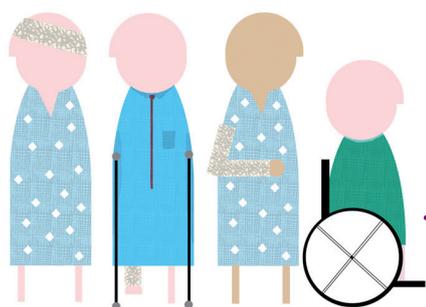
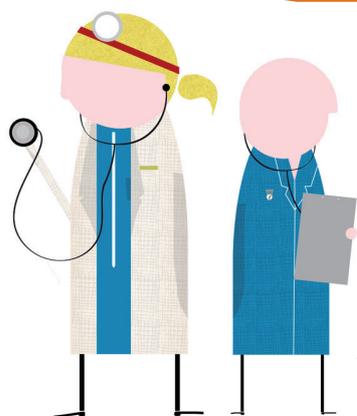


amrc

ASSOCIATION OF MEDICAL RESEARCH CHARITIES



Our vision for  
research in  
the NHS



### **Lord Leslie Turnberg of Cheadle, MD, FRCP, FMedsci**

#### **Scientific adviser, Association of Medical Research Charities**

That the NHS can become a valuable test bed for medical research is well recognised, but it was with the Health and Social Care Act of 2012 that for the first time duties were placed on the new NHS England and Clinical Commissioning Groups to promote and support research in the NHS.

'Placing research at the centre of what the NHS does' and 'Making every health professional and every patient a willing participant' were phrases that tripped off the tongue of Ministers. Quite right too because it is clear that research and the rapid uptake of innovation into clinical practice brings enormous benefits to patients in better and quicker diagnosis, treatments and cures. Furthermore, research has been shown to bring considerable economic benefits for the exchequer in longer, healthier lives, greater productivity and reduced sickness benefits.

So everyone at the top is convinced of the case for making research a key activity for the NHS. But the question now is whether the NHS is ready and capable of implementing these grand ideas?

The AMRC, working with member charities and the wider research community, has attempted to answer this question and developed this '*Vision for Research in the NHS*'. We polled health professionals to gain an idea of their experience of, and attitudes to, research and found that while the majority agreed that research was important, less than a quarter of GPs felt that they should be involved personally. On the other hand patients tell us they are keen to be involved, especially in clinical trials, even though they feel ill-informed of how to do so. We identified a number of barriers to taking part in research for doctors, including pressure of clinical work, burdensome regulation and a lack of information about research opportunities. Our 'Vision' provides a clear set of guidelines that should help overcome some of these barriers and encourage researchers and patients with practical proposals for action. We describe how every patient should be offered opportunities to participate in research, how all medical professionals can understand and recognise the value of engaging in research and how high quality research can become an integral part of what the NHS does. I encourage charities, patients and health professionals to accept our 'Vision' and take its messages forward.

### **Dr Jonathan Sheffield OBE**

#### **Chief Executive Officer, NIHR Clinical Research Network**

Clinical research is a vital part of the work of the NHS. Without clinical research, we cannot improve treatments for patients, or help the NHS to meet the challenges it faces in the future. Great strides have been made in recent years to embed and develop clinical research activity, and this has resulted in a record number of patients having the opportunity to participate in clinical studies. But developing a research culture is an ongoing task, and there is still more work to be done to fully engage stakeholders across the breadth of the research and healthcare sectors.

That is why I welcome this vision from the AMRC, which has important things to say about the need to empower patients, engage clinicians, and ensure that research findings are adopted in order to improve the health and wealth of the nation.

By highlighting both the achievements of the many organisations currently engaged in research activity, and the issues that we collectively face in driving the research agenda forward, the AMRC's vision provides a focal point for debate, and opens the way for constructive dialogue about the research agenda amongst those involved in creating its future.

The term NHS staff is used throughout this report under the definition provided in the NHS Constitution: *"The Constitution applies to all staff, doing clinical or non-clinical NHS work – including public health – and their employers. It covers staff wherever they are working, whether in public, private or voluntary sector organisations"*

Arthritis Research UK, AMRC, Breast Cancer Campaign and British Heart Foundation commissioned ComRes to interview 392 English GPs, hospital doctors and nurses online between 21 March and 5 April 2013. ComRes is a member of the British Polling Council and abides by its rules. Data tables are available on the ComRes website.

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## 02 Foreword

### Every patient is offered opportunities to be involved in research

#### Each and every patient can take part in research

- Promote the NHS Constitution among patients and NHS staff
- Provide information about taking part in research and opportunities to self-refer
- Ensure all patients can take part in appropriate research wherever they live

## 07

### Research is patient-centred

- Involve patients in setting priorities for research
- Develop a quality mark to signify where patients have been involved in the design of a study
- Ensure the results of research studies are made available to research participants study

### Research is embedded in good care

- Require clinical teams to consider every patient's suitability to take part in research as part of their care
- Ensure research activity is specified and reviewed in contracts with all hospitals, primary care and service providers
- Require GPs to share their practice data with the Clinical Practice Research Datalink and respond to requests to invite their patients to take part in research studies

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### All NHS staff see the importance of research

#### NHS staff know how to take part in research and use its findings

- Include research knowledge and use of evidence in basic training for all NHS staff
- Make research experience a desired skill for NHS jobs
- Require all Local Education and Training Boards to include skilled research professionals

#### NHS staff understand the benefits of research to their patients

- Publicise locally and nationally the role of research in improving the quality of care
- Explain how research evidence informs clinical practice
- Include measures of the scope, quality, quantity and adoption of research in the Clinical Commissioning Group Outcomes Indicator Set

#### NHS staff are motivated to engage with research

- Ringfence time for research in NHS contracts
- Develop local and national guidance for those wanting to become active in research
- Use local and national awards to recognise and reward NHS staff at all levels that take part in research research

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### The NHS conducts high-quality research and adopts new treatments

#### All NHS bodies share knowledge to develop and answer research questions and adopt findings

- Publish research results and make data accessible to those who need them
- Encourage NHS commissioners to implement our research charter to ensure their actions are informed by the evidence
- Allow academic Health Science Networks to work independently while encouraging them to share best practice across England

#### The NHS develops research leaders

- Ensure that future NHS leaders can take up research opportunities
- Promote clear career paths for NHS staff engaging in research
- Encourage research active NHS staff to work with colleagues across specialties research

#### The NHS is open to research

- Designate contact points and develop a map to guide people through all aspects of the set up and conduct of studies
- Invest in the infrastructure to conduct research
- Clarify who pays for research costs

## 40 Glossary and calls by organisation



# Every patient is offered opportunities to be involved in research

## Each and every patient can take part in research

- Promote the NHS Constitution among patients and NHS staff
- Provide information about taking part in research and opportunities to self-refer
- Ensure all patients can take part in appropriate research wherever they live

Patients tell us that they want opportunities to be involved in research. In 2011 we polled almost 1000 people, 72% told us that they would like to be offered opportunities to be involved in trials of new medicines or treatments if they suffered from a health condition that affects their day-to-day life<sup>1</sup>. Of 1.2 million UK women contacted to take part in the *UK Collaborative Trial of Ovarian Cancer Screening*, only 32 complained they had been contacted<sup>2</sup>.

But not all patients currently have this opportunity. The latest *National Cancer Patient Experience Survey* found that only one in three of the patients surveyed had had a discussion about research with a health professional but almost all of those (95%) were glad to have been asked. More than half (53%) of those who were not asked would like to have been<sup>3</sup>.

### CASE STUDY 1 – Poor research promotion by NHS Trusts

NIHR Clinical Research Network recently ran a “mystery shopper” survey, which involved visits to 82 hospital sites across 40 NHS Trusts in England.

For each of these visits, mystery shoppers examined the basic points-of-contact for patients (reception desks, patient advice services, patient information centres, noticeboards and hospital websites), to assess whether patients had easy access to information about local clinical research opportunities, and how to get involved.

The survey found that 91% of hospitals did not have any public information about studies they were supporting in basic point-of-contact areas, only 34% of sites had information about clinical research on their websites that was useful to patients and of the 40 Patient Advice and Liaison Services (PALS) only three had any information on research.

In response to the survey the NIHR Clinical Research Network produced a *We do Clinical Research* resource pack that pulled together a selection of best practice, top tips and promotional materials designed to help Trusts increase research awareness and promote the local research opportunities available to their patients. Take-up of the resources provided in the pack has been growing steadily since its publication<sup>4</sup>.

1 Ipsos MORI poll of almost 1000 adults commissioned by Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2011 - <http://www.ipsos-mori.com/researchpublications/researcharchive/2811/Public-support-for-research-in-the-NHS.aspx>

2 Menon et al, BMJ 2008, *Recruitment to multicentre trials--lessons from UKCTOCS: descriptive study*, <http://www.ncbi.nlm.nih.gov/pubmed/19008269>

3 Department of Health, 2012, *National Cancer Patient Experience Survey 2011/12 - National Report*, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/126880/Cancer-Patient-Experience-Survey-National-Report-2011-12.pdf.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/126880/Cancer-Patient-Experience-Survey-National-Report-2011-12.pdf.pdf)

4 NIHR CRN, 2013, *Mystery Shopper Report*, [http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/News/Documents/Mystery%20shopper%20report\\_complete.pdf](http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/News/Documents/Mystery%20shopper%20report_complete.pdf)

## Every patient is offered opportunities to be involved in research

Many patients don't even know that these opportunities are open to them. In the 2012 UK Clinical Trials Gateway survey of 645 people from patient groups and networks, 38% of responders said they knew little or nothing about clinical trials and would like a clear and reliable source of information to learn more<sup>5</sup>.

AMRC, Arthritis Research UK, Breast Cancer Campaign and the British Heart Foundation commissioned a ComRes poll of 392 GPs, nurses and hospital doctors to better understand their experiences of research and how these can be improved.

**Of the almost 400 health professionals we surveyed, 53% told us they are asked by their patients about research opportunities less than once a year<sup>6</sup>.**

The NHS must take steps to ensure patients are encouraged to ask about opportunities to take part in research, can find out about these opportunities themselves and choose how they would like to be involved.

### Promote the NHS Constitution among patients and NHS staff

The NHS is committed to offering patients opportunities to take part in research appropriate to them – this is enshrined in the NHS Constitution:

*“The NHS commits:*

*to inform you of research studies in which you may be eligible to participate (pledge)”<sup>7</sup>*

This commitment is welcome, but not sufficient. Patients need to understand what this commitment means to them and staff need guidance on how they should meet this pledge and why.

The NHS Constitution also contains information about how each patient's records will be handled, including that the data within them will be anonymised and used for research. It is important that people can understand how their data are used and their confidentiality protected. The recent Caldicott Information Governance review recognised that “more could be done to increase awareness of the benefits of research, what it entails, and how health and social care information may be used to support it”<sup>8</sup>.

The Department of Health has proposed to introduce measures to ensure the commitments in the NHS Constitution are delivered and has also announced plans to increase awareness of the Constitution. This is very welcome and the NHS should work with other partners including charities to increase understanding of what the commitments mean in practice and what patients can expect. The NHS should develop a measurable indicator which can demonstrate to patients and staff whether or not the Constitution pledges are being adhered to.

