How can clinical research remain a central mission for the NHS as we emerge from the pandemic?

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About the Authors

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The team also draws upon the expertise of Dr David Landau, Senior Fellow

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Realising the Research Effect

As system attention shifts away from the pandemic and towards recovery, clinical research may find its voice diminished in wider NHS policy. In this long read, Policy Exchange assess what can be done.

The research effect is well known. Better patient outcomes, improved clinician job satisfaction and wellbeing, increased staff recruitment and retention as well as increased investment. But more fundamentally, clinical research is the most important route to improving healthcare delivery – by identifying the best way of preventing, diagnosing, and treating conditions.

The COVID-19 pandemic has demonstrated the difference clinical research can make. The RECOVERY trial was conceived of as two academics Prof Martin Landray and Sir Jeremy Farrar rode the Number 18 bus between Euston and Sudbury in early March 2020. Two years later, RECOVERY has recruited 45,000 participants, and led to the identification of two viable therapeutics for hospitalised COVID patients that are now commonly used. Just as importantly, the trial provided definitive conclusions about the efficacy of other debated treatments such as hydroxychloroquine. Coupled with the vaccine rollout, these scientific breakthroughs have helped chart the course out of the pandemic. That single bus ride might have saved more than a million lives.

Yet despite these successes, the pandemic has also created stiff headwinds. Non-covid clinical trials were paused, and then faced delayed re-starts and sluggish enrolment. This, coupled with losses to fundraising incomes for charity-funded research, has impacted patient access to new treatments. And whereas those designing RECOVERY showed a willingness to tear up convention, other COVID trials suffered from poor design and duplication of effort. Beyond trials and observational studies, the ability of healthcare systems such as the NHS to consistently disseminate research insights and then translate these into routine patient care also faces challenge. The rate-limiting factor is the lack of capacity and workforce in the system. The risk is that research becomes the first thing to be scaled back in response to operational pressures such as general practice, A&E, and elective care, with ownership of the agenda retreating to a few 'islands of excellence' – commonly characterised as urban, university affiliated teaching hospitals with National Institute for Health Research (NIHR) infrastructure.

How can the research community continue to demonstrate its contribution as part of the wider policy debate? What can be best done

to build different types of research capability across the country, without 'levelling down'? And how can we capture the sense of partnership working and pragmatism which defined successes during the pandemic, and apply that to a wider set of healthcare challenges? This was the starting point for a project launched by Policy Exchange in 2021 and delivered in partnership with GlaxoSmithKline and AstraZeneca. We brought together a group of leaders in the clinical research community for a discussion prior to Christmas to scratch at these themes and identify proposals to move the agenda forward.

Home truths

As we consider the possible policy solutions, two fundamentals should be acknowledged:

- **New staff and funded research roles won't suddenly materialise.** Countless reports have identified insufficient staff capacity as the biggest constraint on clinical research. The message has been heard by Government. Whilst it is important that time for research career pathways feature prominently in the upcoming 15-year workforce strategy, the sector must not pin their hopes on a single strategy from Whitehall providing the answers. As one roundtable attendee said, "there is no army of nurse researchers waiting to be deployed, no matter how much resource is available". Proportionate energy must instead go towards creative ways of creating capacity in the system.
- **Extra Government funding is unlikely.** October's three year Spending Review confirmed a £5bn settlement for health research, with DHSC R&D budget reaching £2.0bn per year by the end of this Parliament. The overarching commitment to fund £22bn in R&D spending was pushed back to 2026. This offers helpful clarity after a spate of one-year spending rounds since 2016. But it also clearly defines the envelope for the sector. The pressures on wider Government spending are immense – from net zero and the cost of living to the backlogs in criminal justice and education. In this wider context, calls for extra funding for health research may fall on deaf ears.

With limited staff and not much money, what can be done? Several practical suggestions emerged from the discussion. These are implementable, would incur only moderate costs, and could be delivered within an acceptable timeframe.

1. Streamline the approach to recruit and enrol patients, and to set up studies.

Evidence demonstrates that research still often takes too long to get off the ground, with delays and unwarranted variation across different sites and stages. The solutions fit into two categories: better and more pragmatic trial design (both commercial and non-commercial), and secondly the position of trials within the care pathway.

