The Health Service and Population Research Group (HSPRG) at the Institute of Psychiatry, King's College London, led by Professor Graham Thornicroft, an NIHR Senior Investigator, were honoured with a Queen's Anniversary award for work of outstanding excellence. The award recognises the HSPRG's commitment to enabling the recovery and improving the quality of life of people with mental health problems throughout the world.

#### Nine NIHR Senior Investigators listed as the country's top medical experts

Nine NIHR Senior Investigators were listed in The Times Magazine A-Z of Britain's top doctors.

#### New NMR spectrometer to revolutionise surgery with real-time metabolic profiling

Researchers at the NIHR's Imperial Biomedical Research Centre (BRC) will use a new highresolution solid state nuclear magnetic resonance (NMR) spectrometer to provide diagnostic techniques to the operating theatre. Analysis of tissue samples using the NMR will provide surgeons with an unprecedented level of information about the patient's biological status, allowing them to optimise the patient's treatment in ways that previously has not been possible.

#### NIHR Respiratory BRU opened at Royal Brompton Hospital

The new NIHR Respiratory BRU at Royal Brompton & Harefield NHS Foundation Trusts will provide a conducive environment for clinicians and scientists to develop the next generation of treatment for patients with advanced lung disease.

#### Number of cancer patients taking part in clinical studies quadruples in a decade

NIHR Cancer Research Network figures show the number of cancer patients in the UK participating in clinical studies soared in the last decade from one in 26, to around one in six patients diagnosed. The fourfold increase reinforces the UK's position as world-leader in the proportion of cancer patients recruited to clinical trials and research studies.

#### **Evidence Aid**

The UK Cochrane Centre and several Cochrane Review Groups in the UK, and their partners launched Evidence Aid, a website resource to provide information on systematic reviews relevant to planning for, and responding to natural disasters and other humanitarian emergencies.

#### Over half a million patients recruited into NIHR Clinical Research Network studies

More than half a million people participated in studies supported by the NIHR Clinical Research Network in 2010, compared to 300,000 the previous year.

#### NIHR Centre for Surgical Reconstruction and Microbiology launched

A new Centre for Surgical Reconstruction and Microbiology is launched as a partnership between the NIHR, the Ministry of Defence, University Hospitals Birmingham and University of Birmingham.

#### Team from NIHR Stroke Research Network wins Pharma Times award

The Royal Devon and Exeter Stroke NIHR Research Network team wins the 2010 NIHR/ABPI sponsored *Pharma Times* national Clinical Research Site of the Year award, in recognition of their work improving the care and recovery of stroke patients.

#### New NIHR School for Public Health Research announced

Public Health Minister Anne Milton announces a call for a new NIHR School for Public Health Research designed to build closer relations between researchers and practitioners across Public Health England and Local Authorities. The new school will undertake high quality research to increase the evidence base for effective public health practice.

#### Groundbreaking technology could revolutionise blood pressure measurement

Researchers from the NIHR BRU in Leicester in partnership with scientists in Singapore develop a new blood pressure measurement device. The new device has the potential to enable doctors to treat their patients more effectively because it gives a more accurate reading than current methods. It does this by measuring the pressure close to the heart – the central aortic systolic pressure.

#### New NIHR International Register of Systematic Reviews - PROSPERO launched

Health Minister Lord Howe launched an international research register that will improve the transparency of health research. PROSPERO was developed by the NIHR's Centre for Reviews and Dissemination and is the first online facility to register systematic reviews for research about health and social care from all around the world. The register will allow those commissioning or planning reviews to identify whether there are any reviews already underway that address their topic of interest. This helps avoid unintended duplication of effort.

#### Applied Health Research on Dementia call announced

The NIHR issued a call for research on dementia across seven of the NIHR research programmes, covering the fields of cause, cure and care, including prevention, to support the *Living well with Dementia – A National Dementia Strategy*, and the work of the Ministerial Advisory Group on Dementia Research on ways to improve the volume and impact of dementia research.

#### Brain scans to spot the early signs of Alzheimer's disease

A new method to diagnose Alzheimer's uses an advanced computer programme that compares a patient's brain scan with a database of 1,200 existing images of brains already affected by the disease. The new technique developed by the NIHR BRC for Mental Health at the Maudsley Hospital, together with researchers from the Karolinksa Hospital in Stockholm is 85% accurate and can deliver results in just 24 hours.

#### NIHR/MRC model Industry Collaborative Research Agreement (mICRA) launched

The mICRA will enable research studies involving industry, universities and the NHS to start faster by shortening the negotiation and contracting process. The agreement aims to promote the development of new and improved treatments for patients by reducing bureaucracy and supporting a flourishing research environment.

#### NIHR Leicester Cardiovascular Biomedical Research Unit opened

The Secretary of State Andrew Lansley opened the new NIHR Cardiovascular BRU in Leicester. The new BRU will improve the diagnosis, prognosis and treatment of coronary heart disease and hypertension.

#### £775 million investment for new Biomedical Research Centres and Units announced

The Secretary of State Andrew Lansley announced the NIHR's new open competition for NIHR Biomedical Research Centres and Units providing the largest ever funding, up to £775m<sup>1</sup> over five years from April 2012. This funding for translational research is dedicated to delivering benefits to NHS patients, and helping to secure the UK as a world leader in life sciences.

#### NIHR Cardiovascular BRU officially opened at the Royal Brompton Hospital

Professor Dame Sally C. Davies, officially opens the new NIHR Cardiovascular BRU at Royal Brompton & Harefield NHS Foundation Trust, a joint initiative with academic partner Imperial College London.

#### New NIHR Health Services and Delivery Research programme announced

Professor Dame Sally C. Davies announced the creation of the Health Services and Delivery Research Programme to be established by merging two existing programmes, the Health Services Research and Service Delivery and Organisation programmes. This will allow the development of common aims and methods, focused on the public and decision makers' needs, whilst simplifying the research funding landscape, reducing bureaucracy and management costs.

#### Gene for osteoporosis disorder discovered

Researchers at King's College London and Guy's and St Thomas' Comprehensive BRC discover a single mutated gene that causes Hajdu-Cheney syndrome, a disorder of the bones causing progressive bone loss and osteoporosis. Their study, published in *Nature Genetics*, gives vital insight into possible causes of osteoporosis and highlights the gene as a potential target for treating the condition.

#### Plans to launch the NIHR Research Support Services announced

In March 2011, the Government's *Plan for Growth* announced the imminent launch of the NIHR Research Support Services. This framework of good practice and standard procedures will facilitate consistent local research management and greatly improve performance. In future years, NHS Trusts will publish information on performance and the NIHR will compare outcomes against public NIHR benchmarks.

#### **Outcome of the fourth NIHR Senior Investigator Competition announced**

Twenty-three new Senior Investigators were appointed and fifteen existing Senior Investigators were awarded a second and final term in their role. This maintains the number of NIHR Senior Investigators at two-hundred.

<sup>&</sup>lt;sup>1</sup> Due to the exceptional quality of proposals received, £800m was awarded.

# **Chapter 1: Research**

In 2010/11, the NIHR funded £210.5 million of research grants across a broad range of programmes and initiatives to ensure that patients and the public benefit from the most cost effective, up-to-date health interventions and treatments as quickly as possible.

# **Research programmes**

The NIHR Research Programmes commission and fund research that produces the evidence to enable professionals, policy makers and patients to make informed decisions and provide the means to turn new interventions into better care. The priority is to provide high quality outputs and value for money through a transparent and accountable system.

## Health Technology Assessment programme

The Health Technology Assessment programme is the largest single national research programme for the NHS, with over 115,000 patients participating in trials. It delivers independent research information about the effectiveness, costs and broader impact of healthcare diagnostics and treatments, including interventions used to promote health, prevent and treat disease and improve rehabilitation and long-term care. Research is commissioned through two main funding streams: researcher-led and commissioned, with 57 projects funded in 2010/11.

