

# Report of a Royal College of Physicians and National Institute for Health Research workshop – developing research capacity to ensure successful study development and delivery

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**ABSTRACT** – The landscape and opportunities for clinical research have changed significantly following the creation of the National Institute for Health Research (NIHR) in 2006. This article describes the scale and impact of the NIHR network infrastructure for clinical research and identifies areas for future development in partnership with the National Health Service (NHS), clinicians and research funders.

**KEY WORDS:** National Institute for Health Research, clinical research, life sciences

## Introduction

The need to translate clinical research and innovation into improved clinical outcomes at scale, and the significant economic benefit of a strong life-sciences industry, are well recognised and underpinned the formation of the National Institute for Health Research (NIHR) in 2006.<sup>1</sup> The publication of David Cooksey's report, *A review of UK health research funding*,<sup>2</sup> in 2006 added impetus to the development of several important new structures and systems designed to enhance the productivity of the UK biomedical research sector and deliver patient benefit. Changes to academic clinical training were also proposed; the Royal College of Physicians (RCP) has previously held two workshops aimed, respectively, at addressing issues relating to the coordination of academic training for physicians<sup>3</sup> and identifying the systems through which the National Health Service (NHS) academic vision could be delivered.<sup>4</sup>

In December 2011, the Strategy for Life Sciences of the UK Government was launched. This included a review of the adoption and spread of innovations in the NHS (*Innovation, Health and Wealth: accelerating adoption and diffusion in the NHS*), which identified barriers to the widespread uptake of innovative techniques and technologies by the NHS.<sup>5</sup> Poor access to evidence, data and metrics; insufficient recognition and celebration of innovation; ineffective use of financial incentives; and a lack of effective and systematic innovation architecture were regarded as significant barriers.

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However, for clinical research, the landscape has changed radically since 2006. The NIHR has invested significantly to create a world-class research infrastructure embedded in the NHS to ensure that high-quality commercial and non-commercial clinical research studies can be conducted expeditiously. For many clinicians in the NHS, the primary point of contact with the NIHR is the NIHR Clinical Research Network infrastructure, which accounts for approximately one-third of the total NIHR budget of £1 billion. Progress made since 2006 using network infrastructure is significant. For example, in 2011–2012:

- the NIHR Clinical Research Network pledged research delivery support to 1,307 new studies
- 99% of NHS trusts actively recruited patients into NIHR Clinical Research Network (CRN) portfolio studies
- more than 595,000 participants were recruited to clinical studies, a 5% increase on 2010–11
- the NIHR Clinical Research Network supported the delivery of 388 new commercial contract research studies
- the number of patients recruited to commercial contract studies grew to more than 19,000, a significant increase on the 2010–2011 total of 15,827
- 61% of commercial contract studies recruited their first participant within 30 days of NHS permission, an improvement of nine percentage points
- 62% of NHS trusts engaged in commercial research
- 45% of commercial studies recruited to time and target, which was more than double the figure of the previous year, although this remains the focus of improvement
- 73% of all studies granted Medicines and Healthcare products Regulatory Agency Clinical Trial Authorisation approval (for phase II–IV studies of investigational medicinal products) were supported by the Network
- 61% of research studies submitted for governance approval since April 2012 received NHS permission within 40 days (average of all study sites).

Performance for 2012–13 is given at [www.crncc.nihr.ac.uk](http://www.crncc.nihr.ac.uk).

## NIHR comprehensive clinical research network

Although much progress has been made, it is recognised that there is more work to do to ensure that the world-class infrastructure of the NHS delivers maximum benefit for patients,

researchers and the UK economy. Therefore, the RCP and NIHR Comprehensive Clinical Research Network (CCRN) convened a joint workshop aimed at identifying barriers to the delivery of the UK research programme in focussed areas. Variations in research activity between medical specialties was noted and study delivery performance, ensuring that research is recognised throughout the NHS as core business and the need to engage and motivate clinicians were recognised as challenges.

The NIHR CCRN comprises 25 Comprehensive Local Research Networks (CLRNs). NIHR CRN specialty groups, working in the NIHR CCRN, provide a world-class research infrastructure embedded in the NHS to support the successful delivery of research studies, funded by the NIHR and over 200 NIHR non-commercial partner organisations and industry. This represents a nationally coordinated network of more than 500 local research champions and problem-solvers across the UK.

