



Ten Years of the NIHR: Achievements and Challenges for the Next Decade 23rd Annual Lecture

Professor Dame Sally C Davies

7 November 2016
Royal College of Physicians
London

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About the Author

Professor Dame Sally C Davies FRS FMedSci

Dame Sally was appointed Chief Medical Officer (CMO) for England and Chief Medical Advisor to the UK Government in March 2011, having held the post on an interim basis since June 2010. Dame Sally is an independent advisor to the UK Government on medical matters, with particular responsibilities regarding Public Health.

From 2004-2016, Dame Sally was the Chief Scientific Adviser (CSA) for the Department of Health (DH), where she was actively involved in NHS R&D from its establishment and founded the National Institute for Health Research (NIHR). In 2013, Dame Sally became a Non-Executive Director of Genomics England Ltd, wholly owned and funded by DH, to sequence 100,000 whole genomes from NHS patients by 2017.

Dame Sally was a member of the World Health Organization (WHO) Executive Board 2014-2016 and has led delegations to WHO summits and forums since 2004. She advises many governments and organisations on health and policy, holding positions on a number of Boards.

In March 2013, Dame Sally published her 2011 CMO annual report on infectious diseases. The report brought to light the increasing threat of antimicrobial resistance (AMR), calling for national and international action to address key areas including stewardship, monitoring and surveillance, and antibiotic development. Dame Sally continues to advocate globally on AMR. She has spoken on AMR at numerous events including, the World Health Assembly side event in 2013, the G8 Science Ministers' meeting in 2015, the Global Health Security Initiative in 2015, and the UN General Assembly side event in 2016. She was chair of the 2013 AMR forum at the World Innovation Summit for Health (WISH) and is chair of the WHO Strategic and Technical Advisory Group on AMR. She has raised public awareness of AMR through for example, the publication of *The Drugs Don't Work* book and a TED talk.

Dame Sally received her DBE in 2009. She was elected Fellow of the Royal Society in 2014 and a member of the National Academy of Medicine, USA in 2015.

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1. Introduction

The National Institute for Health Research (NIHR), created in April 2006, is a "virtual" organisation often referred to as the research arm of the NHS. It funds health and care research in the UK, translating discoveries into practical products, treatments, devices and procedures, involving patients and the public in all its work. The NIHR also ensures that the NHS is able to support the research of other funders, thereby encouraging broader investment in, and economic growth from, health research. The NIHR works with charities and the life sciences industry to help patients gain earlier access to breakthrough treatments and it trains and develops researchers to keep the nation at the forefront of international research (NIHR, 2016). Dame Sally Davies and Dr Russell Hamilton were the driving forces behind creation of the NIHR.

This year's OHE Annual Lecture traces the development and impact of the NIHR, including the challenges in establishing it; describes how the NIHR has helped create what the US Institute of Medicine has termed a "learning health care system," (IOM, 2013) including the use of "Big Data" and gathering "real world evidence"; discusses how to demonstrate the value, in terms of both health and wealth, of major NHS investment in R&D; explores how to keep the UK punching above its weight in both public and private biomedical research expenditure and output; discusses NIHR's efforts to increase the number and appreciation of women in science using the Athena SWAN initiative; outlines lessons for both high income and middle income countries about organising health system R&D; and, finally, examines the development of UK research capability in sequencing the human genome and translating the results into clinical practice.