## **Research highlights:**

- The CRASH-2 trial found that early administration of tranexamic acid to patients with recent, severe bleeding injuries saves lives, with no evidence of adverse effects from unwanted clotting. Treating recently injured patients with serious bleeding with this cheap, widely available and easily administered drug to help their blood clot could save thousands of lives. The CRASH-2 trial won the *BMJ* research paper of the year award.
- A rapid response call for research into the H1N1 swine flu pandemic funded 14 studies, an example being a head-to-head comparison of two H1N1 swine influenza vaccines in children aged 6 months to 12 years.

## Health Services Research programme

The Health Services Research programme established in 2009 funds research to improve the quality, effectiveness and accessibility of the NHS. This includes quality of services, access and equity in provision, relevance to the needs of individuals and communities, and effectiveness, efficiency, and experience of health services. The programme funds both

primary research and evidence syntheses, depending on the availability of existing research and the most appropriate way of responding to important knowledge gaps. The first three calls attracted a high level of interest, and 20 projects had received funding by March 2011.

# Research highlights:

- The Improving diagnosis and treatment for children with asthma in South Asian families study, at the University of Leicester, involves researchers working together with children, parents, professionals and community members in the city to improve asthma management for South Asian children. Perceptions and experiences of parents and children will inform new guidance to healthcare commissioners and providers on tailoring intervention programmes.
- Modern medical care involves complex, and often highly specialised interventions, frequently involving many people with different specialist expertise, and multidisciplinary team meetings (MDMs) have become widely established in the management of chronic diseases. A research team at University College London is working to identify the factors that influence MDM effectiveness in terms of decision implementation to inform future practice.

# Public Health Research programme

The Public Health Research programme evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The programme funded 17 projects in 2010/11, covering the health benefits of: community engagement; regeneration programmes; programmes run by professional football clubs; schemes to improve mental health in the workplace; and walking and cycling to work.

## **Research highlights:**

- Getting children to exercise more and eat better diets is likely to reduce the number of children who are overweight and lead to other health benefits, which can last throughout life. Active for Life Year 5, is a school-based research study, taking place in primary schools in Bristol during 2011/13. The study aims to test whether lessons that teach 9-10 year old children about the importance and enjoyment of exercise and having a healthy diet is an effective way to increase the children's physical activity, decrease the amount of sedentary time, and increase their consumption of fruit and vegetables. The study is led by a multidisciplinary team of researchers at the University of Bristol, working in collaboration with Bristol City Council and NHS Bristol.
- The Housing Regeneration and Health study, is evaluating the immediate and longer-term health benefits resulting from a major housing regeneration programme currently underway. The study will focus on whether internal and external housing improvements reduces the number of hospital admissions for conditions such as heart attacks, asthma attacks, falls and burns in people over 60.

### Service Delivery and Organisation programme

The Service Delivery and Organisation programme funds research to improve health outcomes for people by commissioning and funding research and producing evidence that improves practice in relation to the organisation and delivery of healthcare. The programme also builds research capability and capacity amongst those who manage, organise and deliver services, improving their understanding of the research literature, and how to use research evidence effectively in practice. In 2010/11, the programme commissioned 34 research projects. This included a cluster of seven projects looking at aspects of patient safety and three projects to investigate management of unplanned hospital admissions. It also funded the first four projects via its new evidence synthesis work stream, which has been established for the rapid commissioning of secondary research and consultation projects.

## **Research highlights:**

- Managing patient confidentiality and sharing information with family/friend carers can be difficult for mental health professionals, particularly if service users do not consent to sharing information. A study led by Rethink has developed an online training resource for mental health professionals to effectively share information with carers. The e-learning package produced includes an interactive 9-lesson course based upon scenarios provided by carers, service users and professionals. This training resource supports mental health professionals by improving their confidence and competence to share appropriate information with carers.
- A Manchester University study has found that group based interventions and e-health methods can be effective and acceptable ways of supporting children and young people with their self-care for long-term conditions such as asthma and diabetes.

## Efficacy and Mechanism Evaluation programme

The Efficacy and Mechanism Evaluation programme funds studies that evaluate the clinical efficacy of interventions for which proof of concept in humans has already been achieved, and which adds significantly to our understanding of biological or behavioural mechanisms and processes. The aim is to secure the progress of new technologies and interventions through their early clinical trials and on to larger, later clinical trials. This helps to bridge the gap in the translation of ideas from early to later phase clinical trials. It also enables clinical ideas to generate areas for further preclinical scientific research, a process known as reverse translation. The Efficacy and Mechanism Evaluation researcher-led work-stream is managed by the NIHR and funded by the Medical Research Council. The commissioned work-stream is managed and funded by the NIHR with contributions from the Chief Scientist Office in Scotland, the National Institute for Social Care and Health Research, in Wales and the Health & Social Care R&D, Public Health Agency in Northern Ireland. Eleven studies were funded during 2010/11.

## Research highlights:

- A new DNA vaccine that aims to strengthen the immune system of leukaemia patients could enable them to fight the disease more effectively. The DNA vaccine is being trialled with patients with chronic or acute myeloid leukaemia. The trial led by researchers at Southampton University Hospitals, and Imperial College Healthcare NHS Trust, builds on early research funded by the Leukaemia & Lymphoma Research charity.
- The University of Leeds is trialling the use of robotic versus standard laparoscopic resection for rectal cancer. Robotic assistance to facilitate laparoscopic rectal cancer resection could reduce the need to resort to open surgery and lead to improved cancer outcomes, preservation of normal function, and benefits to quality of life.

# Programme Grants for Applied Research

Programme Grants for Applied Research are awarded to leading applied health research groups to support cohesive programmes of research devised to tackle high priority health issues for the NHS. Programme Development Grants enable preparatory work to be undertaken prior to a full programme grant application. During the past year, the establishment of a new College of Experts, a core group of methodological experts and a pool of Patient and Public Involvement reviewers, has strengthened the assessment of research proposals.

# **Research highlights:**

- The Norfolk Diabetes Prevention Study is a £2m programme to screen 10,000 people who are at high risk of type 2 diabetes. The study will offer an exercise, diet, information and motivation programme that may reduce the risk of getting diabetes. Those found to be at a pre-diabetes stage will be assigned mentors - patients who already have the condition - to give advice on diet and lifestyle that may reduce the risk of getting diabetes. Researchers expect that 11% of people will be in the pre-diabetes phase, which means they are at high risk of developing the condition.
- The Evaluation of Exercise on individuals with Dementia study is assessing the impact of mild exercise on the behavioural and psychological symptoms of dementia to determine if moderate activity can help people cope with the devastating effects. The reasons why exercise can help are not fully understood. Some of the theories being investigated range from the regulation of the sleep-wake cycle to how stimulation itself could perhaps prevent the brain from degenerating. Although drugs can slow its advance, there are concerns about the over prescription of anti-psychotics for dementia patients, and more effective treatments are needed for this increasingly common condition.

## Invention for Innovation programme

The Invention for Innovation (i4i) programme supports collaborative projects to develop new healthcare technologies. The programme was re-launched in October 2010 and now welcomes applications for either early-stage or late-stage product development, ranging from the

technical feasibility of a prototype to commercially developing a device or technology ready for clinical testing.

