Open Peer Review on Qeios

Maintaining Research Activity amidst Competitive Tendering of NHS Services in England

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Abstract

For the past ten years, the UK Government has attempted ‘to improve the health and wealth of the nation through research’. Investment into the NIHR and its CRNs has helped make the healthcare system safer, more effective and cost-efficient, as well as improve the research agenda. However, due to commissioning and the service contract tendering process, changes in contract provider (specifically to non-NHS organisations) can hamper ongoing clinical research, affecting both organisations and patients. This paper explores the issues and discusses next steps in the continuity of research activity.

The NHS has a long history of delivering leading edge research in the UK.[1],[2] Approximately ten years ago, concerns regarding both funding and co-ordination of research activity led to the development of the UK Government’s research strategy *Best Research for Best Health*.[3]This strategy set the vision ‘to improve the health and wealth of the nation through research’ and led to the formation of the National Institute of Health Research (NIHR). A recent Department of Health commissioned review reported that the NIHR had been successful in enabling NHS and government funded research to flourish, as well as research funded by other sources such as charities and industry. This one billion pound investment in the NIHR has led to improvements in the health of the nation; has helped make the healthcare system safer, more effective and cost-efficient; as well as putting patients at the heart of the research agenda.[4]It has been estimated that in financial year 2014/15, NIHR supported research activity through its clinical research networks generated £2.4 billion of gross value added and almost 39,500 jobs in the UK.[5]

At such a time of significant investment in both research infrastructure and activity, the NHS in England has undergone major commissioning and structural changes, which we argue have had the unintended consequence of severely hampering the research achievements of the last ten years. One key change has been that NHS services are now subject to a process of procurement through a commissioning process enshrined in the *NHS Procurement, Patient Choice and Competition Regulations 2013* under the relevant sections of the *Health and Social Care Act 2012*.[6]

There are three main commissioning structures through which healthcare is procured: Clinical Commissioning Groups (CCGs), Local Authorities, and Specialist Commissioning through NHS England. The CCG 'any qualified provider' option allows patients to choose treatment options from an approved list held by their CCG. Alternatively, an open and competitive process of tendering through any of the commissioning structures outlined above permit the award of a contract to a single provider. Finally, a 'single tender action' applies if commissioners are satisfied that there is only one capable provider. The competitive approach is not a wholly new phenomenon. Since 1991, previous governments have attempted to open up the provision of 'healthcare' (rather than just the provision of products to the NHS) to market forces by establishing a purchaser-provider split, encouraging a diverse provider market and then putting services out to competitive tender.[7]

There is evidence that NHS services in England are increasingly funded through a process of open competition and are provided by a range of third sector private, non-statutory or social enterprise organisations. The NHS Confederation has calculated that the percentage spent directly on independent providers and private contractors of care in England is in the region of 34 percent, although it should be emphasised this figure includes spending on independent contractors to the NHS, i.e. GPs, pharmacists, dentists and associated prescribing costs.[8]An investigation by *The BMJ* found that since the *Health and Social Care Act* came into force in April 2013, private sector providers have secured a third of the contracts awarded to provide NHS clinical services in England. Its analysis of 3494 contracts awarded between April 2013 and August 2014, disclosed to it by clinical commissioning groups from Freedom of Information Act requests, showed that non-NHS providers secured 45% of contracts. The analysis showed 33% were awarded to private sector providers, 10% to voluntary and social enterprise sector providers, and 3% to other types of provider, such as joint ventures or local authorities. 55% of contracts were awarded to NHS providers – a category which includes NHS hospitals, community and mental health providers, and general practices.[9]More recent analysis for the year April 2018 to the end of March 2019 found the total value of the contracts awarded was £4.9 billion and that the private sector won over 51% of the contract awards by number, which equated to just over 65% of the total value of awards, amounting to just over £3.2 billion.[10]

Such a plurality of providers now providing NHS-funded services raises serious implications for existing research projects continuing once the contract has been assumed by the new provider. There is some evidence that the pace of change of re-tendering NHS services and the growing trend for non-NHS organisations to win these contracts has hampered clinical research, in part because many of these organisations do not have the indemnity required to carry out clinical trials, and thus there is a risk existing clinical trial sites are closed when service provision is taken over by a non-NHS provider.[11]Also, at the time of writing, the Health Research Authority (HRA) does not offer a research approval service to non-NHS organisations. A key objective of the HRA is to protect and promote the interests of patients and the public involved in health and social care research through providing a uniform process of research governance approval for all NHS provider organisations.[12]Consequently, there is a risk of research infrastructure and governance processes in non-NHS organisations that are not of an equivalent standard to those in the NHS.

We argue that the plurality of healthcare providers with varying degrees of organisational research knowledge, infrastructure, processes and capacity leaves patients either at risk of being denied the opportunity of participating in

research or becoming involved in research without the safeguards afforded to them by HRA processes. Worse still, it could mean that patients are denied an opportunity to continue with a clinical intervention as part of a research study if a new healthcare provider is unwilling or unable to fulfil the governance requirements at the point of contract transfer.

In 2016, NHS England divided the country into 44 footprints known as STPs (sustainability and transformation partnerships) to bring together NHS, local authority and other health and care organisations to collaboratively determine the future of their health and care system.[13]The stated evolution of STPs is to move to "accountable care" structures, which the NHS England Chief Executive Simon Stevens stated in 2017 "will, for the first time since 1990, effectively end the purchaser-provider split".[14]However, as stated above, tendering of NHS services continues and an unintended consequence of the NHS procurement process in England has been both a cessation of existing research activity at point of contract handover, and uncertainty as to whether non-NHS provider organisations are able to demonstrate an equivalent standard of governance - including obtaining indemnity cover. NHS England have acknowledged that, aside from the issue of tendering, commissioners are not routinely following guidance to fund research treatment costs, thus, inadvertently hampering research activity.[15]

Therefore, there is a pressing need for commissioning guidance pertaining to research activity that is applicable to all providers of healthcare. To ensure research continuity at the point of contract handover, we would suggest a requirement for qualified providers to demonstrate evidence of indemnity for research activity, underpinned by named management expertise with knowledge, skills and experience regarding research governance of applied health research. Qualified providers should also be encouraged to provide a written commitment within their tender response to continue existing research activity upon successfully being awarded a contract. Regarding commissioner responsibilities, there should be a commitment to fund research treatment costs, and a contractual commitment to undertake research should be embedded within service specifications at the point of procurement. At the stage of tender response, commissioners should ensure that qualified providers are able to demonstrate research governance capabilities. Through its consultation on the NHS Standard Contract, there is currently an opportunity for NHS England to make such changes, which would have the potential to lead to substantial benefit for patients.[15]

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