2. Challenges in Establishing the NIHR

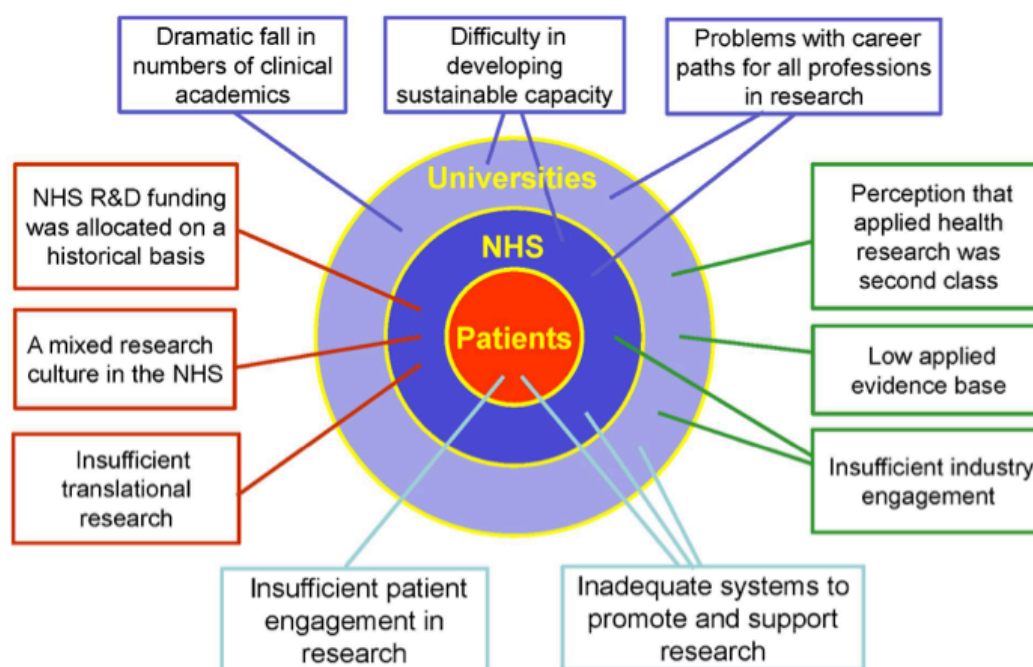
When I became Director General of Research and Development for the Department of Health in 2004, the government did not have a reason to be committed to science in the NHS. It was committed to a minimum level through the Research Councils, but the need to do more was not appreciated. Fortunately, a series of Permanent Secretaries did understand that our ultimate objective was to improve health outcomes through advances in research, not only by developing needed evidence, but also by improving care for patients in research active environments. I argued, in addition, that the NHS and the Department of Health could help strengthen our international competitiveness and drive economic growth and thereby increase both health and wealth. Although today the intersection between health and wealth is generally accepted, it was a new concept a decade ago. Embracing this concept at the outset of the NIHR allowed us to embed it into our activities and ensure that the metrics we collect capture the importance of the connection and the progress made. As we all know, what gets measured gets done.

As a result of a House of Lords report in 1988 on priorities in medical research, the NHS Research and Development programme was initiated in 1991 (House of Lords, 1988). This first effort to coordinate R&D in the NHS had a strong start, with then-substantial funding of about £150 million a year. Shortly thereafter, the Culyer Report, published in 1994, set out a comprehensive strategy for

research funding in the NHS, including the identification of expenditures that had been buried in patient costs (Culyer, 1994). By 1997, the funding streams were combined into the NHS R&D Levy. When we began planning for the NIHR, however, funding allocations still were not optimum; changing those was a key challenge.

We faced numerous other challenges, summarized in Figure 1. Our top teaching hospitals did good research in the 1980s and 1990s, but had not kept pace with changes in the clinical research process that began to focus on team and platform based approaches. In addition, the number of clinical academics had declined as students chose careers in molecular medicine rather than clinical, evaluative research. In part, this reflected a problem in the career paths for clinical research; other options offered more promise.

Figure 1. Challenges Ten Years Ago



Source: R&D Directorate (2006), p. 42

Applied research was viewed as second-class, something that the best and brightest just did not do. Perhaps partly as a result of this, the evidence base for the importance of applied research was scant. Although the NHS R&D programme encouraged patients to participate in research, the level of participation was low. Basic research was poorly translated, missing important benefits for patients. Engaging with the life sciences industry in any way was rare: “industry” was still a dirty word. Strategic coordination across funders was insufficient.

Another crucial challenge was changing the attitude of universities, which too often assumed that the NHS would provide substantial funding for research that might have little, if any, relevance to NHS needs, and sometimes even to the original request for funding. The assumption

was that the researchers knew best, and the NHS should be kept at arm's length. This was not a relationship of respect and equality.