## **Research highlights:**

- The Interactive Bionic Vision research project, led by the University of Oxford is developing a portable computer-assisted visual aid for severely visually impaired individuals. The visual aid looks like a regular pair of glasses, and within its lenses are new types of display that can show the wearer a greatly enhanced view of the world. The discrete glasses frames carry two tiny cameras that detect objects such as people, solid obstacles and signs. Any detected object is indicated to the wearer by illuminating a set of small bright LED lights that are embedded in the transparent lenses of the glasses. The study was selected as an exhibit at the Royal Society's Summer Science Exhibition, which features interactive simulations to enable visitors to experience what the world looks like through different prosthetic techniques and to explore the next generation of visual prosthetics.
- The Point-of-Care Genetic Test Platform to predict an individual's response to specific drug treatment study, is led by Imperial College London and its spinout company DNA Electronics. Despite emerging examples of clinical utility, pharmacogenetic testing is yet to be fully integrated into routine clinical practice in the UK, as current tests are not sufficiently patient-friendly. This study is evaluating a prototype device, the Single Nucleotide Polymorphism Doctor to detect genetic biomarkers known as single-nucleotide polymorphisms. If successful and commercially developed, routine adoption by the NHS could prevent many of the adverse drug reactions that are estimated to cost £466m per year and which block 5,000 beds from use by other patients.

# Research for Patient Benefit programme

The Research for Patient Benefit programme funds regionally derived applied research in health and social care to improve, expand and strengthen the way that healthcare is delivered for NHS patients, other service users and members of the public.

# Research highlights:

- The Keeping Warm in Later Life: tackling money, mindsets and machinery study is developing the use of social marketing as a new approach to getting messages across to older people, families and staff about keeping warm as well as to improve the accessibility of help. Fifty older people (aged 55-95) are participating to investigate the factors that influence behaviour including money and existing mindset. The study is also exploring how to integrate assessment and referral through other contact opportunities e.g. flu jab appointments, as well as working in partnership with other professionals in housing, health, environment, energy efficiency, financial inclusion and welfare.
- The Hands up for Max! research project is being carried out by the University of Bristol to test the effectiveness of an educational intervention to promote hand washing and reduce absenteeism in primary schools. Pupils aged 5 -11 years in 178 maintained primary schools

and special schools in the South West are participating to see how effective this is in reducing staff and pupil absence by reducing the spread of infectious illness. The two-year trial is due to report later in 2011 and will explore any differences in hand washing behaviour, knowledge and attitudes between pupils and staff in the intervention and control groups.

## NHS Physical Environment Research Programme

The NHS Physical Environment Research programme funds research that benefits patients by improving the way property and facilities are managed and maintained, promoting safe, high quality and best value design in the healthcare environment. The programme has two strands:

- The care setting design quality, risks, safety and resilience. Examining a range of topics including infection control linked to both surfaces and ventilation (as part of which, a body of evidence has been built up about Clostridium difficle and MRSA), visual and acoustic privacy, natural light, gender separation, and water safety.
- Decontamination surgical instruments, endoscopes and linen. Such as investigating the protein removal from instruments, including links to vCJD.

In 2010/11 a diverse range of research studies were published including some important evidence about infection control. By demonstrating how buildings, surfaces and ventilation have a role to play in preventing infection, this compliments research undertaken by other NIHR funded programmes that focus on the clinical aspects of infection control.

# Research highlights:

- A 36-month study by Cardiff University is testing the activity of range of antimicrobial surfaces against two major pathogens, methicillin-resistant Staphylococcus aureus (MRSA) and Clostridium difficile. The development of such a methodology will provide the NHS with a robust tool to distinguish the activity of different commercially available antimicrobial surfaces, as well as helping to decide whether these materials (often coming at a premium cost) are needed or not.
- The Health & Safety Laboratory is combining environmental safety expertise with clinical understanding of how inpatients' conditions may affect their perception, cognition or mobility, to develop a toolkit to reduce falls. The toolkit could be used to inform the design of new builds and ward refurbishments, but it is also likely to identify improvements that could be introduced at low cost, for example, adjustments to lighting levels or signposting of toilets that is comprehensible to patients with dementia or visual deficit.

# Systematic Reviews

The findings of individual research studies are rarely sufficient to justify new treatments. Systematic reviews identify, evaluate, combine and summarise the findings of all relevant individual studies. When carried out well, such reviews provide decision-makers with the best possible information about the effects of tests, treatments and other interventions used in health and social care. There are three Systematic Review Programmes: UK Cochrane Centre and Cochrane Review Groups; Centre for Reviews and Dissemination; and Technology Assessment Reviews.

## UK Cochrane Centre and Cochrane Review Groups

The UK Cochrane Centre coordinates the preparation, revision and accessibility of systematic reviews regarding the effects of healthcare interventions that are produced by twenty-three Cochrane Review Groups. The Centre is part of the international Cochrane Collaboration, an independent, not-for-profit consortium dedicated to making up-to-date, accurate information about the effects of healthcare readily available throughout the world. The NIHR is the largest single national funder. The reviews are updated as new information becomes available, which is particularly important and valued in the rapidly changing healthcare environment. During 2010/11, the Cochrane Review Groups produced 253 new reviews and updated 409 existing reviews. Nine Cochrane-NHS Engagement awards were commissioned and are expected to establish sustainable approaches for strengthening the linkage between the NHS and the Cochrane Collaboration, so strengthening the uptake of evidence in NHS decision-making.

## **Review highlights:**

- Relatives of people with dementia often want to participate in research, but their time is
  limited because of their care-giving role. The Feasibility of Recruitment and Training Carers
  of People with Dementia review, aims to engage, educate and inform carers in the
  evidence relating to dementia. Involving and training volunteer 'expert carers' has the
  potential to benefit the carers taking part, and could have wider benefits for carer
  engagement with the NHS and in primary research.
- NHS commissioners can face difficulties when using evidence from systematic reviews to develop guidelines for decommissioning health care interventions that are ineffective or interventions where there is insufficient evidence supporting their use. Health care providers and clinicians can also face problems when implementing the evidence from these guidelines into clinical decisions. The Cochrane-NHS Engagement Project is identifying those challenges to guide the development of approaches to promote and support the application of evidence from systematic reviews.

#### **Technology Assessment Reviews**

Technology Assessment Reviews provide vital support for organisations involved in developing health policy in the NHS. The reviews independently assess the existing evidence base on the

benefits, harms and costs of particular health technologies. Technology Assessment Reviews typically support the NICE Multiple Technology Appraisal Committee or Diagnostic Assessment Committees, and can inform its national clinical guidance to the NHS. Large research reviews estimate the relative effectiveness and cost effectiveness of a range of intervention options. These reports commissioned by the NIHR Health Technology Assessment programme are delivered within 28 weeks by contracted academic or specialist centres.

# **Review highlights:**

- Taking an x-ray that is weight-bearing, full body, or three-dimensional could provide important insight and guide the treatment of many orthopaedic conditions, such as scoliosis. The review will determine the clinical and cost-effectiveness of the EOS 2D/3D X-ray imaging system and inform the first guidance to be produced by NICE's new Diagnostic Assessment Committee, which focuses on the evaluation of innovative medical diagnostic technologies.
- Acute leukaemias are fast moving cancers that attack the bone marrow and blood. Stem cell transplantation is an alternative treatment, which can be used together with chemotherapy. The review suggests that using sibling donor stem cells is more effective than chemotherapy in certain groups of patients, and that using a donor's own stems cells offers no benefit over chemotherapy. The report is a systematic review and meta-analysis of literature in the field of stem cell transplantation, with the aim of generating an inventory of best available evidence to help inform the commissioning of future research.

## Centre for Reviews and Dissemination

The NIHR Centre for Reviews and Dissemination (CRD) based at the University of York is an international centre of excellence in systematic reviews and associated economic analyses evaluating the effects of health and social care interventions and in promoting the use of research evidence in health policy and practice. Underpinning this work is a programme of methodological and dissemination research. CRD also manages three internationally renowned databases, primarily for use by NHS decision makers. All of CRD's research outputs address important health and public health questions, and are readily accessible to NHS decision makers and practitioners. Over the past year, more than four million abstracts were viewed via the CRD Databases.

# **Review highlights:**

 PROSPERO, an international systematic review register developed by the CRD, was launched in February 2011. PROSPERO is the first online facility to register ongoing systematic reviews in health and social care from all around the world. This will allow those commissioning or planning reviews to identify whether there are any reviews already underway that address their topic of interest, and help to avoid unintended and economically wasteful duplication of effort. Registration is web-based and completely free and open to all researchers planning to conduct a systematic review.