5 NIHR, 2013, *UK Clinical Trials Survey: Public and Patient Survey 2012*, [http://www.nihr.ac.uk/files/Publications/UKCTG%20Report\\_Jan%202013.pdf](http://www.nihr.ac.uk/files/Publications/UKCTG%20Report_Jan%202013.pdf)

6 ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

7 NHS, 2013, *NHS Constitution*, <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx>

8 Department of Health, 2013, *Information: To Share Or Not To Share? The Information Governance Review*

## Every patient is offered opportunities to be involved in research

### Provide information about taking part in research and opportunities to self-refer

Patients and the public need clear information on how to take part in research and what that might involve.

There is much information available but it is spread across multiple platforms and is not always user-friendly. The UK Clinical Trials Gateway's own survey found that only 20% had heard of the Gateway before taking part in the survey and recommendations based on the survey findings include suggestions that it should be renamed to make it more patient-friendly and easier to find.<sup>9</sup>

**Whilst many resources exist for clinicians about medical research and how to take part, a fifth (21%) of almost 400 healthcare professionals we asked were either not aware of, or did not use, any of the tailored information resources available to support conversations about medical research with patients. Of those using resources to support conversations about medical research with their patients, peer-to-peer advice from other healthcare professionals and websites such as NHS Choices and patient.co.uk were the most commonly used resources. It was interesting to note that GPs and nurses were far more likely to use medical websites to support their conversations than hospital doctors who were consistently more aware of, and using, a broader range of resources<sup>10</sup>.**

#### CASE STUDY 2 – Sources of information about research

The UK Clinical Trials Gateway launched in March 2011 to provide searchable information on opportunities to take part in research. Other websites exist to give people information about their health including NHS Choices and patient.co.uk and provide links to information about research. NIHR similarly hosts information demystifying the roles of research professionals and explaining how people can take part in research in different ways. Healthtalkonline.org includes information from patients about their experiences of taking part in research.

NIHR has developed a guide to support materials that help Trusts promote clinical research in the NHS called *We do clinical research*<sup>11</sup>.

The NHS needs to talk to patients and the public about research using the media they use. If people are tweeting, the NHS needs to tweet, if people find leaflets helpful, the NHS needs to develop leaflets giving them the information they need and put these in places where they will see them. And if people aren't familiar with terms like "clinical trials", the NHS should talk about research in language that patients and the public can easily understand.

9 NIHR, 2013, *UK Clinical Trials Survey: Public and Patient Survey 2012*, [http://www.nihr.ac.uk/files/Publications/UKCTG%20Report\\_Jan%202013.pdf](http://www.nihr.ac.uk/files/Publications/UKCTG%20Report_Jan%202013.pdf)

10 ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

11 NIHR, 2013, *We do clinical research: a guide to support materials that help Trusts promote clinical research in the NHS* <http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Guidance%20and%20process%20docs/We%20do%20clinical%20research%20-%20resource%20guide.pdf>

## Every patient is offered opportunities to be involved in research

NHS staff need information about research in the places they look for it. Our poll found that GPs and nurses tend to make greater use of websites than hospital doctors<sup>12</sup>. This could be because hospital doctors are more likely to have opportunities to access other sources of information including peer-to-peer support. Sources of information about research should be tailored for specific professional audiences and the media they prefer to use.

Organisations that work with the NHS, including charities and patient groups, can play a valuable role in developing this information for staff, patients and the public and encouraging people to ask about research. The more patients ask about research, the more NHS staff will be encouraged to engage with research and commissioners to embed it in their services.

### CASE STUDY 3 – Cystic Fibrosis Unite website – cfunite.org

Cystic Fibrosis Unite aims to bridge the gap between people with CF and the researchers investigating CF and how best to treat those with the condition. CFUnite has been created by people with CF, parents of children with CF, researchers and clinicians. The main activity is in holding live events online where researchers present the latest research and the lay audience can comment and ask questions. Meeting in person is impossible for people with CF due to the risks of cross-infection. Elsewhere on the CFUnite site researchers may post a lay summary of their recently published work, you can find out about the latest research underway and can register your interest to help design and take part in clinical studies. And you can email them if you want to find out the results of relevant trials. There is also information about how clinical trials are set up and conducted.

*CF Unite is funded by a Wellcome Trust People Award and led by Dr Matthew Hurley.*

### CASE STUDY 4 – Leaflet about taking part in clinical trials developed for people affected by stroke

Working with stroke survivors, the Stroke Association and the Stroke Research Network have developed a booklet for people affected by stroke, designed to answer the most common questions about participating in clinical trials. The leaflet explains why trials are important, using real examples of past stroke research. It also describes the stages of clinical research, consent and explains how stroke survivors can take part<sup>13</sup>.

It is important that we don't just tell people about research, but also give them real opportunities to get involved by self-referring their interest.

This could be through their GP but many patients may have better relationships with other health professionals or charities. There should be opportunities for people to self-refer their interest in taking part in research without contacting their GP.

<sup>12</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013 – [www.comres.co.uk](http://www.comres.co.uk)

<sup>13</sup> The Stroke Association, 2013, *Clinical trials and stroke*, [http://www.stroke.org.uk/sites/default/files/files/Clinical\\_Trials\\_and\\_Stroke%20FINAL.pdf](http://www.stroke.org.uk/sites/default/files/files/Clinical_Trials_and_Stroke%20FINAL.pdf)

## Every patient is offered opportunities to be involved in research

### **CASE STUDY 5 – SHARE: Creating a Scottish register of people interested in research**

People who are interested in taking part in research are often not given the opportunity to do so. SHARE (Scottish Health Research Register), a partnership between the NHS, government and universities in Scotland, was set up in 2012 to improve access to and participation in research. This novel initiative established a Register of people interested in participating in health research. It takes about a minute to sign up to the Register online. By signing up to the Register, people give permission for SHARE staff to use the coded data in their various NHS computer records to check whether they might be suitable for health research studies. When their profile matches a given study, SHARE staff contact them to see if they are interested in taking part. A user-friendly website explains the Register's benefits and confidentiality safeguards, and gives case studies on who joined the Register and why<sup>14</sup>.

### Ensure all patients can take part in appropriate research wherever they live

It is important that people's personal situation – where they live or whether they can drive – should not stop them from taking part in research which is suitable for them to take part in. For example, by grouping appointments on one day so people do not have to make multiple trips, or including help with transport in study design.

### **CASE STUDY 6 – Making research travel easier for older Parkinson's sufferers**

Older people with mobility and cognitive problems face significant logistic and cost barriers to taking part in research. A recent trial funded by Parkinson's UK investigated whether a drug that improves thinking and attention in people with Parkinson's can prevent falls.

Older people with Parkinson's who have mobility issues and additional physical illnesses were the most likely to benefit from this treatment, but it would have been difficult and expensive for them to travel to and from research appointments. The research team developed thoughtful, creative solutions to make this easier. They covered transport costs for participants as well as their partner or carer, helped organise train travel and found a friendly and willing local taxi driver who was reliable and patient (which was particularly important given the balance and mobility problems that people with Parkinson's experience). They avoided scheduling appointments that would have required travel during rush hour. They received positive feedback from older people in the trial, who said they enjoyed the opportunity to 'give something back'<sup>15</sup>.

<sup>14</sup> <http://www.registerforshare.org/>

<sup>15</sup> [http://www.parkinsons.org.uk/research/current\\_research/life\\_with\\_parkinsons.aspx](http://www.parkinsons.org.uk/research/current_research/life_with_parkinsons.aspx)

## Every patient is offered opportunities to be involved in research

To prevent a postcode lottery for research, mechanisms are also needed to enable people to be able to take part in research projects underway elsewhere in England. For example, a project may be underway within one Clinical Commissioning Group's area but patients in other areas may be eligible to take part. Infrastructure such as the Clinical Practice Research Datalink will increase researcher's abilities to invite patients suitable to take part in a research study from a broader geographical area. This is particularly important for rare conditions.

The NIHR Clinical Research Network can help by ensuring a more even geographical spread of studies around the country and by working with Academic Health Science Networks to link up academics and enable patients from other areas to join research studies.

Getting this right will not only increase opportunities for patients to take part in research but also increase the ability of the NHS to recruit suitable patients to research projects which will be attractive to those looking to fund research in the NHS.

### **CASE STUDY 7 – Broadening access to research for patients in hard-to-reach areas**

The NIHR Clinical Research Network provides funds to NHS Trusts to employ research nurses and other clinical research delivery professionals, and in doing so it has improved the infrastructure for delivering clinical research in the NHS. Ninety nine per cent of NHS Trusts now undertake some research studies – which includes traditionally “hard to reach” specialist and smaller Trusts – but there are still pockets of England where research capacity could be increased, in order to bring more opportunities for engagement to the local population.

Kent was one area that local Clinical Research Networks identified as a locality that could benefit from further diabetes research development.

Working together, local Networks began to build delivery capacity in primary care through the DARE research study, engaging seven sites and more than 100 recruits in less than three months.

Delivering the DARE study in GP surgeries has had other positive impacts. The work in primary care is having a snowball-effect on the wider region, with secondary care also coming on board as a result of positive feedback from participating surgeries. In addition, the DARE study is being used as an opportunity to develop the skills of practice nursing staff, by providing on-the-job training to them in the research arena which should help them feel able to conduct future studies more comfortably<sup>16</sup>.

<sup>16</sup> NIHR CRN, *News from the network*; Issue 8, Nov 2012 p10-11, [http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Newsletters/NFTN\\_EMAG\\_issue8\\_no%20audio.pdf](http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Newsletters/NFTN_EMAG_issue8_no%20audio.pdf)

# Every patient is offered opportunities to be involved in research

## Research is patient-centred

- **Involve patients in setting priorities for research**
- **Develop a quality mark to signify where patients have been involved in the design of a study**
- **Ensure the results of research studies are made available to research participants**

## Involve patients in setting priorities for research

Patients are the experts in what it is like to live with their condition. They have valuable insights into questions that need answering to significantly improve their quality of life.

They are also more likely to value research that sets out to answer questions relevant to them. In the same way, when research sets out to answer questions impacting on everyday care, it is easier for NHS staff to understand why the research is being conducted and use the findings to inform their everyday clinical practice.

### **CASE STUDY 8 – Arthritis Research UK USER committee**

Arthritis Research UK's USER committee is made up of healthcare professionals who are not research-active, and informed lay members. It looks at the practicality of doing research and questions the assumptions of researchers, as part of deciding which research should be funded. Patients have an expert knowledge of their condition. In one case, a patient reviewer was the only person to spot that a researcher had assumed that people would only have one artificial joint – many people with arthritis have more than one replacement joint, and so the suggested blood tests would provide unclear results.

The National Evaluation, Trials and Studies Coordinating Centre (NETSCC) will play a very valuable role in involving patients in setting priorities for research. Commissioners (NHS England and Clinical Commissioning Groups) should work with NETSCC to contribute questions they would like answered to inform their commissioning decisions. They should also consider NETSCC priorities when commissioning research. The role of NETSCC should be promoted to patients, public and NHS staff to encourage greater engagement<sup>17</sup>.

## Develop a quality mark to signify where patients have been involved in the design of a study

Patients need to be involved in deciding the questions to be asked, and also in shaping how research studies are designed to answer them.

<sup>17</sup> *Natural Ground – paths to patient and public involvement for medical research charities*, AMRC, 2009 [http://www.amrc.org.uk/our-members\\_natural-ground:-patient-and-public-involvement-project\\_ppi:-natural-ground](http://www.amrc.org.uk/our-members_natural-ground:-patient-and-public-involvement-project_ppi:-natural-ground)

## Every patient is offered opportunities to be involved in research

Patient insights into the design and implementation of a research study can help identify potential barriers to them getting involved, making taking part in the project a better experience for patients, so improving recruitment rates and reducing dropouts. They can also bring fresh perspectives and insights when evaluating findings and can often be drivers for change when findings suggest improvements in clinical practice.