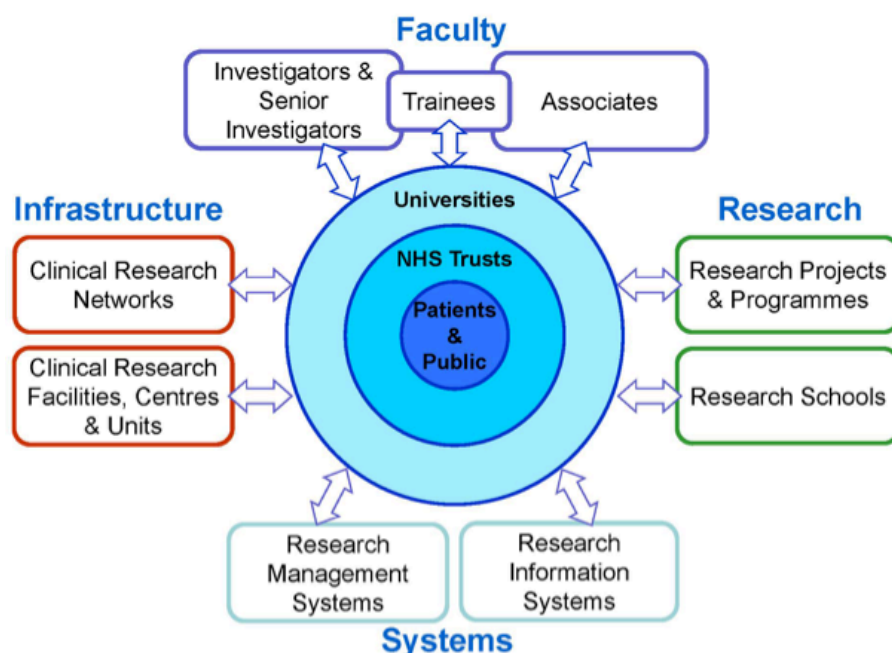
The idea for the NIHR was developed during 2004 and 2005 with my team in the Department of Health, led by Dr Russell Hamilton, Director of Research and Development. After extensive consultation with a wide range of interested parties, we created a strategy. Not everyone agreed with us: we were proposing to change funding allocations to ensure that funds support high-quality research. When we discussed the strategy with the then Secretary of State, Patricia Hewitt, she immediately understood its importance; she became a staunch advocate and made it government policy.

The strategy, which is still relevant and active today, is called Best Research for Best Health, published in 2006 (R&D Directorate, 2006). Our plans, as set out in a draft document, did change somewhat after consideration by the Cabinet and formal public consultation. Although the original plan was not intended to focus solely on the medical, adaptations after the consultation process made it even more general and less medical.

What we envisaged was integrating a health research system into the health care delivery system so that the two would become interdependent and synergistic. The NIHR would do those things that only government should do, for example, fund the Faculty for Education and Skills Development, and fund much-needed upgrades and modifications in the research infrastructure in the NHS. As government, our role also would include funding and standardising system aspects such as ethics committees and information systems. Government also should fund patient-based research where there was market failure—for example, a study of early mobilisation compared to lying still for back pain, or physiotherapy versus strapping for knee ligament treatment.

Over the last ten years of its development and today, the NIHR has been clear about its mission: improving the health and wealth of the nation through research. The NIHR acts as a health research system, that allows the NHS to support outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public.

Figure 2 is a schematic of how the NIHR system is intended to work: each part of the system supports the other, ultimately translating the knowledge from basic research into benefits for patients.

Figure 2. NIHR: A Health Research System

Source: NIHR (2015), p. 8

A set of stated principles guides the NIHR, describing its approach to funding research: transparent, competitive, high quality, high relevance, value for money, focused on delivery, working in partnership. These criteria would eliminate, for example, an otherwise high-quality grant application from a top professor that, say, focuses on a procedure so expensive that it is unlikely to be covered under the NHS. For the NIHR, such research would not provide enough value for the money expended.

