Delivery IVD Research through the National Institute for Health Research.

18 March 2014

Dr Tony Soteriou
Infrastructure and Growth Senior Manager
Goals

• Transform research in the NHS
• Increase the volume of applied health research for the benefit of patients and the public
• Develop and support the people who conduct and contribute to applied health research

Principles

• Transparent
• Competitive
• High quality
• Value for money
• Focused on outcomes
This pathway covers the full range of interventions - pharmaceuticals, biologicals, biotechnologies, procedures, therapies and practices - for the full range of health and health care delivery - prevention, detection, diagnosis, prognosis, treatment, care.
**Efficacy and Mechanism Evaluation (EME) Programme**

- Jointly funded by NIHR and MRC and managed by NIHR, the EME Programme sits between funders of basic science and early clinical research and the more applied NIHR programmes.
- Actively supports the translational pull through of promising interventions*, with significant potential to benefit patients and the NHS in the medium to longer term, from early clinical studies into later phase evaluation.
- Funds science driven clinical efficacy studies to test interventions and provides the opportunity to explore disease or treatment mechanisms, which may in turn lead to improvements in health and patient care.
- Supports and encourages academics and clinicians to work with commercial organisations, in particular SMEs.
- Has committed almost £90 million to internationally competitive research from across the UK during the last 5 years.

*the term intervention is used in the broadest sense and includes any method use to promote health, prevent and treat disease and improve rehabilitation or long-term care.
NIHR Invention for Innovation (i4i)

• Designed to translate med tech innovations into patient benefit for the NHS with end user pull

• Moving technologies and devices towards investor readiness with de-risked, compelling propositions

• “Valley of Death” - funding for novel innovations which are too early stage to be funded by venture capital or private equity

• Mission-critical funding for collaborations: universities, clinicians and med tech industry (focus on SMEs)

• Strong commercial, clinical, technology development and regulatory experience within the funding panel
Next Generation Mobile Diagnostics for HIV
Assisted vision for severely sight impaired individuals

Stephen Hicks

Nuffield Department of Clinical Neurosciences, University of Oxford

National Institute for Health Research

RNIB UNIVERSITY OF OXFORD
Infrastructure

- Clinical Research Networks
- Biomedical Research Centres
- Biomedical Research Units
- Clinical Research Facilities
- Experimental Cancer Medicine Facilities
- Patient Safety Translational Research Centres
- Collaborations for Leadership in Applied Health Research and Care
- Healthcare Technology Cooperatives
- Diagnostic Evidence Cooperatives
- Clinical Trials Unit support
- Research Design Service
NIHR Clinical Research Infrastructure

Invention

Biomedical Research Centres
Biomedical Research Units
Experimental Cancer Medicine Centres
Clinical Research Facilities
Translational Research Partnerships and Collaborations
Patient Safety Translational Research Centres

Evaluation

Healthcare Technology Co-operatives
Diagnostic Evidence Co-operatives

Adoption

Collabs for Leadership in Applied Health Research and Care
Clinical Research Networks
NIHR Biomedical Research Centres: 2012 to 2017

- Newcastle
- Cambridge
- Imperial
- University College
- Great Ormond St
- Moorfields
- Guy’s & St Thomas’
- Maudsley
- Marsden
- Southampton
- Oxford
Blindness gene therapy trial: 'I don't trip over things any more'

16 January 2014 Last updated at 00:14 GMT

Researchers in Oxford say they have improved the vision of patients that would otherwise have gone blind.

BBC News reported the start of the trial two years ago - the results of which have now been published in the Lancet.

The so-called gene therapy is for a rare form of blindness called Choroideremia, but the doctors say it could potentially be used to treat the more common form of age-related blindness which affects 300,000 people in the UK and millions across the world.

Jonathan Wyatt was on the verge of losing his sight when he received the treatment two years ago. He told BBC News how his vision has improved.
Baby born using new IVF screening technique

By James Gallagher
Health and science reporter, BBC News

A baby has been born in the US using a new method for screening embryos during IVF which could dramatically reduce costs, researchers report.

Connor Levy's parents had been trying to conceive naturally for four years.
Blood test 'detects sepsis in hours'

By Helen Briggs
BBC News

A rapid blood test to diagnose blood poisoning, or sepsis, at the hospital bedside could potentially save thousands of lives, say researchers.