# Horizon Scanning Centre

The NIHR National Horizon Scanning Centre, based at the University of Birmingham provides key policy makers with advance notice of selected new and emerging health technologies that might require evaluation, consideration of clinical and cost impacts, or modification of clinical guidance, up to 2-3 years prior to launch on the NHS in England. The Centre identifies key pharmaceuticals, therapeutic vaccines, medical devices and equipment, diagnostic and predictive tests and procedures, rehabilitation aids and therapy, and public health activities that may have a significant impact on patients or the provision of health services in the near future. During 2010/11 the Centre identified 1,200 emerging technologies, and provided horizon scanning technology briefings on just over 100 topics judged to be within timescale and potentially of some significance to patients and/or the delivery of health care.

### **Research highlights:**

- Completed technology reviews regarding developments for the preservation and optimisation of organs for transplantation for the National Specialised Commissioning team.
- The Centre collaborated with other UK-based horizon scanning agencies, the Department
  of Health and the Association of British Pharmaceutical Industry (ABPI) to develop and
  deliver UK PharmaScan, a database of pharmaceutical pipelines products. The web-based
  database went live for manufacturers to enter data from their development pipelines in
  summer 2010, with continued monitoring and development to improve coverage and
  completeness.

# **Research Schools**

The NIHR currently funds two national research schools in the key areas of Primary and Social Care that bring together top academics and practitioners to conduct leading edge clinical research to benefit patients and the public.

The NIHR is also establishing a new Public Health Research School whose aim is to increase the evidence base for effective health practices. It is designed to build closer relations between researchers and practitioners across Public Health England and Local Authorities. A call was issued in February 2011, inviting applications to deliver a five-year programme of high quality research to deliver the key objectives of the School. The new Public Health Research School will draw on leading academic institutions with excellence in applied public health research, including evaluations, and place emphasis on what works practically that can be applied across the whole country. The new school is expected to launch in early 2012.

## School for Primary Care Research

The School for Primary Care Research, founded in October 2006 and with a revised membership from 1 October 2009, is a partnership between the eight leading academic

centres for primary care research in England. The School undertakes high quality research to inform the development of clinical practice in primary care, and provides strategic leadership in primary care research. The School has five programmes:

- Prevention and early diagnosis of serious disease
- Monitoring and management of patients with long term conditions
- · Co-morbidity and patient centred outcomes
- New approaches to patient-practitioner interaction
- New research methods for primary care.

## Research highlights:

- The study Telemonitoring and self-management in the control of hypertension: a randomised controlled trial, reported the important first evidence that patient self monitoring of blood pressure with self titration of antihypertensives is effective at lowering blood pressure, and was fast tracked by the *Lancet*, supported by an editorial.
- Secondary analyses from the landmark Birmingham Atrial Fibrillation Treatment of the Aged (BAFTA) trial, supported by the School has guided NHS Policy statements on stroke prevention in atrial fibrillation, adding to earlier data from the Saline versus Albumin Fluid Evaluation (SAFE) and BAFTA trials. This has led to new NHS policies on cost-effective detection of atrial fibrillation and strategies for better anticoagulation in such patients, local incentive policies and changes to Quality and Outcomes Framework indicators.

# School for Social Care Research

The School for Social Care Research is a partnership between six leading academic centres of social care research in England. The School commissions and conducts high-quality research studies and reviews, and supports the development of innovative methods for translating research to improve adult social care practice. This research supports the improvement of social care practice, as well as overall healthcare, by increasing individuals' independence, quality of life and wellbeing. In 2010/11, the School launched its second public call for research proposals, receiving 35 full proposals, eight of which were funded. Four internal projects were commissioned, and twenty-two studies are now underway. During the year, the School appointed five Senior Fellows and over twenty Fellows, bringing the total number of Senior Fellows to six and Fellows to sixty-five.

## **Research highlights:**

 Together with the NIHR Dementia and Neurodegenerative Diseases Network, the School is working with the ENRICH (Enabling Research in Care Homes) project to encourage research in care homes. The Schools methods review looking at research in care homes is being finalised for publication. Research in care homes has the potential to improve the lives of residents, to reassure their families, and develop the skills of the staff supporting them.  The School published a scoping review, carried out by the Centre for Disability Research at Lancaster University exploring the issue of prevention in relation to adult social care services for people with learning disabilities. Individuals and families require a wider range of support than crises intervention services alone. This review confirms that prevention and early intervention for people with learning disabilities can improve their lives, provide better opportunities and reduce the stress for their family carers.

# Clinical Trials Unit support funding

The NIHR Clinical Trials Unit support funding was established in 2008 to offer registered Clinical Trial Units additional financial stability and flexibility, to enable them to increase their capacity to support research funding applications and active projects. The awards are intended to support Clinical Trial Units by increasing the ability to offer longer contracts to staff and build research capacity. The expected result of this investment is a rise in the number of quality research applications submitted to the NIHR Evaluation, Trials and Studies programmes, such as the Health Technology Assessment programme. Twenty-two Clinical Trial Units are now in receipt of support funding, with a rigorous annual review process to ensure that funded units are performing to the required standard.

# Centre for Surgical Reconstruction and Microbiology

The NIHR Centre for Surgical Reconstruction and Microbiology is a new initiative that brings both military and civilian trauma surgeons and scientists together to share advanced clinical practice in the battlefield and innovation in medical research to benefit all trauma patients in the NHS at an early stage of injury.

The Centre for Surgical Reconstruction and Microbiology, which opened in January 2011, is a partnership between the NIHR, the Ministry of Defence, University Hospitals Birmingham and the University of Birmingham. The Centre is based at the Queen Elizabeth Hospital in Birmingham, where injured service personnel are currently treated after evacuation from the frontline in Afghanistan. The centre forms a central point in England for trauma research where knowledge can be translated into real improvements in care for all NHS patients. It is the first and only research centre of its kind in the UK to focus on both military and civilian care and treatment.

# INVOLVE

The INVOLVE programme supports greater public involvement in NHS, public health and social care research. INVOLVE works with researchers, commissioners and the public, for example, patients, service users, and or carers, to create an environment where public perspectives are integrated in all aspects of research to enhance its quality, relevance and acceptability. INVOLVE continues to support the development of the evidence base to widen our knowledge and understanding of public involvement in research.

### **Research highlights:**

- The Mapping Public Involvement in NIHR Funded Research study, undertaken with the National Research Ethics Service (NRES), analysed information on public involvement in research routinely collected by the NRES as part of the application process for ethical approval of research projects. The study created baseline information on public involvement across all sources of research funding, including Charities, Research Councils and Industry as well as the NIHR programmes.
- INVOLVE published *invoNET Bibliography 3*, an annotated bibliography of over 170 references and abstracts on the nature, extent and impact of public involvement in NHS, public health and social care research. The references and abstracts provide evidence, knowledge and learning about public involvement in health and research, of value to researchers.

# **Chapter 2: Infrastructure**

The NIHR invested £604 million in 2010/11 to provide the facilities the NHS needs to stay at the forefront of research that delivers high-quality care for patients and the public.

Early-phase and experimental medicine research is supported predominantly by the NIHR's Biomedical Research Centres and Units, Clinical Research Facilities and Experimental Cancer Medicine Centres.

# NIHR Biomedical Research Centres

There are twelve NIHR Biomedical Research Centres based within England's leading NHS and University partnerships, driving forward innovation and translational research in biomedicine. The Centres support the NHS and academia to work seamlessly together, attract top international researchers in experimental medicine, and improve the transfer of pioneering new diagnosis and treatments into practice.