### CASE STUDY 9 – Patient involvement improving recruitment

Regional patient and carer focus groups identified solutions for a major study (DOMINO-AD) which was failing to recruit sufficient patients.

The study, funded by the Medical Research Council and the Alzheimer's Society, looked at medication effectiveness in moderate to severe stages of Alzheimer's disease. Two local research networks (in South West England & East Anglia) ran patient and carer focus groups which raised ideas for improving recruitment and retention. Both networks showed a consequent marked increase in their recruitment rates, which were significantly faster than elsewhere.

The impact of the involvement of people was particularly illustrated in East Anglia, where a major recommendation from their patient and carer focus group was to promote the study more effectively in primary care.

This recommendation made the network confident that embarking on a lengthy process of developing recruitment with the primary care research network would bear fruit. The local network therefore rolled the study out to local general practices, and experienced a sustained increase in recruitment to the study.

INVOLVE provides information on how to involve members of the public throughout a research project<sup>18</sup>, from identifying and prioritising topics, commissioning, designing and managing, undertaking, disseminating, implementing and evaluating impact<sup>19</sup>.

NIHR is leading the way in this by requiring that every NIHR research project must include patient involvement as part of the approval process. A quality mark should be developed to highlight studies where patients have contributed to the design to ensure patient feasibility. This will provide reassurance and encouragement to patients as they decide whether to participate in the research.

### Ensure the results of research studies are made available to research participants

Patients take part in research studies in the hope that findings will help them, and to improve care for others in the future. They are interested in the outcomes of the study, and to know how their altruistic act may help others in future. Researchers need to consider from an early stage what information will be fed back to patients taking part.

<sup>18</sup> <http://www.invo.org.uk/resource-centre/resource-for-researchers/>

<sup>19</sup> NIHR CRN, D Stewart, 2011, *Making the Difference by actively involving people*, <http://www.crnc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/PPI/Documents/Making%20the%20difference%20May%202011.pdf>

## Every patient is offered opportunities to be involved in research

They also need to consider the way in which this information is shared. The overall findings of research studies should be shared with patients who have taken part in a way that they can understand, and could valuably be made available to everyone. Many charities already do this, developing lay summaries of findings.

### **CASE STUDY 10 – CancerHelp UK**

Cancer Research UK runs the CancerHelp UK clinical trials database which aims to list all cancer studies recruiting in the UK – not just those supported by Cancer Research UK. CancerHelp UK works with trial teams to produce summaries of studies to provide useful, easily understandable information for the public. This helps patients with cancer identify which studies they could potentially participate in as well as giving information on both positive and negative studies that have been completed. The database has more than 1,500 studies listed including approximately 500 studies recruiting people in the UK, and more than 400 summaries of study results<sup>20</sup>.

CancerHelp provides a model on how to make information about clinical research accessible to patients and NHS staff which could valuably be extended to other conditions. Such information should be made publicly available through websites that patients regularly use and NHS staff should be made aware of their presence in order to better inform patients about taking part in research relevant to their condition.

<sup>20</sup> <http://www.cancerresearchuk.org/cancer-help/>

## Every patient is offered opportunities to be involved in research

### Research is embedded in good care

- Require clinical teams to consider every patient's suitability to take part in research as part of their care
- Ensure research activity is specified and reviewed in contracts with all hospitals, primary care and service providers
- Require GPs to share their practice data with the Clinical Practice Research Datalink and respond to requests to invite their patients to take part in research studies

### Require clinicians to consider every patient's suitability to take part in research as part of their care

To offer each and every patient the opportunity to be involved in research they are eligible to take part in, the clinical team caring for them in primary or secondary care settings needs to be aware of research underway and consider whether their patient is suitable to take part when they are planning their care.

The booklet *Action on Access*<sup>21</sup> developed by the National Cancer Research Institute Consumer Liaison Group, suggests some practical steps that can be taken by clinicians to do this and embed research within good care, rather than seeing it as an 'add-on' activity or administrative burden.

These include providing clinical staff with up-to-date information about clinical studies available and encouraging one clinician in a team to take the lead in developing 'trial awareness' which they can share with others. In secondary care settings, they propose that considering whether a patient is suitable to take part in any current research should be one of the core responsibilities of the multi-disciplinary team meeting held to assess a patient's care.

#### CASE STUDY 11 – Making research discussions routine in older mental health care

Healthcare professionals often fail to discuss research opportunities or records patients' willingness to participate in research during routine healthcare appointments. The Memory and Research Centre (MARC) in Southern Health NHS Foundation Trust worked with the South Coast DEnDRON (the Dementias & Neurodegenerative Diseases Research Network) to change professional culture and improve recruitment of older people with cognitive problems into research. They engaged the Trust executive Board and held a MARC awareness day for all clinicians. They introduced a simple system for recording patient willingness to participate in research (by adding a simple tick-box to a consent form which was in routine clinical use).

This approach increased patient referrals to MARC by 23% and led the Trust to set research as a key priority<sup>22</sup>.

21 NCRI Consumer Liaison Group, 2012, *Action on Access: Widening patient participation in clinical trials*, [http://www.ncri.org.uk/includes/Publications/reports/action\\_on\\_access\\_report\\_final.pdf](http://www.ncri.org.uk/includes/Publications/reports/action_on_access_report_final.pdf)

22 <http://www.patientsinresearch.org/wp-content/uploads/SC1-for-website.pdf>

## Every patient is offered opportunities to be involved in research

Ensure research activity is specified and reviewed in contracts with all hospitals, primary care and service providers

To provide opportunities to conduct research and improve care for people whatever condition they have, and wherever they are treated, all care providers must be able to host research.

### CASE STUDY 12 – Enabling research in care homes

The Enabling Research in Care Homes (ENRICH) programme, led by DeNDRoN (the dementia and neurodegenerative diseases research network) has developed a network of “research ready” care homes, where staff and residents are willing and able to take part in research, giving residents access to research studies in dementia.

As part of the ENRICH programme, DeNDRoN has developed a toolkit which provides practical support and information about research within a care home setting for researchers, care home staff, residents and relatives. The toolkit explains the complexities of conducting research in a care home setting and provides useful advice, including case studies to demonstrate the practicalities of conducting research, signposts to governance and policy information, and tips on how to engage residents and their relatives.

The toolkit is widely supported and has been welcomed by Martin Green, Chief Executive of English Community Care Association, the largest representative body for community care in England<sup>23</sup>.

NHS England and the Clinical Commissioning Groups have a duty to promote research and the use of research evidence<sup>24</sup>. The mandate from the Department of Health to NHS England includes the requirement “to ensure that the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research funded by both commercial and non-commercial organisations”<sup>25</sup>.

To deliver this, when commissioning services, NHS England and the Clinical Commissioning Groups must include research in their invitations to tender, and assess potential service providers on their ability to host research and, where relevant, use research evidence to improve the care they provide.

When commissioning service providers, they should include research responsibilities in their contract with them and assess them on this when evaluating the contract, considering opportunities for improvement. To ensure harmonisation across the NHS, research responsibilities should be included in standard contracts.

<sup>23</sup> NIHR CRN, November 2012 *News from the network* p16-17 [http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Newsletters/NFTN\\_EMAG\\_issue8\\_no%20audio.pdf](http://www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/Documents/Newsletters/NFTN_EMAG_issue8_no%20audio.pdf)

<sup>24</sup> Health & Social Care Act 2012 <http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>

<sup>25</sup> Department of Health, 2012, *The Mandate: a mandate from the government to the NHS Commissioning Board: April 2013 to March 2015*, <https://www.gov.uk/government/publications/the-nhs-mandate>

## Every patient is offered opportunities to be involved in research

### CASE STUDY 13 – DeNDRoN model contract wording

The Dementia and Neurodegenerative Diseases Research Network (DeNDRoN) piloted work in the south west of England to collaborate with the Clinical Commissioning Groups to ensure that appropriate wording was added to their invitations to tender and contracts documentation. This wording was designed to ensure that giving patients access to research is considered equally with other aspects of patient care. There was also an emphasis on ensuring that it was prominently mentioned to ensure that the requirements as set out in the NHS Mandate to 'ensure the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research' is fulfilled.

### Require GPs to share their practice data with the Clinical Practice Research Datalink and respond to requests to invite their patients to take part in research studies

Every time you visit an NHS hospital or your GP, information is recorded and stored in a patient record. These are a valuable resource for health research. Access to the data in these records helps researchers better understand trends in conditions and the outcome of treatments, for example identifying the link between smoking and lung cancer. And access to these data also allows researchers to identify patients to invite to take part in trials of new drugs.

These patient records contain personal information and must be handled very carefully and accessed safely with regard for people's confidentiality.

### CASE STUDY 14 – Using anonymised patient data to investigate the safety of MMR vaccines

Routinely collected NHS data allows researchers to investigate the benefit and safety of treatments and public health interventions in a large nationally representative sample. This is particularly valuable when investigating rare adverse outcomes. Public concern that MMR vaccination might lead to autism led to a dramatic decline in vaccination coverage. Vaccination fell below the level required for herd immunity and led to the re-emergence of endemic measles in England and Wales in 2008.

Using anonymised patient data from the General Practice Research Database (now Clinical Practice Research Datalink), researchers at the London School of Hygiene and Tropical Medicine compared the vaccination history of nearly 1300 people with a diagnosis of autism or other pervasive developmental disorder (PDD) with around 4500 age/sex matched controls. The study found no association between MMR vaccination and a diagnosis of autism/PDD.

Researchers using national databases in Europe and North America came to similar conclusions, generating a robust body of evidence on the safety of the MMR vaccine<sup>26</sup>.

<sup>26</sup> Smeeth et al., Lancet, 2004, *MMR vaccination and pervasive developmental disorders: a case-control study*, <http://www.ncbi.nlm.nih.gov/pubmed/15364187>

## Every patient is offered opportunities to be involved in research

To enable researchers to access patient data while effectively safeguarding people's confidentiality, the Clinical Practice Research Datalink (CPRD) was announced in 2011 in the *Strategy for UK Life Sciences*<sup>27</sup>. This provides efficient access to NHS patient records for academic, public and private researchers with effective safeguards for confidentiality. Building on the 15 years experience gained with the General Practice Research Database (GPRD), CPRD links anonymised NHS patient data from GP practices and hospitals, enabling researchers to study information about a patient's whole journey of care through the NHS without accessing any identifiable data. This allows them to conduct many types of observational research to improve and safeguard public health. CPRD can also help researchers check whether there are enough patients to make a study feasible and identify patients to invite to take part in research projects they wish to undertake.

CPRD allows patients to decline from having their data used. GP practices can mark a patient's data as not to be submitted, even in an anonymised form, for research projects.

CPRD offers huge potential for health research, but this depends on securing large population coverage and the quality of the data collected. GPs should be required to share their data with CPRD while respecting the individual wishes of their patients. They should be offered training and resources such as the UK Clinical Research Collaboration leaflet *Health records save lives*<sup>28</sup> to help them discuss this with their patients, and invite them to take part in research relevant to them.

High quality data should be recorded about a patient throughout their treatment. All NHS staff should be given education and training to develop the skills to record, handle, use and share data effectively.