Early studies at King's College London suggest the condition can be diagnosed in two hours using a simple blood test.

Current diagnostic methods take up to two days, which may delay treatment with life-saving antibiotics.

The condition - caused when the body's immune system overreacts to infection - causes 37,000 UK deaths each year.

In the study, published in the journal PLOS ONE, researchers identified a biomarker for diagnosing sepsis rapidly in blood samples.
46 gene sequencing test for cancer patients on the NHS

The first multi-gene DNA sequencing test that can help predict cancer patients' responses to treatment has been launched in the National Health Service (NHS), thanks to a partnership between scientists at the the National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC), a collaboration between Oxford University Hospitals NHS Trust and Oxford University
Healthcare Technology Cooperatives

**New NIHR Healthcare Technology Cooperatives:**

Building on the pilot scheme (2008), the NIHR launched an open competition in January 2012. The NIHR announced the designation and funding of eight new HTCs on 13 December 2012.

The eight new HTCs launched on 1 January 2013 receive £6.4m of funding over 4 years.

**HTC clinical areas & themes:**

- Chronic gastrointestinal disease; Brain Injury; Cardiovascular disease; Devices for Dignity; Wound Prevention and Treatment; Colorectal Therapies; Mental Health and neurodevelopmental disorders; Trauma Management.
Diagnostic Evidence Co-operatives focus on clinical areas or themes where evidence of the clinical validity, clinical utility, cost-effectiveness and care pathway benefits of in vitro diagnostic medical devices (IVDs) has the potential to lead to improvements in healthcare services and the quality of life of NHS patients.

The NIHR is providing over £4 million funding to 4 NHS Organisations for a four-year period starting 1 September 2013.

The Diagnostic Evidence Co-operatives bring together a wide range of experts and specialists from across the NHS and industry, including clinicians and other healthcare professionals, patients, NHS commissioners and researchers and investigate a number of different clinical areas.
NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs)

13 NEW Collaborations from January 2014

Greater Manchester
North West Coast
East Midlands
West Midlands
Oxford
West
South West Peninsula
Wessex
South London
Yorkshire & Humber
East of England
North West London
North Thames

Pilot scheme to 2014
NIHR CLAHRC performance

<table>
<thead>
<tr>
<th>Research projects</th>
<th>Implementation projects</th>
<th>Peer reviewed publications</th>
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<tr>
<td>754</td>
<td>454</td>
<td>903</td>
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</table>

<table>
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<tr>
<th>Subjects recruited</th>
<th>External income generated</th>
<th>Higher degrees</th>
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<tr>
<td>2,619,289</td>
<td>£54 million</td>
<td>1079</td>
</tr>
</tbody>
</table>

* Dissemination and capacity building – international conferences, policy education and training, thematic conferences and local meetings and courses
NIHR Clinical Research Infrastructure

NOCRI supports industry through:
- Introductions
- Sign-posting
- Establishing collaborations
- Managing relationships

NIHR Office for Clinical Research Infrastructure (NOCRI)

NOCRI@nihr.ac.uk
www.NIHR.ac.uk/NOCRI
NIHR Clinical Research Network

NIHR Dementias & Neurodegenerative Diseases Research Network

NIHR Diabetes Research Network

NIHR Medicines for Children Research Network

NIHR Mental Health Research Network

NIHR National Cancer Research Network

NIHR Primary Care Research Network

NIHR Stroke Research Network

NIHR Comprehensive Clinical Research Network
NIHR Clinical Research Network

Key achievements in 2012 / 13

• more than 630,000 participants recruited to NIHR Clinical Research Network Portfolio studies

• 99% of NHS Trusts participated in CRN Portfolio studies

• 63% of NHS Trusts participated in CRN commercial Portfolio studies

• In the last nine months alone, 23 multi-centre commercial studies, supported by the NIHR Clinical Research Network, have achieved first global patient
NIHR Clinical Research Network performance

The Number of Commercial and Non-Commercial Studies Opening to Recruitment by Financial Year