Five Centres have a comprehensive remit, working across a range of disease and therapeutic areas. A further seven centres work in specialist areas: ageing; cancer; genetics and developmental medicine; mental health; microbial diseases; paediatrics and child health; and ophthalmology.

## **Research highlights:**

- The Biomedical Research Centre for Ophthalmology based at Moorfields Eye Hospital is undertaking research into paediatrics and inherited eye disease. It aims to perform detailed phenotyping and genotyping to identify the genetic mutations causing inherited and developmental eye disease, and to develop molecular diagnosis and improved genetic counselling in the clinical setting. This research is also funded by charities such as Fight for Sight, British Retinitis Pigmentosa Society, British Eye Research Foundation and the Guide Dogs for the Blind Association.
- The Oxford Biomedical Research Centre has identified new biomarkers to help diagnose and manage pre-eclampsia in pregnant women. Pre-eclampsia is a major cause of maternal and perinatal morbidity and mortality, and a significant economic burden on the NHS. The novel biomarker for pre-eclampsia - soluble ST2 is significantly increased in the circulation of women who develop pre-eclampsia prior to the onset of the disease. A patent application has been filed and the Centre is working with a US company Critical Diagnostics, to develop and evaluate a highly sensitive assay for soluble ST2.

# NIHR Biomedical Research Units

Sixteen NIHR Biomedical Research Units bring together some of England's leading health researchers and clinicians to carry out translational clinical research in a number of areas of high disease burden and unmet clinical need. These include cardiovascular disease; deafness and hearing problems; gastrointestinal disease; musculoskeletal disease; nutrition, diet and lifestyle; and respiratory disease.

## **Research highlights:**

- The Nottingham Biomedical Research Unit in Hearing working with several research partners including the University of Nottingham's School of Clinical Sciences Biomaterialsrelated infection group and its School of Pharmacy is developing a revolutionary controlledrelease antibiotic pellet, which can be implanted in the middle ear during surgery to fit grommets. The pellets slowly release antibiotics to target any infections, reducing the risk of repeated grommet operations. In the future, this could be used to advance treatment, greatly improving the lives of thousands of children who have glue ear, as well as resulting in significant cost savings for the NHS. The research team responsible for developing the biodegradable pellet has won the ENTEX short papers prize as well as prizes at the ENT UK annual meeting and Otorhinolaryngologic Research Society Meeting.
- The Barts and The London Biomedical Research Unit in Cardiovascular Disease has been involved in a landmark randomised clinical trial, published in the *Lancet* in collaboration with the medical device company Ardian, to demonstrate the effectiveness of their new catheter-based treatment for therapy-resistant hypertension. The Symplicity Catheter System is used to perform a procedure termed renal denervation. Once in place within the renal artery, the device delivers low-power radio-frequency energy to deactivate the surrounding renal sympathetic nerves. This, in turn, reduces activity of the sympathetic nervous system, which reduces blood pressure. The trial demonstrated the potential of this medical device to significantly impact the standard of care for the large number of patients suffering from hypertension and whom are resistant to current available therapies.

# **Clinical Research Facilities for Experimental Medicine**

The NIHR funds the necessary recurrent NHS research support costs of Clinical Research Facilities for Experimental Medicine. Clinical Research Facilities provide a purpose-built environment for patient-centred research where clinical researchers are able to make use of cutting-edge clinical facilities, technologies and expertise and have access to patients. They support collaborations between basic and clinical scientists, which help to ensure that advances in biomedical research feed through into improvements in healthcare. Many studies facilitated by Clinical Research Facilities are collaborative studies with industry.

### Research highlight:

 The University of Cambridge has a partnership agreement with GlaxoSmithKline to collaborate in the early phase development of novel treatments. Researchers in the Institute of Metabolic Science and Neuroscience have undertaken proof-of-concept studies to show that anti-obesity agents modulate activity of higher central nervous system centres. They are also collaborating to investigate the benefits of a GlaxoSmithKline compound in eating disorders.

# **Experimental Cancer Medicine Centres**

The NIHR funds fifteen Experimental Cancer Medicine Centres in partnership with Cancer Research UK. Experimental Cancer Medicine Centres focus on speeding up the process of cancer drug development and the search for cancer biomarkers 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. Since the initiative started in 2007, Experimental Cancer Medicine Centres have collaborated with over 60 industry partners, and with larger Centres including the Institutes of Cancer Research at Manchester and Oxford, helping to position England as a world leader in the battle against cancer.

### **Research highlights:**

- Researchers from the Experimental Cancer Medicine Centres at Leeds and at Barts opened a first in man study with GlaxoSmithKline's aurora kinase inhibitor 1070916A. This was the first trial in Cancer Research UK's Clinical Development Partnerships Programme, which enables companies to progress oncology agents outside of their core focus that would not otherwise be developed. Leeds and Barts benefit from access to this novel agent, whilst GlaxoSmithKline retains the rights to the compound and the option to further develop and commercialise the drug.
- The Combinations Alliance is a joint initiative between the Experimental Cancer Medicine Centre Network and Cancer Research UK's Drug Development Office to collaborate with pharmaceutical companies to deliver investigator led combination studies of novel agents. AstraZeneca is the first company to be involved, but discussions are taking place with other pharmaceutical companies to expand adoption of the business model and forge even stronger links with industry in the future.

# Patient Safety and Service Quality Research Centres

The NIHR Patient Safety & Service Quality Research Centres focus on investigating ways to improve the safety, quality and effectiveness of the services that the NHS provides to its patients. The centres carry out a broad range of themed research funded from a variety of sources, including using information to drive quality and safety; medication safety; design and

assessment of technology for quality and safety; patient involvement in safety and quality; improving safety in elderly care; and improving safety in surgery.

# Research highlights:

- The Imperial Patient Safety & Service Quality Research Centre is a partner in the 'Care Station' project for improving the efficiency and safety of care at the bedside, which will be trialled and move to manufacture in the coming year. This is one potential solution of the Designing Out Medical Errors (DOME) study that focuses on high-risk healthcare processes on hospital wards. The DOME project is also supported by the Engineering and Physical Sciences Research Council in collaboration with the Helen Hamlyn Centre at the Royal College of Art and the Imperial Business School.
- The Kings Patient Safety & Service Quality Research Centre's Managing Complications in Medicine and Maternity project examined the barriers and facilitators on the use of track and trigger tools in acute medicine and maternity care. Findings regarding patients' experiences of acute deterioration have informed the matron role as advocate for concerned patients and relatives, and access to outreach services for high-risk groups. The Centre is working to develop real-time patient feedback as part of the dignity improvement programme. The findings are informing an expert advisory group established by the Division of Health Systems and Public health at WHO Regional Office for Europe on patient safety and patient rights and has informed the 1000 Lives Plus programme in Wales.

# NIHR Clinical Research Network

Later phase clinical studies are supported by the NIHR Clinical Research Network, which provides the practical support researchers need to deliver studies in the NHS in line with study timescales and patient recruitment targets. This support provided, which is for both commercial and non-commercial studies, includes advice on study feasibility, access to systems to streamline clinical trial set-up (including costing and contracting for commercial studies), R&D approvals, and provision of on-the-ground staff and resources to ensure efficient patient recruitment and study delivery. The NIHR Clinical Research Network is made up of eight networks:

- Cancer
- Dementia and Neurodegenerative Diseases
- Diabetes
- Medicines for Children
- Mental Health
- Stroke
- Comprehensive
- Primary Care.

The NIHR Clinical Research Network (NIHR CRN) supports research studies on the NIHR CRN Portfolio. These research studies are funded by the NIHR, research councils, more than 140 charities, and other public sector funders, covering the broad spectrum of clinical specialities. The NIHR CRN also actively encourages and supports life-sciences companies to undertake clinical research in the NHS in England and works to extend the opportunities for patients to participate in these studies.