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<sup>27</sup> BIS, Office for Life Sciences, 2011, *Strategy for UK Life Sciences*, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf)

<sup>28</sup> [http://www.nihr.ac.uk/files/Publications/NIHR%20Patient%20Health%20Records%20leaflet\\_Nov11.pdf](http://www.nihr.ac.uk/files/Publications/NIHR%20Patient%20Health%20Records%20leaflet_Nov11.pdf)

## All NHS staff see the importance of research

### NHS staff know how to take part in research and use its findings

- Include research knowledge and use of evidence in basic training for all NHS staff
- Make research experience a desired skill for NHS jobs
- Require all Local Education and Training Board to include skilled research professionals

### Include research knowledge and use of evidence in basic training for all NHS staff

To embed research throughout the NHS, all staff need to feel confident that they understand how and why research is conducted and can use the findings to improve the care they give their patients or to inform the decisions they make to help other staff to do so.

Even if they do not plan to directly conduct research themselves, NHS staff need to understand that research is a core role of the NHS and be able to interpret research findings and their implications for their clinical practice and management decisions. This will improve the quality of care for patients in two ways: they will benefit from healthcare informed by the latest evidence; and staff caring for them will be more likely to consider opportunities for them to take part in research.

**When we asked almost 400 health professionals whether they have experienced barriers to being involved in medical research over the last two years, one in five of the GPs and nurses responding felt that they lack the necessary skills or experience to take part in medical research and a third (34% and 32% respectively) told us they were not very confident in talking about research with their patients<sup>29</sup>.**

It is welcome that the *Education Outcomes Framework*<sup>30</sup>, which sets outcomes which Health Education England (HEE) and Local Education and Training Boards (LETBs) will deliver, includes a goal to develop a 'Flexible Workforce Receptive to Research and Innovation'. To deliver this objective, the NHS will not only need world class research leaders, but a workforce with the right experience and opportunities.

HEE should ensure that all NHS staff are given the tools to understand research and to assess and use evidence to inform their decisions when caring for patients or supporting clinical staff. This training should prepare them to make use of research throughout their careers and should include information on how to keep up-to-date about research underway, develop skills in the critical appraisal and evaluation of evidence and increase their familiarity with NHS research infrastructure and bodies which can provide further support and information.

<sup>29</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk),

<sup>30</sup> Department of Health, 2013, *Education Outcomes Framework*, <https://www.gov.uk/government/publications/education-outcomes-framework-for-healthcare-workforce>

## All NHS staff see the importance of research

The Medical Royal Colleges could play a role in promoting this research confidence among NHS staff; there should be greater consistency in the research competencies included in curricula across the specialties. The Royal Colleges should share best practice to deliver this. The current *Shape of Training* review<sup>31</sup> will make recommendations to restructure medical training in the NHS and should ensure that all trainees have the opportunity to gain these research skills.

To ensure this training is effective and prevent any risk of this becoming a tick-box exercise, these skills should be properly assessed as part of every trainees' annual review. Royal Colleges, LETBs and postgraduate deaneries should all play a role in promoting good practice here. The *Education Outcomes Framework*<sup>32</sup> proposes two outcomes to assess this:

*“Organisations improve services and modify their delivery to meet new demands. Staff respond to the opportunities to develop their understanding, knowledge, skills and their contribution.”*

*“Organisations display a culture, which values research and innovation, and provide the practical support and the leadership to sustain this.”*

NHS staff should also have access to further training and development opportunities should they want to get more involved in research during their career.

### CASE STUDY 15 – Building a skilled community

Having a skilled workforce, able to deliver clinical studies safely and effectively, is an essential part of the infrastructure that allows research to happen in the NHS environment.

The NIHR Clinical Research Network has contributed to this by training more than 10,000 people in Good Clinical Practice in 2011/12.

The training allows the research delivery workforce to explore best practice, and contextualise the work of delivery clinical studies in terms of their own individual roles and the local conditions. More than that, the training sessions are praised by participants as providing a valuable forum where clinical professionals can meet with others engaged in research, discuss issues and share thoughts on an informal level.

<sup>31</sup> <http://www.shapeoftraining.co.uk/>

<sup>32</sup> Department of Health, 2013, *Education Outcomes Framework*, <https://www.gov.uk/government/publications/education-outcomes-framework-for-healthcare-workforce>

## All NHS staff see the importance of research

### Make research experience a desired skill for NHS jobs

For NHS staff to want to engage with research, these skills need to be respected and encouraged and seen as valuable to career progression.

**Our poll of almost 400 health professionals found that almost 1 in 5 (18%) of those asked felt that lacking seniors or mentors involved in research was a barrier to them getting involved in medical research in the last two years.**

**Almost 1 in 10 (9%) felt that research is not encouraged in their local health area and a similar number (10%) did not see any benefit for their career in taking part<sup>33</sup>.**

Including research experience as a desired competency for clinical NHS jobs is a clear demonstration of the value of these skills for NHS professionals and will encourage staff to take opportunities to take part in research. It is also important for NHS managers to see the importance of research.

Increasing the knowledge and experience of research among NHS staff at all levels, including among NHS managers, will foster an environment which encourages NHS staff to take part in research projects and use research evidence to inform and change their clinical practice, and drive change among their colleagues.

### Require all Local Education and Training Boards to include skilled research professionals

Local Education and Training Boards (LETBs) are responsible for the training and education of NHS staff, both clinical and non-clinical, within their area. They are led by representatives from local providers of NHS services with membership from other groups. There are 13 LETBs across England, all of which are committees of Health Education England (HEE).

Together HEE and LETBs are responsible for delivering the Education Outcomes Framework, which includes developing a “flexible workforce receptive to research and innovation”. This is defined as: “The workforce is educated to be responsive to changing service models and responsive to innovation and new technologies with knowledge about best practice, research and innovation, that promotes adoption and dissemination of better quality service delivery to reduce variability and poor practice.”

The draft Care and Support Bill scrutinised in 2012/2013 included proposals to establish HEE as a non-departmental public body. The Parliamentarians who scrutinised the Bill recommended that a strong duty be placed on HEE to promote research, which would also filter down to LETBs. This has been included in the Care Bill published on 10 May 2013. This is a welcome move and mirrors the duties on the Secretary of State, NHS England and Clinical Commissioning Groups, “to promote research and the use of research evidence”.

LETBs will play a key role in equipping NHS staff with research skills, so it is concerning that research did not feature strongly in LETB applications for authorisation. HEE’s research strategy will be crucial to ensure education and training in research is delivered effectively across England, and they must support LETBs to do so.

<sup>33</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

## All NHS staff see the importance of research

HEE's retention of an advisory group on academic training for medical professionals is welcome, particularly as its remit will include academic trainees and broader research training across the workforce. This group must meet regularly and be given a high priority by HEE and the Department of Health.

For LETBs to successfully promote research and equip NHS staff with research skills, they need to include skilled research professionals who can share their experience and insights into how to foster these skills locally, and build links to local providers and academic institutions. Postgraduate deans within the LETBs are responsible for medical trainees; they should be full members of the LETB board and supported to deliver flexible local systems working with local Higher Education Institutes.

When developing these systems, they should consider how education and training should be tailored to equip all NHS staff with the research skills they need.

As the proposed Academic Health Science Networks are established, these could play a valuable role alongside LETBs, helping connect up those involved in research across a region, share resources and provide opportunities for researchers to meet others involved in research and develop networks of peer-to-peer support.

LETBs should report to HEE on their promotion of research and engagement with local networks, allowing HEE to identify and share best practice to ensure this is replicated elsewhere.

## All NHS staff see the importance of research

### NHS staff understand the benefits of research to their patients

- Publicise locally and nationally the role of research in improving the quality of care
- Explain how research evidence informs clinical practice
- Include measures of the scope, quality, quantity and adoption of research in the Clinical Commissioning Group Outcomes Indicator Set

### Publicise locally and nationally the role of research in improving the quality of care

NHS staff, including NHS managers, should understand how giving opportunities to patients to take part in research improves the care they receive, and helps us improve care for others.

**When we asked 130 GPs what if any would be their motives for taking part in medical research, 10% told us that they do not see any benefit of conducting medical research<sup>34</sup>.**

Internal staff communications, local and national communications can all play a role in explaining the importance of research to patient care now and in the future. From newsletters and posters in GPs surgeries and hospitals, to local news stories, and nationally on NHS Choices and the UK Clinical Trials Gateway, these can all explain how research projects have resulted in new treatments and improved healthcare for patients.

Examples and case studies demonstrating the value of research from the perspective of the staff and patients involved in projects, or those benefitting from research findings, are very powerful. Allowing people to relate to them and see themselves in these roles.

#### CASE STUDY 16 – Setting goals and making noise when you achieve them

Raising awareness of research successes can help to change the research culture among staff and patients.

Highly commended for the Health Service Journal Progressive Research Culture Award 2012, sponsored by the NIHR Clinical Research Network, Pennine Acute Hospitals NHS Trust highlighted the impact that research had on patient care through the local hospital newsletter “Pennine News” and when appropriate through local media.

The Trust also supported the wider publicity campaign to promote their achievement nationally, helping to raise the profile of research generally amongst patients, the public and fellow clinicians. Supporting initiatives such as these is contributing to a growing sense of transparency about research delivery performance, and encouraging Trusts to see research as an important part of maintaining a positive relationship with the public and a strong reputation for service.

<sup>34</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

## All NHS staff see the importance of research

Organisations outside the NHS, including charities, have a role to play talking to the public about research they have funded and how it improves care – NHS staff are members of the public and charity supporters too.

### Explain how research evidence informs clinical practice

Not only does the NHS need to talk about how research is improving practice, it should also ensure that its communication, training and resources help health professionals to understand this link and value research because of this.

**When we asked almost 400 health professionals what their motives would be for taking part in medical research, nurses (74%) and hospital doctors (65%) were much more likely than GPs (35%) to see the link between research and providing patients with more treatment options<sup>35</sup>.**

When NHS staff are involved in a research project, from commenting on patient information, recruiting patients or caring for patients involved in the trial, the findings of the research should be shared with them, especially highlighting any implications of the study findings for practical patient care. Researchers should consider at an early stage how they will feedback their findings to patients and staff involved.

It is increasingly important that primary care providers recognise the key role of research in improving the care they can give to their patients, especially as GPs take a greater role in commissioning services and more care preferentially takes place in a primary setting. Professional bodies, charities and the NHS should actively promote these benefits to primary care clinical teams and GP commissioners.

### Include measures of the scope, quality, quantity and adoption of research in the Clinical Commissioning Group Outcomes Indicator Set

The NHS should set metrics to measure how well it is delivering research. These will clearly demonstrate to NHS staff how research is benefitting their patients and will also be valuable to demonstrate to external investors that the NHS is 'open for business'.

It is important that these measures monitor not just the volume of research underway, but also attempt to assess the quality of that research. Measures should assess the extent and speed of adoption of findings from research in hospitals and clinics, and demonstrate how NHS staff are balancing their obligations to research alongside challenging service improvement targets. They should also look not just at the number of patients recruited to research but how many were offered opportunities to be involved.

<sup>35</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

## All NHS staff see the importance of research

The Clinical Commissioning Group Outcomes Indicator Set aims to create a set of measures to hold Clinical Commissioning Groups to account for the quality of services and the health outcomes achieved through commissioning. This will provide clear, comparative information about the quality of health services and associated health outcomes.

The Indicator set aims to assess five domains:

- Preventing people from dying prematurely
- Enhancing quality of life for people with long-term conditions
- Helping people to recover from ill health or following injury
- Ensuring that people have a positive experience of care
- Treating and caring for people in a safe environment and protecting them from avoidable harm.