Partnerships were meant to be inclusive: between government, charities and industry; between the NHS and universities; between research leaders and research facilitators; across different health care professions and research disciplines; and between researchers and patients. Many critics thought this was just not worth trying or that our plan was to draw funding from hospitals and spend it in opaque ways. Some resisted the change to the old order, where lead researchers were regarded as superior and those clinicians who contributed patients or data were not recognised fully when, in fact, research could not proceed without them.

An important aspect of our plan was to anchor industry in the UK to attract its involvement and its expertise in translating knowledge into better health care interventions. An essential component of our system is a successful NHS Clinical Research Network that delivers on its promises. Of course, the infrastructure has a far wider role: charities, Research Councils, and a wide range of others depend on the infrastructure we fund. NIHR works closely with other research funders through, for example, the Office for Strategic Coordination of Health Research. In 2013, we helped establish, and continue to help fund, Genomics England, which is intended

to further medical innovation by sequencing 100,000 whole genomes from NHS patients and their families who have rare diseases and cancer. By integrating the health research system NIHR can identify what research is most needed, thus minimizing the prospects for market failure, i.e. not having the research needed to provide the best care possible under the NHS.

3. The Learning Health Care System

Clinical Practice Research Datalink (CPRD) has its origins in the General Practice Research Database established in 1987. CPRD provides anonymised primary care records for public health research (CPRD, 2016). Beginning in 2012, the NIHR and the Medicines and Healthcare products Regulatory Agency (MHRA) have co-funded and expanded the CPRD. This non-profit research service enables researchers and the life sciences industries to access linked, and bespoke, datasets from several NHS data sources. The longitudinal database includes 21 million patient lives collected over 25 years in 1.8 billion consultations. Data collected include prescription drug exposure, diagnoses and symptoms, referrals, laboratory tests, vaccination history and demographic data.

The CPRD has gone from strength to strength, providing data for over 1,600 peer reviewed publications, many from the commercial sector. Most recently, the CPRD has provided support for a pragmatic trial on diabetes, which has required the recruitment of medical practices. CPRD provides real-world patient data extracted from primary care datasets of patient records; that data are supplemented by patient reported outcomes. The first trial of its kind globally was sponsored by AstraZeneca; it demonstrates how the UK can contribute to advancing research efficiently and cost effectively.

CPRD has been building its data products and has started to receive pilot data from EMIS and SystmOne practices in general practice and, if that goes well, we hope to build on it. They have released three new linked data sets based on this new data since March 2016. So now CPRD have routinely linked data sets for research available on a quarterly released schedule.

Five of the large NHS Trusts with large NIHR Biomedical Research Centres (BRCs) agreed to participate in the NIHR Health Informatics Collaborative (HIC) to make NHS clinical data more readily available to researchers, industry and the NHS community. This focuses on five therapeutic areas: viral hepatology, acute coronary syndromes, ovarian cancer, renal transplantation and critical care. This collaboration allows the HIC members to create cohorts across multiple institutions rapidly and to draw much, or all, of the required clinical data directly from information systems, thus substantially reducing study costs.

The HIC has greatly improved interoperability across databases and has improved the quality of data—both completeness and consistency—and enhanced data availability through better automation and governance. The Trusts involved are Oxford University Hospitals NHS Foundation Trust, the Cambridge University Hospitals NHS Foundation Trust, Guy's and St Thomas' NHS Foundation Trust, the Imperial College NHS Trust, and the University College London

NHS Foundation Trust. The collaboration is evidence that the large hospitals and academic colleagues now understand that modern research is not about competing—except perhaps for grants and other research funding—but about cooperating to ensure that the patients and the data available can provide valid, valuable results.

The NIHR HIC was one of four government-funded initiatives included in the launch of the Health Data Finder (HDF) earlier this year. The other partners are the NIHR, CPRD, NHS Digital and Public Health England. The impetus came from the Ministerial Industry Strategy Group, which is co chaired by a minister and a senior executive from a major pharmaceutical company. The Health Data Finder for Research allows researchers to determine what UK health care data sets are available and directs them to custodian experts who can grant access to the data. Its objective is to increase collaboration among data controllers, streamlining and harmonising their approaches. Plans are in progress to expand the data with prescribing data from the NHS Business Services Authority, likely available in 2017. Data controllers now are actively seeking out the HDF with offers to include their data.