During 2010/11:

- Ninety seven percent of NHS Trusts contributed patients to NIHR CRN studies
- 1,334 non-commercial studies were initialised on the NIHR CRN Portfolio, which constitutes a 26% increase on the previous year
- 324 commercial studies were included on the NIHR CRN Portfolio, which constitutes a 36% increase on the previous year
- 564,698 patients were recruited to research studies, a 24% increase on the previous year. Of these 15,827 patients participated in commercial life industry trials a 7% increase on the previous year.

Throughout 2010/11, collaboration between life sciences companies, NHS Trusts and the NIHR CRN continued to play an important role in the improved performance of commercial research studies. This was demonstrated by the North West Exemplar Programme. The 18 studies involved in the programme together reported a medium study set up time of 59.5 days, and five of the studies recruited the first patient globally, showing that the NHS is a viable environment for commercially sponsored late-phase research. The NIHR CRN is now working with NHS Trusts to embed nationally the good practice identified in the Exemplar Programme and elsewhere in the country.

It has been a particularly positive year for NIHR CRN engagement with the med-tech industry, with the number of commercially sponsored studies almost tripling from 16 studies in the 2009/10 year to 49 studies in 2010/11. In addition, the NIHR CRN has published a med-tech route-map, one of the growing set of tools available to companies to help them to understand and access the support available in a streamlined and effective way.

# Research highlights:

- The NIHR Cancer Research Network supported the HYMN (Hyperthermia plus Mitomycin) multi-centre trial investigating a new treatment for bladder cancer. The trial is comparing hyperthermia and Mitomycin chemotherapy with other standard treatment for bladder cancer. The new treatment improves the absorption of the chemotherapy - killing the cancerous cells. It has already been trialled in Europe, where studies show over half of those treated in this way remain disease free after two years. The study was developed through the National Cancer Research Institute and is funded by Cancer Research UK.
- The NIHR Comprehensive Research Network supported the Swiss-based pharmaceutical company Roche, in the delivery of research into the use of a biopharmaceutical drug to

treat rheumatoid arthritis. Not only has this extended treatment options for patients on the trial, but also the funds obtained from running the commercial trial in the NHS have been reinvested into providing more hands-on staff to deliver further studies.

# NIHR Collaborations for Leadership in Applied Health Research and Care

Applied health research and translation of research findings into improved patient outcomes are carried out by the NIHR's Collaborations for Leadership in Applied Health Research and Care (CLAHRCs). These collaborative partnerships between a university and its surrounding NHS organisations are focused on conducting and applying health research that is transferable across the NHS to provide the highest quality of patient care and outcomes.

## **Research highlights:**

- The CLAHRC for Greater Manchester has developed the Greater Manchester Stroke Assessment Tool (GM-SAT) to help optimise the delivery of the six month stroke review. The GM-SAT is a simple, evidence-based assessment tool, which is used to identify and address individuals' unmet post-stroke needs from across health, social and emotional care domains. Together with its supporting materials, it provides everything needed to undertake a review, from the questions to ask, through to documentation for recording and communicating review outcomes to other professionals involved in an individual's care. This work is being undertaken in NHS Bury, NHS Heywood, Middleton and Rochdale, NHS Oldham and NHS Tameside and Glossop.
- In collaboration with Merck Sharp and Dohme, the Leicestershire-Northamptonshire-Rutland CLAHRC is performing a randomised clinical trial to determine the effectiveness of Near Patient Testing as a screening tool for use in community pharmacies. This randomised study will compare the effectiveness of the current self-assessment tool used for GP referral and the immunoassay-based Near Patient Testing for opportunistic screening for patients with Type 2 Diabetes and impaired glucose regulation. The trial will investigate if screening using a self-assessed risk score followed by the Near Patient Testing in pharmacies will increase uptake of a confirmatory test conducted at the GP surgery compared to screening with a risk score alone.

# Healthcare Technology Cooperatives

Healthcare Technology Cooperatives (HTCs) work to accelerate the development and adoption of innovative technologies to help people with debilitating conditions deal with their daily challenges. Based in an NHS Trust they are a new type of NHS-led virtual organisation that promote collaboration between clinicians, patients, academia and industry, acting as a focus for "technology pull" into the NHS. They provide a national resource to address areas of unmet clinical need, where innovations in treatments and technologies have the potential to make a high impact by both reducing morbidity and improving quality of life for a large

population of patients. There are currently two pilot HTCs co-funded by the NIHR, the Technology Strategy Board, the Engineering and Physical Sciences Research Council and the Medical Research Council: Devices for Dignity (D4D) working in the area of urinary continence; and Enteric - the Bowel Function HTC focused on enteric disorders.

# Research highlights:

- Devices for Dignity (D4D) and one of their commercial partners Medical Devices Technology International Ltd are developing a new device based around NICE guidelines on the identification and management of Lower Urinary Tract Symptoms. The hand-held electronic device is used by the patient to record times, volume passed and desire to urinate. The device will process the information quickly, encourage compliance and will benefit the patient by replacing the time consuming and tedious calculations required with a paper diary. The aim of this project is for the handheld device to interface directly with the clinician's computer or the data transmitted to the clinician by email, which is predicted to reduce appointments and diagnostics costs by 20-35% and decrease inappropriate referrals to secondary care by between 30-70%.
- One of Enteric's research teams has developed a new surgical stapler, which won the
  prestigious Cutlers Surgical Prize, 2011. The Prize was awarded for a stapler specifically
  developed for use in the APPEAR (Anterior Perineal Plane for Ultra Low Anterior
  Resection) procedure. The APPEAR technique could prove invaluable in preventing the
  need for a permanent colostomy for the 3,000 or so individuals whose cancer is located at
  the very lowest part of the rectum.

# NIHR Office for Clinical Research Infrastructure

The NIHR Office for Clinical Research Infrastructure (NOCRI) was established to maximise the impact of the investment of NIHR funding through the NIHR clinical research infrastructure.

One of NOCRI's main areas of focus is building and maintaining effective relationships with infrastructure staff at all levels. It has established a programme to facilitate collaborative projects, share best practice and identify joint technical or practical solutions. NOCRI is working with the NIHR CRN and R&D Directors from NHS Trusts to champion the use of the NIHR Research Support Services programme as well as the model Industry Collaborative Research Agreement (mICRA), to help drive the flow of innovative research for patient benefit.

A vital function of NOCRI is to guide industry and other organisations through the NIHR clinical research environment. NOCRI provides life sciences research partners, including pharmaceutical, biotechnology, contract research organisations, device and diagnostic companies, plus charity and public sector research funders, with a clear knowledge of the opportunities, expertise and support services provided by the NIHR infrastructure. One of the ways this has been achieved is through the development of a series of booklets, which

showcase successful models for research partnerships between universities, NHS organisations and life science industries.

# model Industry Collaborative Research Agreement

Collaborative research between industry, academia and the NHS is increasingly important. Industry is looking to ensure a steady flow of innovative new therapies through its development pipelines. This is potentially an important growth area for UK research. However, contracting between companies and academic/NHS organisations is sometimes delayed by protracted discussions over intellectual property, research risk and equity sharing.

The model Industry Collaborative Research Agreement (mICRA) was developed by a working group led by NOCRI and the Medical Research Council, specifically to be used in the development of contracts for clinical research collaborations. The mICRA was launched in February 2011 and will help to reduce the time and cost of initiating collaborative clinical research studies.

# **Translational Research Partnerships**

Translational Research Partnerships are a new initiative, which bring together world-class investigators in the UK's leading academic and NHS centres to support collaboration with the life sciences industry in early and exploratory development of new drugs and other interventions.

Research centres that make up the Partnerships have been selected to work together based on their proven ability to deliver in experimental medicine and translational research. There are currently two Translational Research Partnerships based on the pilot Therapeutic Capability Clusters announced in the Office for Life Sciences Blueprint, focusing on one of the following areas:

- Joint and related inflammatory diseases including rheumatoid arthritis, osteoarthritis and synovitis.
- Inflammatory respiratory disease including asthma, allergy, chronic obstructive pulmonary disease, cystic fibrosis, acute lung injury and respiratory infection.