Research is integral to the delivery of each of these five domains and yet this is not currently well reflected within them.

NHS England should use key performance indicators in research as part of their annual review process to both assess and publicise to NHS staff and the public how well each Clinical Commissioning Group is supporting research and delivering benefits for patients. This will also help identify and share good practice.

## All NHS staff see the importance of research

### NHS staff are motivated to engage with research

- Ringfence time for research in NHS contracts
- Develop local and national guidance for those wanting to become active in research
- Use local and national awards to recognise and reward NHS staff at all levels that take part in research

### Ringfence time for research in NHS contracts

Research is a core role of the NHS and part of good patient care. However lack of time to become involved in research can render research a marginal activity.

**Two thirds (62%) of almost 400 health professionals told us that not having sufficient time to be involved had acted as a barrier to them taking part in medical research in the last two years<sup>36</sup>.**

NHS staff should feel confident to become involved in research, using its findings and encouraged to take part. Providing ringfenced time in NHS contracts and job plans for staff to conduct research would reflect that research is a core role of the NHS. Annual reviews of job plans should ensure that research responsibilities are clearly set out.

This would provide clear leadership and encouragement for staff to get involved in research themselves.

**Of the 130 GPs we polled, the majority (79%) believed it was very important for the NHS to support research but only 22% felt it was important for them to be personally involved. Lack of time was a key issue for these GPs, with nearly three quarters (73%) naming it as the biggest barrier preventing them from getting involved in research<sup>37</sup>.**

Ringfenced time would give staff the space to undertake the education and training they need to confidently handle research findings and take part in research themselves, encouraging many to take up opportunities that may be open to them. This dedicated time will also have a positive feedback effect across the NHS; increasing research capacity and familiarity with research and so speeding adoption of new treatments..

### Develop local and national guidance for those wanting to become active in research

NHS staff who want to get involved in research need information and guidance to help them take part.

**When we asked almost 400 health professionals whether they experienced any barriers to taking part in research, over a quarter (27%) told us that they did not have access to the practical support they need to take part<sup>38</sup>.**

36-8 ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

## All NHS staff see the importance of research

This should be available locally to help them find out about and access opportunities for local education and training, to join them up with existing networks of peers involved in research and provide information on local opportunities to get involved in research.

This should also be available nationally, giving information about NHS research infrastructure, national schemes that NHS staff can get involved in, resources available and opportunities such as mentoring schemes that they could take part in.

There are a broad range of resources available already but these need to be publicised to NHS staff, making them easy for them to find and use in their general day to day practice.

### CASE STUDY 17 – Encouraging professional debate on research

Recognising that clinical research deserves a national platform, the NIHR Clinical Research Network collaborates with *The Guardian* on the 'clinical research zone' – a specialist area within *The Guardian's* online Healthcare Professionals Network which is dedicated to clinical research delivery. The Zone promotes awareness of research, supports the dissemination of best practice, and provides a national space where professionals can discuss and explore the benefits of research – often with patients involved in that discussion.

One of the key features of the Zone is the Trust League Table which shows the national picture of Network-supported research activity across all NHS Trusts in England. Taken from the NIHR Clinical Research Network Portfolio, this data reveals which Trusts are leading the way in providing opportunities for patients to take part in clinical research. The league tables raise the level of debate amongst NHS leaders and clinicians by making Trust performance on research delivery transparent both to healthcare delivery professionals, and patients/the public.

A further feature of the Zone is the online Q&A sessions, which enable professionals and members of the public to question prominent figures from the research delivery environment on topics of interest. Senior figures from AMRC, the Department of Health, the NHS and the NIHR have been involved in these Q&As, which are then summarised as articles on the clinical research zone to support future learning.

These platforms offer opportunities to promote research career paths and encourage both official and unofficial mentoring.

### CASE STUDY 18 – The Academy of Medical Sciences runs a portfolio of schemes designed to support clinicians to undertake research

Postdoctoral clinical academic trainees can take advantage of the Academy's mentoring scheme, which pairs trainees with Academy Fellows for one-on-one support. The scheme is designed to provide role models and encouragement for clinical academic trainees at a point in their career when they are making big decisions that affect their career and their families. The mentoring scheme and a series of regional career development events are supported by NIHR and other funders.

## All NHS staff see the importance of research

In 2012, the Academy launched INSPIRE, a five year, UK-wide initiative aimed at engaging medical and dental students with research. The 32 UK medical schools that were recently awarded an INSPIRE grant will spend the next two years delivering local, innovative activities that seek to foster a 'research aware' generation of clinicians entering the NHS. The scheme is supported by the Wellcome Trust.

### Use local and national awards to recognise and reward NHS staff at all levels that take part in research

Experience of taking part in research should be prized. Using financial and non-financial awards to recognise research excellence at both a local and national level can effectively encourage people to value and engage with research.

Local awards recognising and promoting achievement can be set up to incentivise and reward research.

#### **CASE STUDY 19 – Using awards and recognition to motivate and engage staff**

Portsmouth Hospitals NHS Trust had always undertaken some clinical research studies, however until 2009 research was considered a low priority by both clinicians and the Trust leadership. A five-year research strategy was drawn up to give more strategic direction to the research department, and to improve systems.

To embed a research culture across the Trust, Portsmouth deliberately sought to increase opportunities for patients to participate in high-quality research studies, create an expert research workforce, establish efficient research management and governance systems and provide forward-looking clinical treatments to patients through research.

A main feature of the Portsmouth approach was a scheme to acknowledge research activity across the workforce. This involved publicly recognising teams and individuals through internal staff awards such as Top Researcher and Top Recruiting Research Team for Interventional Studies. These internal awards have been a great success at building morale.

Portsmouth did not stop at internal recognition for its achievements. It also entered the Health Service Journal Research Culture Award 2011, sponsored by the NIHR Clinical Research Network, receiving a "highly commended" citation from the judging panel. This put Portsmouth's achievements on the national stage, and they have since taken part in a number of initiatives to share what they have learned with other Trusts.

These should reward not just individuals involved in research but recognise that no one person delivers research and reward whole teams.

On a larger national scale, Clinical Commissioning Groups who are leading and delivering on research should be recognised.

## The NHS conducts high-quality research and adopts new treatments

### All NHS bodies share knowledge to develop and answer research questions and adopt findings

- **Publish research results and make data accessible to those who need them**
- **Encourage NHS commissioners to implement our research charter to ensure their actions are informed by the evidence**
- **Allow Academic Health Science Networks to work independently while encouraging them to share best practice across England**

Research and innovation is nothing without evaluation and adoption. The NHS needs to develop a research ecosystem that encourages all NHS bodies to share knowledge and become involved in the development of research questions, the conduct of research, and the evaluation and adoption of its findings.

### Publish research results and make data accessible to those who need them

Patients choose to take part in research because they hope that the treatment will benefit them, and because they want to improve treatment for others in the future. To ensure this can happen, we believe trials must be registered and the findings of research made available for others to learn from them.

The detailed data from clinical trials are also valuable for conducting further analyses. Some funders ask that researchers provide data management and sharing plans as part of their research proposals and many funders are considering how to improve access to these data. Processes should be put in place to allow approved researchers access to the underlying data with appropriate safeguards to protect patient confidentiality.

Clinical trials are conducted across the world, so action to increase transparency and improve healthcare needs to be taken on a global scale. At a national level, the NHS can take steps to ensure that trials conducted with the NHS are registered and the results of these are published. They can also work with other funders to address the practical challenges involved in making the underlying data accessible to conduct further analyses while protecting patient confidentiality.

The Health Research Authority, with its remit to protect and promote the interests of patients and the public in health research, should also play an important role in promoting transparency and ensuring research is registered, results published and data made accessible to those who need them. Patients and the public should be confident that the findings of research that they have participated in will be used and disseminated to benefit others.

### Encourage NHS commissioners to implement our research charter to ensure their actions are informed by the evidence

Within the new NHS structures, NHS England and Clinical Commissioning Groups are responsible for commissioning patient services. When doing this they need to be informed by the latest research findings. Promoting this research agenda will be challenging while also adapting to new and unfamiliar roles. Our research charter proposes steps commissioners can take to do this.

# The NHS conducts high-quality research and adopts new treatments

## Our Research Charter for NHS England and Clinical Commissioning Groups

NHS England and Clinical Commissioning Groups have a duty to promote research and the use of research evidence

To achieve this duty they should:

- Appoint an individual at board level with responsibility for research
- Include participation in NHS research in provider contracts
- Develop a balanced scorecard of measures to assess research and the use of research evidence in delivering care and report on these quarterly at board meetings
- Take part in research prioritisation exercises – with NIHR NETSCC, local HEIs and other relevant bodies
- Consider relevant research findings and evaluations when commissioning services
  - Develop structures to routinely access relevant evidence and inform the redesign of services and commissioning policy
  - Routinely evaluate services and consider how quality can be improved
  - Engage with NICE, Public Health Observatories, CLAHRCs, The Cochrane Library, NIHR NETSCC, local HEIs and other relevant bodies
- Promote best practice in the handling, use and sharing of data by providers when commissioning services
- Develop a process and earmark a recurring budget to ensure excess treatment costs are managed without causing delays to research.

Making research a board level responsibility which must be reported on will ensure it is firmly on commissioner's agendas.

To deliver on their duties, CCGs' commissioning decisions need to be informed by the evidence. There are multiple bodies available to help them identify and assess relevant evidence. These include NICE, the public health observatories and NIHR NETSCC. At a more local level, engagement with Academic Health Science Centres and Networks, CLAHRCs and local higher education institutions should inform their work.

## CASE STUDY 20 – CLAHRC activity informing national practice

The Leeds, York and Bradford Collaboration for Leadership in Applied Health Research and Care (CLAHRC), working with the Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) was the first UK centre to provide universal testing for gestational diabetes. The CLAHRC team and obstetricians reviewed the risk factors for gestational diabetes and piloted universal screening for pregnant women. The evaluation showed a significant increase in detection rates from 2-7% cent in pregnant women which will allow clinicians to target treatments to effectively reduce adverse pregnancy outcomes. The NICE guideline committee for diabetes in pregnancy has since provided a route for incorporating the results into national practice<sup>39</sup>.

Their local Clinical Senates and strategic clinical networks will be able to provide local insights and nurture an objective culture. Many of them may also be able to help them evaluate the effectiveness of services and identify how quality can be improved.

<sup>39</sup> NIHR, 2013, *Annual report 2011/12*, <http://www.nihr.ac.uk/files/Publications/NIHR%20Annual%20Report%202011-12%20final.pdf>

## The NHS conducts high-quality research and adopts new treatments

Our polling of healthcare professionals suggests relatively low awareness of these research organisations:

**Our survey of almost 400 health professionals including 130 GPs found that around half knew something about the National Institute for Health Research and the NIHR Clinical Research Network (53% and 51%). Awareness fell to around a quarter for Academic Health Science Centres, Biomedical Research Centres and Biomedical Research Units (23%, 28% and 28% respectively).<sup>40</sup>**

We know that GPs are time-stretched and they tell us lack of time is a major barrier to them taking part in research<sup>41</sup>. As GPs take up a commissioning role, they need help to access the resources available, NHS England will need to do more to explain to commissioners how they can work with the multiple bodies available to help them identify and assess relevant evidence and encourage staff to work with them to promote research.

Clinical Commissioning Groups should also take practical steps to address barriers to research, such as earmarking a recurring budget to manage payment of excess treatment costs and promoting best practice in the handling, use and sharing of data by providers when commissioning services.