The workshop compared clinical need and research activity in three of the NIHR specialty areas: musculoskeletal diseases, hepatology and/or gastroenterology, and respiratory medicine, with the aims of reconciling the research workforce with the deployment of current resources, academic training and identifying metrics of success. Presentations from leaders of the three specialty areas outlined the burden of disease and associated morbidity and mortality, and the numbers of research studies that each area is engaged with. All three have complete, or near-complete, geographical participation from the 25 CLRNs and the devolved nations. Moreover, the numbers of studies from each were among the top six nationally in terms of the CCRN portfolio. However, there was an imbalance within specialties in terms of perceived need (eg large numbers of patients with osteoarthritis or common gastrointestinal pathologies) and academic activity (more studies in systemic lupus erythematosus, scleroderma and hepatitis).

Difficulties in empowering local research leads and the constraints of current information technology (IT) systems were seen as common challenges to all three specialty areas. By contrast, in certain areas (eg hepatitis and cystic fibrosis) the UK has achieved internationally competitive enrolment and completion of studies. In this regard, links between national charities, industry and specialty societies needed strengthening in some areas, building on the strong links that currently exist between some charitable funders of research (eg Arthritis Research UK) and the NIHR CCRN. Strategic, overarching bodies, such as the UK Respiratory Research Collaboration, have been effective. Active management of the performance of industry studies was highlighted as being crucial to success, including setting robust recruitment targets at the outset. Robust study feasibility is also essential for non-commercial studies and is often not adequately addressed by applicants to research funding bodies, or indeed through the grant peer-review system. Examples of network interventions to 'rescue' studies that were failing to recruit to 'time and target' were cited. Identifying and enrolling new study sites can be expedited using the specialty groups, but the expert knowledge held by these groups is sometimes not fully capitalised on. The relevance and impact of websites to ensure effective patient and public engagement and the value of effective patient education, drawing

attention to their right to be recruited into studies (as set out in the NHS Constitution), was emphasised by all three specialties.

Identifying 'hubs' for research to which patients can be referred to can sometimes be a more effective approach than simply increasing the numbers of recruitment centres, although district hospitals are effective in specific areas and the networks have had considerable success in this domain, with a significant increase in numbers of patients treated in district general hospitals recruited to research studies. Strong primary care engagement is also vital to increase research participation.

New initiatives from the NIHR in developing academic careers were presented. These included the engagement of research fellows and academic trainees, and exploring the potential of enabling trainees to spend time in clinical trial units. Placement in so-called 'Cochrane' appointments to encourage participation in the development of systematic reviews, secondments to industry, initiatives in leadership and mentorship, and a focus on assistance in applications for the 'first grant' were welcomed.

Following these presentations, breakout groups attempted to address specific questions. First, how can a culture be promoted and sustained in the NHS that embeds research in clinical practice? It was agreed that providing 'academic tasters' to those in training would be desirable. Increasing awareness of academic careers both among medical students and foundation year trainees should be a priority and the new INSPIRE programme of the Academy of Medical Sciences, supported by the Wellcome Trust, should help deliver such progress in medical schools. Targeting the new consultant, possibly with a research 'start-up pack', was proposed. A 2-year period in which such individuals would be mentored and encouraged to obtain further funding with formal evaluation of progress using clinical and academic appraisal could be instigated. A culture that is driven by the trust board highlighting the importance of research both to the trust and commissioners was also thought to be essential. Including research and academic attainment in core trust board quality indicators was promoted as a means of achieving this, and good examples of board indicators were shared.

Second, groups attempted to identify barriers to undertaking research in the NHS and practical steps that key stakeholders could take to overcome these. Continuing to tackle bureaucracy, including research and development approvals, remains of fundamental importance, although significant progress in several areas was noted and participants welcomed recent efforts to address these, including the feasibility study by the Health Research Authority for further streamlining of NHS research approvals. Promoting 'generic' costing and contract templates and consent forms, all of which now exist, and accelerating the development of national patient registries and databases were thought to be desirable. Service pressure and lack of motivation were also thought to be significant barriers to progress, but examples of where these barriers had been overcome were cited. For example, creating honorary clinical associate professors for 5-year periods for individuals who make significant contributions to research from a clinical base was cited as one example of a local initiative (Leeds) designed to support engagement by the NHS consultant workforce. Universities should be encouraged

to develop such designation and recognition schemes with partner NHS Trusts. It was also noted that the NIHR CCRN provided approximately 3,500 clinical sessions in support of research in England in 2011–2012, some of which are allocated to those working in non-teaching hospitals.