In March 2011, the Government's *Plan for Growth* announced that NOCRI would take on responsibility for co-ordinating the initiative and provide a single point of contact for industry engagement.

# **Chapter 3: Faculty**

The NIHR invested £81.4 million throughout 2010/11 in building a strong research community and supporting career training for researchers.

The NIHR Faculty encompasses the researchers and people who lead or support research that receives NIHR and DH Policy Research Programme funding – in the NHS, universities and other organisations. The Faculty also includes all Trainees supported on NIHR training and career development schemes.

The Faculty aims to attract, develop and retain the best clinical, health service and public health research professionals, focusing their talents on health research that meets the needs of patients and the public. It supports researchers at all levels by funding training and career development, and offering programmes for developing present and future research leaders.

# NIHR Faculty membership

The Faculty comprises the following members:

- Senior Investigators selected through annual competitions from the most pre-eminent NIHR researchers
- **Investigators** who are directly engaged in undertaking NIHR or the Department of Health's Policy Research Programme funded research, including lead researchers, other senior researchers, and research assistants
- **Associates** who support research led by others. They include clinical and clinical support staff, and scientific, laboratory, technical and administrative staff
- **Trainees** benefit from one of the NIHR training schemes; they include Academic Clinical Fellows, Clinical Lecturers, Clinician Scientists and Research Fellows.

## Senior Investigators

NIHR Senior Investigators are some of the nation's most outstanding researchers. There are 201 Senior Investigators in post, who provide leadership support to the NIHR and its activities including:

- Helping to plan and speak at research and training events
- Providing support and mentoring to fellows and trainees
- Offering advice to the NIHR, serving on numerous advisory panels

- Advising parliamentary select committees
- Developing major partnerships with life sciences industry, bringing new investment into the nation
- Promoting NIHR research internationally, and nationally, to involve healthcare managers and policy makers, and patients and the public
- Optimising the implementation of legislation and regulations, through production of new guidance.

Whilst Senior Investigators come from a variety of health professional and academic backgrounds, they include many senior doctors. In 2010/11, one hundred and thirty seven held Clinical Excellence Awards, of which thirty-nine held the highest, platinum level award. Nine Senior Investigators were listed in *The Times*' A-Z of Britain's top medical experts.

# Investigators

NIHR Investigators are the research staff who are active in undertaking NIHR or DH Policy Research Programme funded research. In 2010/11 there were 1452 Investigators named as the lead researcher for an NIHR or DH Policy Research Programme research awards, each of whom was leading a team of Investigators. The Faculty is establishing an Investigators advisory group, which will help formulate initiatives to develop Investigators.

## Associates

NIHR Associates provide essential support to research led by others. They mainly work through NIHR research networks and other infrastructure organisations. They include clinical staff, (often research nurses); clinical support staff, scientific, laboratory and technical staff, study facilitators and practitioners, and research managers.

During 2010/11, a project was initiated to understand the development needs of NIHR Associates. This has resulted in a range of support activities being offered to Associates, including the development of an Associates portal, which provides specially commissioned training, career development materials and other content.

# Trainees

The NIHR funds, and manages on behalf of others, training schemes to attract and develop promising individuals with the potential to lead high quality patient and people-based research. The training and career development of research trainees is delivered through a number of schemes managed by the NIHR Trainees Coordinating Centre. The support offered includes an annual national meeting, workshops and networking opportunities, and mentoring. Some of the more advanced trainees, who are beginning to lead teams of their own, are offered an opportunity to develop leadership skills.

The schemes are aimed at a range of levels, from new researchers to established independent scientists. More experienced trainees have contributed to national and international health

policy formation and its communication to patients.

## • NIHR Research Fellowship Programme

This scheme is open to qualified individuals irrespective of their professional backgrounds. In 2010/11, 44 applicants were successful across four levels of award (Doctoral, Postdoctoral, Career Development and Senior).

# • NIHR Integrated Academic Training Programme

The Integrated Academic Training (IAT) Pathway is open to doctors and dentists, to enable them to combine research training with their professional training. In 2010, 266 pre-doctoral Academic Clinical Fellowship Posts and 134 post-doctoral Clinical Lectureship posts were made available. These positions have made a major contribution towards rebuilding the clinical academic community that contracted in the 1990s. In addition, five new In-Practice Fellowship awards were made to General Practitioners, and three to General Dental Practitioners.

# • NIHR Clinician Scientist Awards

Clinician Scientist Awards support individuals who have demonstrated their independence as research scientists, their ability to lead a research team, and who show significant potential to become a research leader. Seven of these awards were made in 2010/11.

# • CNO Clinical Academic Training (CAT) and CSO Healthcare Scientist Fellowships

These programmes are targeted at specific professional groups - Nurses, Midwives and Allied Health Professionals, and Healthcare Scientists. They enable trainees to continue to develop their clinical skills while undertaking research training. These awards are managed by the NIHR on behalf of the Chief Nursing Officer (CNO) and the Chief Scientific Officer (CSO) respectively. During 2010/11, twenty-one personal awards were made (Clinical Doctoral Research Fellowships, and Clinical Lectureships). An additional award was also made at Senior Clinical Lectureship level, in partnership with the Higher Education Funding Council for England. A second cohort of 70 CAT funded students were also recruited onto Masters in Clinical Research courses.

## • NIHR Research Methods Programme

This programme provides support and training to build research capacity and capability in medical statistics, health economics, clinical trial design, operational research and modelling. Eighteen Fellowships were awarded in 2010/11. In addition, the NIHR is supporting Masters studentships in Medical Statistics (spread over five institutions) and Health Economics (three institutions). The intake is 32 students for each of three years, split between the two fields and should have a significant impact on improving capacity.

# NIHR Leadership Support and Development Programme

The NIHR Leadership Support and Development Programme provides NIHR research leaders, who may have very significant responsibilities leading large teams with multi-million pound budgets, the opportunity to develop leadership skills to help them be more effective. The Programme offers an 18-month process of development based on individuals' day-to-day work rather than on classroom exercises. As well as for senior leaders, there are programmes for development leaders who have the potential to fill senior positions, and for trainees who are beginning to lead their own research teams. During 2010/11, 342 individuals were involved with the programme.

# NIHR Faculty Training Forums

In 2010/11, the NIHR Faculty established the Biomedical Research Centres and Units Training Forums to harness collective training expertise, share ideas and best practice, and develop training policy. A Biomedical Research Centre Training Camp held in the summer of 2010, introduced 70 doctoral students to the skills they need to master to develop their academic careers.

# Additional support for researchers

## NIHR Research Design Service

The NIHR Research Design Service offers NHS researchers expert advice and support on research design, methodology, Patient and Public Involvement, and building a strong research team. They ensure that research proposals for submission to NIHR research programmes for applied health, social care and public health research are of high quality and patient focused.

There are currently 130 advisers in ten Research Design Services across the country, including methodologists, statisticians, and health economists, providing advice and support to investigators wanting to develop suitable applications. During 2010/11, the Research Design Service advised on over 2300 new research proposals that led to 300 outline submissions and more than 800 full research applications.

## NIHR Flexibility and Sustainability Funding

NIHR Flexibility and Sustainability Funding is allocated to research-active NHS organisations in proportion to the total amount of other NIHR income received by each organisation, and on the number of NIHR Senior Investigators associated with the organisation. Flexibility and Sustainability Funding is also allocated to NIHR Clinical Research Networks. In 2010/11, 125 NHS Trusts and 102 NIHR Clinical Research Networks received Flexibility and Sustainability Funding £100m.

Flexibility and Sustainability Funding provides a funding stream that Trusts can use to sustain and strengthen research capacity in those areas that are of strategic importance to the NHS. In their reports on the use of Flexibility and Sustainability Funding last year, many Trusts acknowledged the significant impact of this funding in supporting and increasing their NIHR activity.