Commissioners familiar with research evidence can valuably contribute to the identification of research priorities. Research addressing their unanswered questions will both help them make better decisions in future and appreciate the value of research in helping them to achieve their goal to improve healthcare for patients.

### Allow Academic Health Science Networks to work independently while encouraging them to share best practice across England

It is envisaged that there will be about 15 Academic Health Science Networks across England.

These are intended to:

*“Present a unique opportunity to align education, clinical research, informatics, innovation, training & education and healthcare delivery. Their goal will be to improve patient and population health outcomes by translating research into practice and developing and implementing integrated health care services. Working with AHSCs, they will identify high impact innovations and spread their use at pace and scale throughout their networks.”<sup>42</sup>*

To deliver this, they need to be free to innovate and develop local expertise. However they should be encouraged to share their successes, spreading best practice nationally to address variance in research capability and the adoption of proven innovations across England.

Such national interaction could also allow them to share effective tools employed by local Commissioners and develop a national repository of information and evidence about commissioning decisions.

<sup>40</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013 – [www.comres.co.uk](http://www.comres.co.uk)

<sup>41</sup> *ibid*

<sup>42</sup> NHS, 2011, *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*

# The NHS conducts high-quality research and adopts new treatments

## The NHS develops research leaders

- **Ensure that future NHS leaders can take up research opportunities**
- **Promote clear career paths for NHS staff engaging in research**
- **Encourage research active NHS staff to work with colleagues across specialties**

### Ensure that future NHS leaders can take up research opportunities

NHS staff that are motivated to take part in research or would like to follow a research career should be encouraged and supported to take opportunities to do so. Barriers that prevent them getting involved should be addressed.

NHS staff should be able to balance their clinical duties with research activities including relevant education and training. The NHS should nurture future research leaders. Those training for research careers should have the flexibility to move in and out of research, or balance their duties as required. This should not count against them but be viewed as positive for their professional development. Those who enter research careers at a later stage which is standard practice in some specialties, must also be given this flexibility. It is also important to recognise that some NHS staff may not want to follow a full research career but want the freedom to choose to take part in research at points in their career. Career structures should not hinder their professional progression should they wish to do so.

#### **CASE STUDY 21 – Ensuring NHS staff can take up research opportunities**

Dr Chris Lamb is a gastroenterology registrar working in the Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University.

He received funding through a prestigious Wellcome Trust Translational Medicine and Therapeutics grant to undertake a four-year MRes/PhD fellowship. This is a new funding stream, specifically designed to train future clinical academic leaders to translate maximal patient benefit from research by working at the interface of the NHS, universities and the pharmaceutical industry. Due to close integration of healthcare and academia, NHS patients and UK organisations are ideally placed and fundamental to the success of global translational research.

Support from his local Trust, allowing Chris to take four years away from full time clinical duties, has been central to enable him to take this research opportunity. He balances his now part-time clinical commitments with his research work and where necessary, travel to San Francisco, where he collaborates with a large pharmaceutical research and early drug development company. The flexibility of his employer and colleagues in allowing him to arrange clinical commitments to suit this timetable, and to swap on-call duties to attend meetings and travel when necessary, is crucial to allow him to undertake this work.

## The NHS conducts high-quality research and adopts new treatments

### Promote clear career paths for NHS staff engaging in research

NHS staff at the beginning of their careers need help to see how their choices will open up different career paths. Developing structured research career paths can help them to picture a successful research career and encourage them down this route.

#### **CASE STUDY 22 – Promoting research careers in nursing**

The Royal College of Nursing has promoted information on pursuing a career in research for over a decade. This includes mapped out research career pathways within a range of settings. Each pathway is presented as a matrix, to demonstrate the facility to develop a career along a single pathway or by developing a greater knowledge by moving between pathways. The information described includes: the typical role, experience, knowledge, training, skills and qualifications expected at each stage along each pathway. They also host tools which allow nurses to find out what skills and competences they may need to work at different levels in these pathways. Increasingly nurses are pursuing integrated clinical-academic career pathways. More information can be found on the RCN website<sup>43</sup>.

Alongside promoting structured career paths, NHS staff must be encouraged to see these as flexible, allowing them to mould them to their own needs, wants and career development. They should not be faced with a choice between professional progression and a research career but be able to balance the two.

#### **CASE STUDY 23 – The need for flexible career paths**

Dr Richard Lee is a Consultant Senior Lecturer in Ophthalmology at Bristol University and part of the successful NIHR Moorfields Biomedical Research Centre which has attracted international acclaim.

Throughout his career, he has taken considerable personal risks in the face of uncertain research funding and it has been necessary for him to work outside traditional clinical training structures to reach where he is today. This has been achieved through exceptional mentorship and institutional flexibility.

A key element of his success has been aligning his clinical practice with his research expertise from a relatively early career stage, enabling him to gain rapid progression to senior roles within his clinical service and research group.

Such tailored support for exceptional individuals such as Richard to pursue bespoke career paths is critical to maintaining and developing research excellence in the UK.

<sup>43</sup> <http://www.rcn.org.uk/development/researchanddevelopment/career/career>

## The NHS conducts high-quality research and adopts new treatments

### Encourage research active NHS staff to work with colleagues across specialties

Innovation is catalysed at the boundaries of specialties, where different approaches can spark new ideas. Patients themselves are likely to have contact with many different clinical specialties during the course of their treatment, an increased understanding of their whole treatment path could lead to the development of treatments that will significantly improve their quality of life.

The NHS Chief Executive's report *Innovation, Health and Wealth* lays out the ambition for the UK to provide an unrivalled ecosystem that brings together business, researchers, clinicians and patients to translate discovery into clinical use for medical innovation with the NHS and beyond<sup>44</sup>.

*“Our ambition must be for an NHS defined by its commitment to innovation, demonstrated both in its support for research and its success in the rapid adoption and diffusion of the best, transformative, most innovative ideas, products, services and clinical practice.”*

Promoting interdisciplinary research in the NHS will be key to delivering this. Clinical teams, bringing specialties together in multi-disciplinary meetings are successfully fostering interdisciplinary working. We need to ensure that this practice is replicated in research.

The national disease-focused research networks provide an arena to broker this conversation across specialties. But to strengthen this engagement, we need lead individuals to develop an understanding of other specialties, able to speak different languages and see new opportunities between the two.

These individuals will be able to lead a shift in attitudes towards experimentation and innovation amongst academics, clinicians and managers at all levels and across all specialties in the NHS.

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<sup>44</sup> NHS, 2011, *Innovation, Health and Wealth: Accelerating Adoption and Diffusion in the NHS*

# The NHS conducts high-quality research and adopts new treatments

## The NHS is open to research

- Designate contact points and develop a map to guide people through all aspects of the set up and conduct of studies
- Invest in the infrastructure to conduct research
- Clarify who pays for research costs

### Designate contact points and develop a map to guide people through all aspects of the set up and conduct of studies

The NHS research infrastructure is very complex involving multiple bodies, networks and organisations. This can be difficult for both funders and researchers to navigate and a lack of coordination between organisations can increase the time and costs involved in getting a research study off the ground. This acts as a disincentive to conducting research.

Researchers and funders need a map and points of contact to guide them through the system. Existing resources and toolkits need to be well signposted and tailored to their audiences needs.

This includes the NIHR Office for Clinical Research Infrastructure (NOCRI) which aims to help public, charity and industry research funders work in partnership with NIHR infrastructure.

NOCRI provides information on NIHR infrastructure and has developed a series of model agreements to speed up the contracting process for clinical trials and clinical investigations of medical devices carried out in the NHS. NOCRI should explore how better to interact with partners beyond the commercial sector including medical research charities.

**40% of hospital doctors polled cited difficulties navigating regulatory processes as a barrier to them taking part in medical research in the last two years<sup>45</sup>.**

Difficulties navigating the regulatory and governance pathway act as a barrier for would-be researchers. As recommended by the Academy of Medical Sciences in its report, *A new pathway for the regulation and governance of health research*<sup>46</sup>, there should be a national one-stop-shop to streamline this process and reduce duplication of effort for funders and researchers seeking approvals.

The Health Research Authority (HRA) is currently undertaking a feasibility study for a single HRA Assessment of legal aspects of research projects, such as data protection, insurance arrangements and ethical review. Should this prove successful, it should be implemented as a permanent role of the HRA and sufficient funding made available to ensure it can function effectively.

It is also possible for streamlining to take place at a local level.

<sup>45</sup> ComRes poll of 392 health professionals commissioned by Arthritis Research UK, Association of Medical Research Charities, Breast Cancer Campaign, British Heart Foundation, 2013, [www.comres.co.uk](http://www.comres.co.uk)

<sup>46</sup> Academy of Medical Sciences, 2011, *A new pathway for the regulation and governance of health research*, <http://www.acmedsci.ac.uk/p47prid88.html>

## The NHS conducts high-quality research and adopts new treatments

### CASE STUDY 25 – Greater Manchester Comprehensive Local Research Network

The number of clinical studies in Greater Manchester has more than doubled since 2009-2010 from 320 to 684 and the average (median) time to get NHS R&D Permission has almost halved each year for the past two years; down from 60 days in 2010-2011 to 17 days in 2012-13.

The main driver has been making performance and implementation public information. Assessing performance and the degree of adoption of national procedures and reporting it to Trust Boards and Chief Executives as a matter of routine has focused R&D directors and their staff on managing delivery of network objectives.

### Invest in the infrastructure to conduct research

For investors to see the NHS as a valuable location for research, the NHS must provide high-quality research infrastructure. This includes high-quality facilities, and a skilled workforce to conduct research.

### CASE STUDY 26 – Clinical Research Infrastructure Initiative

Recognising the need for significant investment into clinical research infrastructure to speed up the translation of scientific advances into real benefits for patients, the Clinical Research Infrastructure Initiative supported by the Wellcome Trust, the Wolfson Foundation, the British Heart Foundation, the Medical Research Council, the Irish Health Research Board and the Departments of Health – England, Scotland, Wales and Northern Ireland allocates funding to support key clinical research infrastructure in the UK and Ireland.

This funding has supported the development of a cohort of Clinical Research Facilities for Experimental Medicine (CRFs). NIHR is now investing £102 million in the NHS infrastructure for 19 CRFs over the period September 2012 to March 2017. This provides the necessary recurrent NHS infrastructure costs of CRFs such as clinical research nurses, technicians and facility running costs, the capital funding for buildings and equipment is provided by all partners. This partnership funding gives patients access to brand new treatments, diagnostics and care. It is also crucial in helping us secure sustainable economic growth.

This also includes the infrastructure to set up and conduct research trials, which often requires coordination across multiple healthcare settings. In busy hospitals, someone with visible lead responsibility for research can drive coordination and ensure the existing infrastructure is useable. Alongside central coordination, potentially at an Academic Health Science Network level, this can support a more collaborative and streamlined system to speed up research.

### CASE STUDY 27 – Dedicated R&D posts to facilitate research

One way of expanding research culture is facilitation and support. Whilst Research & Development (R&D) teams have the responsibility for overseeing research governance, putting the focus on facilitation and support can ensure local research teams remain motivated and research sponsors return in future.

## The NHS conducts high-quality research and adopts new treatments

Dedicated posts in R&D, communications, and patient and public involvement, can strengthen engagement with patients, carers and the public, and help to develop long-term relationships with commercial partners and funding bodies.

University Hospital Southampton NHS Foundation Trust established R&D leads across its four clinical divisions to promote and review research activity. The R&D team was expanded with the creation of two research facilitators, a research communications manager and commercial roles.