Infrastructure support for competing successfully for grant funding has also been developed significantly by NIHR. The Research Design Service has regional offices that cover the whole of England with the remit of helping relatively inexperienced applicants to develop successful grant applications, including formulating research questions, building a team, involving patients and carers, designing a study, utilising appropriate methodologies and identifying suitable funding sources.

In addition to providing research infrastructure support, the NIHR also acts as a major research funder, with a wide range of grant schemes (and support for research units and centres) that interface with those of other funders (notably the Medical Research Council) to provide support throughout the whole innovation pathway from invention, through evaluation and adoption, to diffusion.

Training, mentoring and supporting research-active staff to deliver high-quality, applied health sciences research of direct patient benefit and developing a culture across trusts in which research and innovation are embedded in routine clinical services are essential to any strategy to develop research capacity in the NHS. As noted above, allocating dedicated research sessions to clinicians, engaging the trust board and clinical body, developing research facilitator posts within research offices associated with specific clinical groups to aid grant development and project management, and rewarding and incentivising clinicians in consultant job planning are all essential components of a successful strategy, and examples of each of these were noted.

National societies have had a key role, even when not acting as research funding bodies. Thus, the British Society of Gastroenterology (BSG) submitted its top 13 research questions to the NIHR Evaluation Trials and Studies programme (NETS). Engaging with its constituency in this manner facilitated the on-time recruitment of 3,400 patients to an endoscopy-based study of Barrett's oesophagus at 110 sites. However, the BSG also identified the pressures of research and development bureaucracy, lack of incentives and time pressures as probable barriers to developing research capacity in the future, possibly also contributing to the observation that academic appointments in gastroenterology have proved unpopular. Whether this is because the craft nature of the specialty restricts the extent to which parallel academic and clinical training can be pursued is uncertain, but the RCP has a key role in addressing the challenge.

By contrast, national charities, such as Arthritis Research UK, have been able to enhance the landscape by funding research capacity and funding infrastructure. In part, this has involved harnessing the power of clinical data via centralised informatics resources coupled to biobanks. Arthritis Research UK has also nominated six centres undertaking pharmaceutical trials: two are evaluating the use of devices in osteoarthritis and one is developing an investigation of childhood arthritis. Such a national

strategy for developing research infrastructure, as well as support for eight clinical studies groups (CSGs) led by senior investigators, has engaged UK industry and other funders. The expensive nature of trials, limited numbers of patients and an often-challenging recruitment environment have been the drivers for these developments, which are aimed at providing more rapid, streamlined and cost-effective pathways to deliver robust outcome measures that lead to improved patient care resulting from both observational studies and clinical trials. It is clear that, in the future, identifying the best question to be asked about a specific intervention for specific disorders will take on further prominence and the move towards stratified medicine remains a key driver.<sup>6</sup>

## Concluding remarks

Significant progress towards transforming the UK clinical research infrastructure has been made since 2006, although research activity varies across disease areas. An imbalance within specialties in terms of patient need and academic activity needs to be addressed, particularly by research funders. National specialty societies can assist in advising funding bodies in this regard. Some charities have been able to enhance the landscape by building people capacity, harnessing the power of clinical data and providing infrastructure. Engagement of trust boards, empowering local research champions and improving the capability of information systems are essential prerequisites for progress.

Research and development bureaucracy, lack of incentives and time in job plans remain barriers to research participation for some clinicians, but in many organisations NIHR infrastructure, leaner research approval systems and training and research funding opportunities offer unrivalled opportunities for clinical engagement and patient participation in research that are not only the preserve of those working in, or treated by, major teaching trusts.

The vision of improving the health and wealth of the nation is being realised. Close collaborative working between a wide range of stakeholders, including Royal Colleges, funders and specialty societies, is key to building on what has been accomplished so far and the physician's role remains central to making further progress.

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