Flexibility and Sustainability Funding can be used to generate more successful applications for NIHR funding, leading in turn to a higher Flexibility and Sustainability Funding allocation; and plays an important role in:

- Attracting and retaining researchers
- Increasing the involvement of research communities in NIHR programmes
- Strengthening and protecting the clinical academic base
- Providing training funds for Trust R&D Departments to prepare to join the NIHR Research Support Services.

# **Chapter 4: Systems**

£24.4million has been invested in updating the national research management systems that support research, including reducing unnecessary bureaucracy and focusing on creating a health research structure that is simple, robust and effective.

The NIHR is working to simplify and streamline administrative and regulatory procedures governing research trials and studies to make it easier for researchers to undertake highquality research for the benefit of patients and the public.

# NIHR Research Support Services

The NIHR Research Support Services is a framework of good practice and standard procedures for local NHS research management. It was developed and tested with the support of a wide range of stakeholders including industry, investigators, regulatory authorities, Trust Chief Executives and Research & Development (R&D) managers. The framework is simplifying and speeding up local research management as well as enabling operational risk to be managed proportionately through:

- A Trust R&D operational capability statement that empowers the R&D office to manage processes effectively within the organisation
- Planning tools that enable the R&D office, with the Principal Investigator, to quickly
  assess and manage the key risks in order to complete the NHS permission process
  and deliver the study
- Guidelines for standard operating procedures that help develop consistent, streamlined and risk-proportionate research governance practice across the NHS in England.

In March 2011, the Government's *Plan for Growth* confirmed a May 2011 launch date for the NIHR Research Support Services to facilitate consistent local research management, greatly improve performance, and stop unnecessary duplication of checks. NHS Trusts will be required to publish metrics regularly on performance and from 2012, publish outcomes against public NIHR benchmarks, including an initial benchmark of 70 days or less from the time a Provider receives a valid research protocol to the time when that Provider recruits the first patient for that study. In future NIHR funding to providers of NHS services will become conditional on their playing their part in a national system of research governance, as measured by a balanced scorecard and a set of benchmarks, including a benchmark of 70-days for the recruitment of the first patient in clinical trials.

# **UK Clinical Trials Gateway**

The UK Clinical Trials Gateway is an online resource providing easy to understand information about clinical research trials running in the UK. Phase 2 of the Gateway was successfully launched on schedule in March 2011. Phase 3 of the system will be developed throughout 2011 for release in 2012 in line with the announcement in the Government's *Plan for Growth*, to open up information about clinical trials so that patients, their clinicians and the public can find out about trials that may be relevant to their condition.

The most important aspect of the UK Clinical Trials Gateway and what makes it unique from other similar systems, is the availability of lay summaries, which provide trial information in user-friendly language that has been reviewed by an ethics committee. This and other aspects of the Gateway's design make the information more accessible for patients, trial participants and non-technical readers alike. Some of the information provided will enable individuals to locate the organisers of trials, which may be of interest to them. If someone wishes to join a trial, he or she, or the clinician can contact the research team. However, the Gateway is not designed to be a recruitment system.

The UK Clinical Trials Gateway was developed and is managed by the NIHR on behalf of all the UK Health Departments, in conjunction and with the support of a number of clinical research charities, research professionals and patient representatives. Access to the Gateway will be made available via the NHS Choices and NHS Evidence websites in the near future.

# Integrated Research Application System

One of the NIHR's goals is to remove unnecessary bureaucracy in the research application process. It has gone a long way to achieving this through working in partnership with the National Research Ethics Service (NRES), and other bodies involved in the regulation and governance of health research in developing the Integrated Research Application System (IRAS).

IRAS is an intuitive web-based system for applying for permissions and approvals for health and social care/community research in the UK. It complements and supports other activities to simplify and standardise processes, including the NIHR's Co-ordinated System for Gaining NHS Permission (CSP) to streamline local NHS permission so that clinical research studies can be approved much more quickly. It provides a single dataset, which is tailored to the particular research activities of a study and encompasses all the information needed for the regulatory and governance applications for that particular study. This means that applications are simultaneously completed without duplication. IRAS is now well established as the only system for preparing applications to most of the review bodies in the UK. This has led to the previous separate forms and systems for applications being phased out.

During 2010/11, major improvements have included:

- Addition of application for the National Offender Management Service
- All forms for notification of substantial amendments now available through IRAS
- Upgrades and additions to functionality in response to feedback from researchers.

# Pilot Health Research Support Service

The Research Capability Programme is developing a national service for researchers that enable them to make good use of routinely collected health information. The NHS collects healthcare information every day, across a wide range of NHS settings including, hospitals, GP Practices and walk-in centres. A Pilot Health Research Support Service has been established to pull together the information that researchers need, linking it to create data sets so that researchers can carry out their studies. Through these studies, researchers will be able to analyse patterns and solutions that help make treatments more effective and improve the safety and quality of patient care - leading to better health outcomes and quality of life.

The Health Research Support Service protects the privacy of patients by removing certain identifying details, for example, their name and address, before the researcher is allowed to use the information. It also works to ensure that the researchers carrying out the study have all the relevant permissions and approvals, before they receive any information.

The Research Capability Programme has achieved overarching ethics endorsement for the pilot studies and overarching endorsement from the Ethics and Confidentiality Committee of the National Information Governance Board. This reduces the administrative burden of the individual researcher whilst upholding rigorous principles of information governance with the Pilot Health Research Support Service.

## **Research highlights:**

 The Pilot Health Research Support Service has provided its first linked, anonymous dataset for a research study at Kings College London, investigating how mental disorder in patients impacts upon the diagnosis and treatment of cancer, and to understand if there is any delay in cancer diagnosis and the affect it can have on a patient's survival.

### Financial summary NIHR funding for 2010/11

	Spend (£m)
Area Research programmes	2010/11
Research programmes	
Sonvice Delivery and Organisation	
Service Delivery and Organisation Programma Grante for Applied Research	
Programme Grants for Applied Research	
Invention for Innovation	
Research for Innovation Speculation and Creativity	
NHS Physical Environment	
Systematic Reviews (Cochrane, Centre for Review and Dissemination and TARs)	
Horizon Scanning Centre	
Schools: Primary and Social Care Research	
Methodology	
Cohort studies	
INVOLVE	0.6
UK Innovation and Investment (one-off NIHR contribution to national investment fund)	25.0
Health Innovation Challenge Fund	2.4
Health protection (funded by NIHR from 1 April 2010)	10.5
Other, including legacy programmes and management not attributed to specific programmes <sup>(2)</sup>	19.7
Programmes total	210.5
Faculty trainees	
Integrated Academic Trainees (including academic clinical fellowships, lectureships and clinician scientist	
awards)	56.7
Fellowships (including legacy training awards)	11.1
Senior Investigators	4.7
Other (including academic units, clinical academics and management)	8.9
Faculty total	81.4
Infrastructure	
Networks (topic specific networks, Primary Care and Comprehensive networks)	300.9
Biomedical Research Centres	
Patient Safety and Service Quality Research Centres	
Biomedical Research Units	
Clinical Research Facilities for Experimental Medicine	
Experimental Cancer Medicine Centres	5.7
Excess treatment costs	4.2
Collaborations for Leadership in Applied Health Research and Care (CLAHRUS)	
Research Design Service	10.3
	100.1
	604.0
Sustama	004.0
Systems	12.0
Busting bureaucracy information systems	
Local research ethics committees	
Ather	3.7 2 0
Systems total	2.9 24 1
	020.2
NIHR capital allocations - research capability programme pilots	920.3 0.9
	0.0
I OTAL NIHK SPEND	921.1

1) Spend on HTA excludes £7m 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/UK Biobank; mental health and forensic mental health, cancer including prostate; patient safety.