According to Heidi Nield, Assistant Director of Research at the Trust, the appointment of these roles was key to supporting study teams and embedding research at all levels.

As new structures are developed and the NHS transitions to a new model of care, it is important that the NHS balances service delivery with the NHS' central roles in training and research. This will ensure the NHS develops the capabilities and capacity to conduct research across primary, secondary and tertiary care settings and take up its findings rapidly to improve care for patients.

### CASE STUDY 28 – A move to more personalised medicine requires new infrastructure and training

There are many different types of breast cancer, meaning there are likely to be fewer “one-size-fits-all” treatments in the future – instead we will target specific drugs to specific types of breast cancer. These drugs will work better, smarter and save lives. They will also stop patients facing unnecessary side effects of drugs that will not work for them and reduce wasted NHS spending on ineffective treatments.

To develop and deliver personalised treatments to patients, the NHS needs to conduct specific tests to find out which type of breast cancer a patient has in order to tell which treatments will work for them. At present, these tests can take a long time. For example, HER2 testing has been in use in the NHS since 2006 to find out if patients are likely to benefit from the drug Herceptin. But we know some patients are still not receiving their test results as quickly as they should be. This could delay their treatment if they are eligible for Herceptin. The NHS needs to invest in the infrastructure to allow it to conduct these tests efficiently and train staff to roll out these new tests quickly and effectively. Unless we act now, this will act as a barrier to the development and uptake of new personalised medicines which offer considerable benefits for patients<sup>47</sup>.

### Clarify who pays for research costs

Many of the research studies underway in the NHS are funded by external partners including medical research charities and industry. In 2011, AMRC members funded 32% of active NIHR-led non-commercial studies that were open to recruitment during 2011/12, and 26% of new non-commercial studies entered on to the Clinical Research Network Portfolio.

Clinical research in the NHS incurs research, support and treatment costs which are paid by different funders. Research can only take place if the costs are attributed correctly, and

<sup>47</sup> Dixon et al., *BMJ*, 2012, *HER2 testing in patients with breast cancer*, <http://www.ncbi.nlm.nih.gov/pubmed/22689887>

## The NHS conducts high-quality research and adopts new treatments

if funders agree to pay. Mistakes in attribution can lead to delays or prevent studies from starting.

With AcoRD<sup>48</sup> the Department of Health has established a mechanism to meet some of the costs of research occurring in the NHS and funded by charities that are members of AMRC. The agreement recognises the unique contribution medical research charities make to excellent research in the NHS.

However, difficulties still arise when the cost of treating someone involved in a research project is higher than the cost of standard treatment; patients may need extra diagnostics, drugs or procedures as part of the testing of the new treatment which can increase the cost. In the past it has been difficult to obtain funding to cover these Excess Treatment Costs from commissioners, leading to them being thrown back to charity funders which can make research too expensive for them to take forward. These problems act as disincentives for researchers, funders and commissioners and can stop research going ahead.

### **CASE STUDY 29 – Arthritis Research UK forced to redirect research funds due to lack of payment of Excess Treatment Costs**

In July 2011, Arthritis Research UK agreed to fund the Arthritis Research UK Gout Trial Phase 2, a two year trial assessing the effectiveness and cost effectiveness of nurses treating patients with gout in primary care, rather than in secondary care under a consultant.

The first patient was expected to be recruited in February 2012. Even though the research team had worked with the Nottingham City Primary Care Trust (PCT) to define the excess treatment costs (ETCs), when the ETCs required to fund the research nurse salaries were requested from other PCTs in the East Midland area, the applications were refused, preventing the study from starting.

In July 2012, Arthritis Research UK agreed to support these NHS costs, which increased the overall costs of the trial by 22%, so that work could get underway. Recruitment of patients into the study subsequently began in March 2013, over a year after the intended start date. Negotiations also continue with respect to payment of ETCs.

The Department of Health's mandate to NHS England includes an objective for NHS England to 'ensuring payment of treatment costs for NHS patients taking part in research funded by Government and Research Charity partner organisations.'

This must be delivered in practice. Guidance must clearly state that NHS England is responsible for covering these costs, and there must be clear and standardised processes for obtaining excess treatment costs.

<sup>48</sup> <https://www.gov.uk/government/news/attributing-the-costs-of-health-social-care-research-development-acord>

### Secretary of State for Health

The Secretary of State for Health has responsibility for the Department of Health, including the NHS. He or she is directly accountable to the public and Parliament for this. The Health and Social Care Act 2012 put duties on the Secretary of State regarding research:

*1E Duty as to research* *In exercising functions in relation to the health service, the Secretary of State must promote –*

- (a) research on matters relevant to the health service, and
- (b) the use in the health service of evidence obtained from research.

### Department of Health

The Department of Health (DH) provides strategic leadership for public health, the NHS and social care in England. It is responsible for executing the duties of the Secretary of State, including allocating budgets within the NHS and other health and care services under its control.

### NHS England

The main aim of NHS England, previously known as the NHS Commissioning Board, is to improve the health outcomes for people in England. It was formally established as an executive non-departmental public body (ENDPB) on 1 October 2012. It is responsible for the authorisation and oversight of Clinical Commissioning Groups (CCGs) and commissions some services directly. It has the following duties in the Health and Social Care Act 2012 relevant to research and innovation:

*13K Duty to promote innovation*

*(1) The Board must, in the exercise of its functions, promote innovation in the provision of health services (including innovation in the arrangements made for their provision).*

*(2) The Board may make payments as prizes to promote innovation in the provision of health services.*

*(3) A prize may relate to –*

- (a) work at any stage of innovation (including research);*
- (b) work done at any time (including work before the commencement of section 23 of the Health and Social Care Act 2012).*

*13L Duty in respect of research*

*The Board must, in the exercise of its functions, promote –*

- (a) research on matters relevant to the health service, and*
- (b) the use in the health service of evidence obtained from research.*

The NHS Commissioning Board took up its full statutory duties and responsibilities on 1 April 2013.

### Clinical Commissioning Groups (CCGs)

Clinical Commissioning Groups (CCGs) are responsible for the delivery of local healthcare services through commissioning and strategic management. 211 CCGs cover England. Their governing board must include GPs and at least one registered nurse and a doctor who is a secondary care specialist. CCGs will be supported by other staff to carry out their functions. CCGs have the following duties in the Health and Social Care Act 2012 relevant to research and innovation:

*14X Duty to promote innovation*

*Each clinical commissioning group must, in the exercise of its functions, promote innovation in the provision of health services (including innovation in the arrangements made for their provision).*

*14Y Duty in respect of research*

*Each clinical commissioning group must, in the exercise of its functions, promote –*

- (a) research on matters relevant to the health service, and*
- (b) the use in the health service of evidence obtained from research.*

NHS England is expected to have 27 Local Area Teams (LATs) to cover England with local responsibilities for:

- *CCG development and assurance*
- *emergency planning, resilience and response*
- *quality and safety*
- *partnerships*
- *configuration*
- *system oversight*

### Clinical senates

Clinical senates will help CCGs, Health and Wellbeing Boards (HWBs) and the NHS England to make strategic decisions by providing advice and leadership. There are 12 Clinical Senates in England comprised of a range of clinicians and professionals from health, including public health and social care, alongside patients, public and others.

### National Institute for Health Research (NIHR)

The National Institute for Health Research (NIHR) is the research arm of the NHS, with an annual budget of almost £1 billion. During 2011/12, this budget included £202.2 million for research across a broad range of programmes and initiatives and £609.5 million in the facilities the NHS needs to stay at the forefront of research that result in high-quality care for the public. There are a large number of NIHR organisations, covering different parts of research co-ordination and delivery at a national and local level.

### NIHR Clinical Research Network (NIHR CRN)

A subsidiary of NIHR, the NIHR Clinical Research Network (NIHR CRN) aims to make it possible for all patients and health professionals across England to participate in relevant clinical trials. It allocates and manages funding to meet NHS Service Support (e.g. additional nursing time; pathology sessions; lab costs; imaging; additional out-patients costs).

Although the Clinical Research Network operates as one organisation, it currently works across eight networks:

- Six “Topic” Research Networks (covering Cancer, Dementia and Neurodegenerative Diseases, Diabetes, Medicines for Children, Mental Health and Stroke)
- A Primary Care Research Network to support research in this part of the health service
- A Comprehensive Clinical Research Network, which covers all other disease areas, comprising 25 Comprehensive Local Research Networks.

NIHR CRN is simplifying its structure to 15 Local Clinical Research Networks. This is expected to be completed in spring 2014. Together they will cover the whole of England, with the same boundaries as the emerging Academic Health Research Networks. Each Local Clinical Research Network will be responsible for the efficient delivery of clinical studies in its region for all the therapy areas combined.

The work of all the networks is coordinated by the NIHR Clinical Research Network Coordinating Centre (NIHR CRN CC) through local recruitment and management centres. The NIHR CRN is the English component of the UK Clinical Research Network (UKCRN), developed under the auspices of the UK Clinical Research Collaboration ([www.ukcrc.org](http://www.ukcrc.org)).

### [Collaborations for Leadership in Applied Health Research and Care \(CLAHRCs\)](#)

NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) are collaborative partnerships between local universities and the surrounding NHS organisations. They support the translation of research evidence into practice in the NHS by identifying and evaluating new interventions that are effective and appropriate for everyday use in the NHS taking into account the way that healthcare is increasingly delivered across sectors and a wide geographical area.

The nine CLAHRCs established in October 2008 are now in the final year of their five year funding. A new, single-stage competition to designate and fund NIHR CLAHRCs for the next five years closed on the 13 May 2013.

### [Academic Health Science Networks \(AHSNs\)](#)

Local NHS organisations and universities will form Academic Health Science Networks (AHSNs) and link up with local industry and service providers to speed up the diffusion of proven innovations within the NHS and health-related sectors. It is planned that these will spread best practice and innovations quickly across the country and in doing so, drive economic growth and improve patient care. It is envisaged that there will be about 15 Academic Health Science Networks across England.

### [Academic Health Science Centres \(AHSCs\)](#)

Academic Health Science Centres (AHSCs) are partnerships between one or more universities and healthcare providers focusing on research, clinical services, education and training. They are intended to ensure that medical research breakthroughs lead to direct clinical benefits for patients. The following AHSCs are currently in operation in England.

- Cambridge University Health Partners (Cambridge)
- Imperial College Healthcare (London)
- King's Health Partners (London)
- Manchester Academic Health Science Centre (Manchester)
- UCL Partners (London)

The Department of Health has launched a new open competition to designate new AHSCs for the next 5 years from 1 April 2014. This new round is expected to establish around 15 new AHSCs, roughly one per Academic Health Science Network.

### [Service providers](#)

This is the term given to any organisation, whether NHS, charity, not-for-profit or private that provides health care or support services for the NHS.

### [Healthwatch](#)

Healthwatch England, established in October 2012, leads and supports the Healthwatch network, which is made up of 152 community-focused local Healthwatch organisations. These will represent the public's view on health and care services to national and local NHS authorities.

Healthwatch England will work with local Healthwatch and will also:

- advise the NHS Commissioning Board, English local authorities, Monitor and the Secretary of State.
- have the power to recommend that action is taken by the Care Quality Commission (CQC) when there are concerns about health and social care services.