With the former, there are opportunities to learn from the successes in the pandemic. Elements of the design of RECOVERY: a flexible 20-page protocol, accelerated ethical approval, straightforward recruitment and swift data collection and publication could be applied to other trials, although this won't be universal. Other simple innovations – consolidating the e-learning for healthcare professionals into a small number of 5-minute videos – made a difference to engagement across trusts. National government should take a leadership role in nurturing pragmatic design behaviours and removing existing barriers to identifying patients. It feels odd, for example, that a healthcare professional involved in running a trial is prevented from accessing the health records of a patient outside of their care who might benefit, even if they are being treated in the same hospital.

On the latter, more needs to be done to bring the 'research door' to the front of the pathway. Whilst the arguments around emulating the opt-out arrangements found in other areas like organ donation or pensions are fraught with political risk, there are more modest steps which could be taken to make existing rules and guidance more permissive. The recently announced consultation on clinical trials legislation demonstrates the Government is looking at this area seriously, as does wider initiatives such as Our Future Health which aims to combine the health records with blood samples of 5 million UK adults Changing the consent mechanism to reflect new models of care, for example the higher proportion of remote outpatient appointments could be accompanied by an assumption of 'consent to contact' about research by the care-giving organisation. These would not be controversial for patients in the way that assumed consent for research on healthcare data evidently is.

2. Embrace creative thinking on the workforce.

With shortages of FTE research staff likely to be prolonged, extra capacity may be identified in the form of the voluntary sector. This is already being used by the NIHR Clinical Research Network, which has drawn upon two different cohorts of volunteer in supporting studies: medical students, and those in higher education, and then the NHS Volunteer Responders scheme. The wider contribution of volunteers to the pandemic response is clear - 90,000 people have given their time to the vaccine rollout – already contributing a cumulative 1.1 million hours. The motivation of these people (many of them skilled retirees) to make a difference to the health and care of their communities is an asset which could be mobilised

for clinical research across a variety of roles – from supporting with trial setup and data entry to everyday assistance such as driving participants to study sites. This would require pragmatism in areas such as GCP training, and the use of different 'bands' to ensure that the roles appeal to different types of volunteers.

Whilst potentially exciting, we must be realistic about the limitations of this idea. Attendees at the roundtable remarked that volunteers will not be able to backfill the research vacancies which are numerous much like other areas within the NHS. Nor can a temporary and unpaid workforce be expected to setup and run studies to professional standard or consistency. But if we can define the opportunity in narrow, targeted terms, then volunteer capacity, alongside patient empowerment, and real-time data transfer and automation, could help research infrastructure can weather the storm.

3. Be an effective and adaptable partner to the NHS (in its many guises).

Many participants in our discussion reflected that too often, research feels like an 'ask' of clinical teams as opposed to a joint endeavour. Given the existing pressures, those operating in front line clinical roles will be legitimately asking: "How is this study going to help improve the health outcomes of the population I am responsible for?" It is the responsibility of the research community (including the pharmaceutical industry) to accept this challenge, designing propositions which are attractive to partner organisations, especially those lacking research pedigree. This includes 'docking' with other elements of the NHS transformation agenda. If the Government has made hospital building a manifesto priority, how can we ensure that these new facilities also lead to a step change in clinical research, rather than building more of the same? This was a key theme from the recent Wolfson Economics Prize which invited radical new thinking on hospital design.

We also need to be open minded to the types of research undertaken in different places. Whereas somewhere like Moorfields has world-leading capabilities in gene therapy, it was traditional District General Hospitals such as West Suffolk, Great Yarmouth or South Tees that were able to enrol the highest proportion of patients into applied research studies for COVID-19 therapeutics. We need to find a way of achieving balance in how research activity is ranked and appraised so that these specific strengths develop in parallel, without falling into the trap of developing a strategy which tries to replicate the same thing, everywhere.

Taking the long-term view

The last two years have shown that research is an integral part of clinical care. But the future feels more uncertain. As we look to the next few years, the NHS will have to become accustomed to 'split screen' thinking as it manages the transition to new Integrated Care Systems whilst dealing

with the backlogs across every specialism. Research must fight to ensure it remains central to the equation. This article has outlined some policy suggestions, but the agenda requires political leadership too. As we have outlined before, successive Governments deserve their share of credit for backing the sector and taking the long-term view. This patient approach must continue under the current Health and Social Care Secretary. If it does, he will find that the benefits – much like London buses – are multiple and far reaching.

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