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>Commercial Studies</th>
<th>Non-Commercial Studies</th>
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<tbody>
<tr>
<td>2008/09</td>
<td>647</td>
<td>58</td>
</tr>
<tr>
<td>2009/10</td>
<td>726</td>
<td>157</td>
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<tr>
<td>2010/11</td>
<td>909</td>
<td>241</td>
</tr>
<tr>
<td>2011/12</td>
<td>1164</td>
<td>302</td>
</tr>
<tr>
<td>2012/13</td>
<td>1340</td>
<td>306</td>
</tr>
</tbody>
</table>
Recruitment in 2012/13

78,324 participants in total recruited into the NIHR-portfolio of cancer studies in England

49,347 cancer (& pre-malignant) patients (21.3% of incident cases)

More than a 5 fold increase from 2001
15 Local Clinical Research Networks

North East and North Cumbria
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

North West Coast
Royal Liverpool and
Broadgreen University Hospitals
NHS Foundation Trust

Greater Manchester
Central Manchester University Hospitals
NHS Foundation Trust

West Midlands
The Royal Wolverhampton NHS Trust

West of England
University Hospitals Bristol
NHS Foundation Trust

South West Peninsula
Royal Devon and Exeter
NHS Foundation Trust

South East
University Hospital
Southampton NHS Foundation Trust

North West London
Imperial College Healthcare
NHS Trust

Yorkshire and Humber
Sheffield Teaching Hospitals
NHS Foundation Trust

East Midlands
University Hospitals of Leicester
NHS Trust

Eastern
Norfolk and Norwich University Hospitals
NHS Foundation Trust

Thames Valley and South Midlands
Oxford University Hospitals
NHS Trust

North Thames
Barts Health NHS Trust

South London
Guys’ and St Thomas’ NHS Foundation Trust

Kent Surrey and Sussex
Royal Surrey County Hospital
NHS Foundation Trust
Patients and the public

97% of the public believe it’s important the NHS supports research into new treatments

Source: Ipsos MORI poll (June 2012) commissioned by the Association of Medical Research Charities, Breast Cancer Campaign and the British Heart Foundation
Why is the Government committed to Research in the NHS?

• improve **health outcomes** through advances in research
• improve **quality of care** by NHS participation in the research process
• strengthen International competitive position in **science**
• drive **economic growth** through investment by life science industries
Britain is a world leader in scientific research. And that is vital to our future economic success. That is why I am proposing that we do not cut the cash going to the science budget. Spending on health research will be protected.”

George Osborne
20 October 2010
Policy focus on growth

A review of UK health research funding

Sir David Coddrey
December 2006

The Plan for Growth

March 2011
The health & care system from April 2013

KEY
- Providing care
- Commissioning care
- Improving public health
- Empowering people and local communities
- Supporting the health and care system
- Education and training
- Safeguarding patients' interests
AHSNs, AHSCs and the research and innovation landscape
NIHR BioResource

7 NIHR BRCs and one NIHR BRU:
Cambridge
Imperial
Guy’s and St Thomas’
South London and Maudsley
Oxford
University College London Hospital
Newcastle
Leicester Cardiovascular (BRU)

Healthy volunteers and patients provided samples (of blood or saliva) and agreed to be recalled by genotype and phenotype to participate in experimental research studies.

Four themes:
Rare Diseases
Cardiovascular & Metabolic Disease
Infectious, Immunological & Inflammatory Disease
Neuroscience

Launch: March 2014
Genomic Technologies: 100,000 whole genomes

- Potential of Genomics, in the form of whole genome and exome sequencing, to transform healthcare

- Life Sciences One Year On announcement

- Unique position of the NHS as a single, national healthcare provider

- Genomics England established

- Wealth creating possibilities
Conclusion

1. A time of unprecedented opportunity
   - Unprecedented opportunity for clinical and applied health research
   - Political drive
   - Clear national strategy
   - Supportive national structures
   - Alignment between major funders
   - Increased funding
   - Scientific advances across disciplines
Conclusion

2. A time of unprecedented expectation
- Unprecedented expectation on clinical and applied research
- Delivering health gain
- Delivering wealth gain
- Harnessing the research potential of NHS
- Faster translation of basic research into applied research
- Faster translation of applied research into patient benefit
- Transforming public health through better evidence
Conclusion

3. Successful delivery will be achieved through relentless focus on
   • Partnership and collaboration
   • Scientific opportunity
   • Translation
   • Health benefit
   • Economic benefit
   • Excellence
   • Leadership
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