Local Healthwatch, which launched in April 2013, will take on the work of the Local Involvement Networks (LINKs) to:

- represent the views of people who use services, carers and the public on the Health and Wellbeing boards set up by local authorities.
- provide a complaints advocacy service from 2013 to support people who make a complaint about services.
- report concerns about the quality of health care to Healthwatch England, which can then recommend that the CQC take action.

### Health and wellbeing boards

The Health and Social care Act 2012 established health and wellbeing boards as a forum where key leaders from the health and care system can work together with councils, democratically-elected representatives and patient representatives (from Healthwatch for example) to have strategic influence over commissioning decisions across health, public health and social care.

Health and wellbeing boards operated in shadow form during 2012-13. Boards took on their statutory functions in April 2013.

### Local authorities

Local authorities are the democratically-elected councillors and officials of local councils. The Health and Social Care Act transferred responsibility for local public health from Primary Care Trusts to local authorities in April 2013. Local authorities will coordinate with NHS services through their membership of health and wellbeing boards.

### Public Health England (PHE)

Public Health England (PHE) is an Executive Agency, meaning its Chief Executive is accountable to the Secretary of State for Health. It became fully functional in April 2013 and replaces the Health Protection Agency (HPA).

PHE will provide laboratory diagnostic services and expert advice to other agencies on issues of public health, including for example, infectious disease and control of hazardous materials, as well as conduct research.

### Biomedical Research Centres (BRCs)

Biomedical Research Centres (BRCs) are funded by NIHR through open competition on a five year basis. They are based within the facilities of NHS and university partnerships. Their function is to translate fundamental biomedical research into clinical research that benefits patients. Different centres have different research themes.

### Biomedical Research Units (BRUs)

Biomedical Research Units (BRUs) are funded by NIHR through open competition on a five year basis. They are based within the facilities of NHS and university partnerships and are smaller than Biomedical Research Centres, comprising of fewer Principle Investigators and have a single disease area research focus. They are intended to achieve “critical mass” by bringing together researchers from small groups. A BRU’s function is to translate fundamental biomedical research into clinical research that benefits patients. Different centres have different research themes.

### Health Research Authority (HRA)

The Health Research Authority (HRA) was established on 1 December 2011 as a Special Health Authority. The Care Bill published on 10 May 2013, proposes to make the HRA a non-departmental public body. The purpose of the HRA is to protect and promote the interests of patients and the public in health research.

The HRA is piloting a simplified and streamlined HRA assessment for all research in the NHS; combining and replacing aspects of the current review by NHS Research and Development (R&D) and Research Ethics Committees (RECs), which are currently conducted locally.

The functions of the National Research Ethics Service (NRES) have been transferred to the HRA, bringing together the functions previously provided by the National Patient Safety Agency and the Research Ethics Committee Appointing Authority. The Integrated Research Application System (IRAS) has also come into the HRA, allowing UK-wide e-submission of applications for ethical approval.

### Health Education England (HEE)

Health Education England (HEE) is the national leadership organisation responsible for the education, training, and development of the NHS workforce. It is currently a Special Health Authority but is expected to be made a non-departmental public body by the Care Bill, published on 10 May 2013. The Care Bill includes provisions for research:

- (2) *HEE must, in exercising its functions, promote –*  
(a) *research into matters relating to such of the activities listed in section*

*63(2) of the Health Services and Public Health Act 1968 (social care services, primary care services and other health services) as are relevant to HEE's functions, and (b) the use in those activities of evidence obtained from the research*

### Local Education and Training Boards (LETBs)

Local Education and Training Boards (LETBs) are committees of Health Education England (HEE). There are 13 across England. Their role is to carry out the functions of Health Education England (HEE) at a local level, the three main functions of a LETB are to:

- identify and agree the local needs for education and training to deliver the right people and skills to meet future service needs
- plan and commission high quality education and training in its region in order to secure future workforce supply and improve patient outcomes
- bring providers and relevant stakeholders together to provide a forum for developing the whole workforce.

All providers of NHS services will need to be a member of, and be involved with the work of the LETB. As committees of HEE, LETBs will be governed by boards that include representatives of local providers. LETBs will be required to bring key stakeholders together to develop a skills and development strategy that meets the needs of providers, responds to commissioning plans and to the views of patients, communities and staff.

### Deaneries

The deaneries are responsible for the management and delivery of postgraduate medical education in addition to supporting the continuing professional development of all doctors and dentists. There are 13 deaneries in England and one each for Wales, Scotland and Northern Ireland. There is also a defence Postgraduate Deanery.

### Monitor

Monitor is the sector regulator for health, with a primary duty to protect and promote the interests of people who use health care services by promoting provision of healthcare services which is:

- (a) economic, efficient and effective; and  
(b) maintains or improves the quality of services.

It is independent of central government and directly accountable to Parliament.

## Calls by organisation

### Department of Health

- Develop a measureable indicator to demonstrate to patients and staff whether or not the NHS Constitution pledges are being adhered to. (p8)
- Allow Academic Health Science Networks to work independently while encouraging them to share best practice across England. (p32)
- Create a national one-stop-shop to streamline the process of applying for research approvals and reduce duplication. (p36)
- Invest in the infrastructure needed to conduct research. (p37)

### NHS England

- Involve patients in setting priorities for research. (p13)
- Ensure research activity is specified and reviewed in contracts with all hospitals, primary care and service providers. (p17)
- Include research responsibilities in standard contracts. (p17)
- Make research experience a desired competency for NHS jobs. (p22)
- Use measures of the scope, quality, quantity and adoption of research in the Clinical Commissioning Groups Outcomes Indicator Set to measure how well CCGs are delivering research and working to improve this. Report results back to commissioners, NHS staff and the public. (p25)
- Use key performance indicators in research as part of CCGs' annual review process. (p26)
- Ringfence time for research in NHS contracts. (p27)
- Recognise and reward CCGs who are leading and delivering on research (p29)
- Implement AMRC's research charter to ensure commissioning decisions are informed by the evidence and promote research. (p30)
- Provide resources to support commissioners to work with the multiple bodies available that can help them identify and assess relevant evidence. (p32)
- Allow Academic Health Science Networks to work independently while encouraging them to share best practice across England. (p32)
- Ensure that future NHS leaders can take up research opportunities. (p36)
- Clarify who pays for research costs and develop guidance laying out clear and standardised processes for obtaining Excess Treatment Costs. (p39)

### Clinical Commissioning Groups

- Involve patients in setting priorities for research. (p13)
- Ensure research activity is specified and reviewed in contracts with all hospitals, primary care and service providers. (p17)
- Require GPs to share their practice data with the Clinical Practice Research Datalink and respond to requests to invite their patients to take part in research studies. (p18)
- Make research experience a desired skill for NHS jobs. (p22)
- Ringfence time for research in NHS contracts. (p27)
- Implement AMRC's research charter to ensure commissioning decisions are informed by the evidence and promote research. (p30)
- Ensure that future NHS leaders can take up research opportunities. (p36)

### NHS Trusts

- Make research experience a desired skill for NHS jobs. (p22)
- Ringfence time for research in NHS contracts. (p27)
- Use local and national awards to recognise and reward NHS staff at all levels that take part in research (p29)
- Encourage research active NHS staff to work with colleagues across specialties. (p34)
- Ensure that future NHS leaders can take up research opportunities. (p36)

## Calls by organisation

### Academic Health Science Networks (AHSNs)

- Work alongside LETBs to connect up those involved in research across a region, sharing resources and providing opportunities for researchers to meet others involved in research. (p23)
- Take opportunities to share best practice with other AHSNs across England (p32)

### NHS communication teams

- Promote the NHS Constitution among patients and NHS staff, providing guidance for patients and staff to understand this. (p8)
- Take steps to encourage patients to ask about opportunities to take part in research, and provide patient-friendly information for them to find out about research opportunities themselves using the media they use. (p8 and 9)
- Explore how communication teams can support steps to make the results of research studies being made available to research participants. (p14)
- Use local and national communications to explain the importance of research to patient care now and in the future and explain how research evidence informs clinical practice. (p24 and 25)
- Publicise local and national guidance for those wanting to become active in research to NHS staff. (p27)
- Use local and national awards to recognise and reward NHS staff at all levels that take part in research (p29)
- Promote clear career paths for NHS staff engaging in research. (p33)
- Designate contacts points and develop a map to guide people through all aspects of the set up and conduct of studies. (p36)

### NIHR

- Create opportunities for people to self-register their interest in taking part in research. (p10)
- Involve patients in setting priorities for research. (p13)
- Develop a quality mark to signify where patients have been involved in the design of a study. (p13)
- Use local and national awards to recognise and reward NHS staff at all levels that take part in research (p29)
- Take steps to ensure that trials conducted within the NHS are registered and the results of these are published. Work with other funders to address the practical challenges involved in making the underlying data accessible to conduct further analyses while protecting patient confidentiality. (p30)
- Promote clear career paths for NHS staff engaging in research. (p33)
- Encourage research active NHS staff to work with colleagues across specialties. (p34)
- Designate contacts points and develop a map to guide people through all aspects of the set up and conduct of studies. (p36)
- Invest in the infrastructure needed to conduct research. (p37)

### NIHR CRN

- Ensure a more even geographical spread of studies around the country. Build links with Academic Health Science Networks to link up academics and enable patients from other areas to join research studies. (p12)
- Encourage research active NHS staff to work with colleagues across specialties. (p34)

### NIHR Office for Clinical Research Infrastructure (NOCRI)

- Explore how better to interact with partners beyond the commercial sector including medical research charities. (p36)

## Calls by organisation

### Health Research Authority

- Ensure patients and the public can be confident that the findings of research that they have participated in will be used and disseminated to benefit others. (p30)
- Should the current feasibility study for a single HRA Assessment of aspects of research projects prove successful, implement this as a permanent role of the HRA. (p36)

### Health Education England (HEE)

- All NHS staff should be given education and training to develop the skills to record, hand, use and share data effectively. (p19)
- Include research knowledge and use of evidence in basic training for all NHS staff. (p20)
- Give NHS staff access to further training and development opportunities in research skills should they want to get more involved in research during their career. (21)
- Assess every trainee's research skills as part of their annual review. (p21)
- Retain the advisory group on academic training for medical professionals, giving this high priority and ensuring it meets regularly. (p23)
- Require LETBs to report on their promotion of research and engagement with local networks. Identify and share best practice. (p23)
- Promote clear career paths for NHS staff engaging in research. (p33)
- Ensure that future NHS leaders can take up research opportunities. (p36)

### Local Education and Training Boards (LETBs)

- All NHS staff should be given education and training to develop the skills to record, hand, use and share data effectively. (p19)
- Include research knowledge and use of evidence in basic training for all NHS staff. (p20)
- Promote research confidence among trainees. (p21)
- Make postgraduate deans within LETBs full members of the LETB board. Support them to deliver flexible local systems working with local Higher Education Institutions. (p23)
- Report to HEE on promotion of research and engagement with local networks. (p23)

### Deaneries

- Promote research confidence among trainees. (p21)

### Medical Royal Colleges

- Promote research confidence among trainees. (p21)
- Develop a greater consistency in the research competencies included in curricula across specialties. (p21)

### Clinicians

- Respond to your patient's questions about opportunities to take part in research. (p8)
- When conducting research, consider from an early stage what information will be fed back to patients and staff involved. (p14 and 25)
- Consider every patient's suitability to take part in research as part of their care (p16)
- Be confident to take up research opportunities and support colleagues to do so. (p36)

### Charities and patient groups

- Promote the importance of research to patient care now and in the future. (p24)

### Patients

- Ask healthcare professionals about opportunities to take part in research. (p8)

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