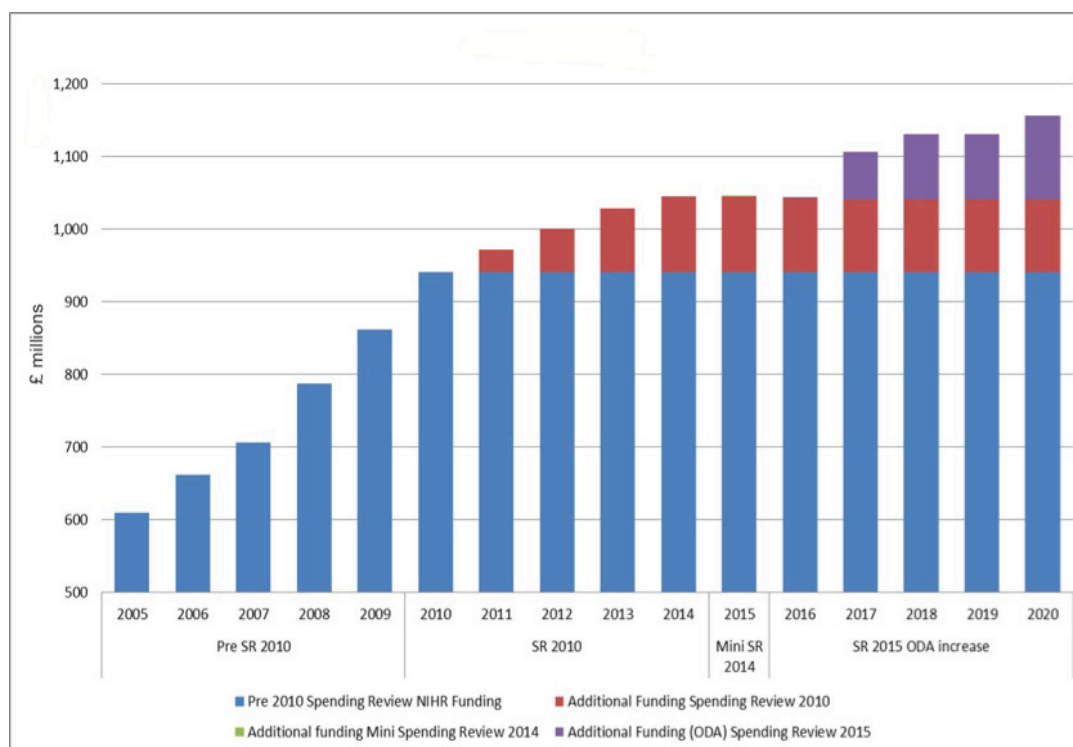
The next steps are to implement the shared metadata catalogue with catalogue tools for local deployment; expand data sets to agreed therapeutic areas, specifically breast, lung, colorectal and prostate cancers, in tandem with the 100,000 Genomes Project; and continue work on improving functionality and coordination.

A somewhat different kind of database is the NIHR Central Research Study Portfolio Management System. Developed and managed by the NIHR Clinical Research Network Coordinating Centre, this provides up-to-date, nearly real-time, access to information about research activities undertaken or supported by the NIHR.

What the NIHR continues to do, then, is facilitate high-quality research by helping researchers identify the appropriate data sources and navigate the bureaucracy for gaining access. Protecting patients by managing access to their data is essential, and must be done properly, but it also must be done as simply as possible, avoiding unnecessary delays for the researcher.

4. Demonstrating the Value of Major NHS Investment

One indicator of the perception of the value of the NIHR is the increase in the funding it has received. In 2004, my budget was just £150 million. Over the next three years, we released over £400 million from the NHS that we transformed into competitive funding. In Figure 3, the funding for the NIHR before the 2010 spending review is shown in blue. The orange bars show the additional funding after that review. The new funding in purple is government-mandated assistance for official development assistance, known as ODA: both the NIHR and the Research Councils provide additional funding that may fund research in UK universities, but the ODA projects must address topics relevant in the developing world.

Figure 3. NIHR Budget, 2005-2020, in £m

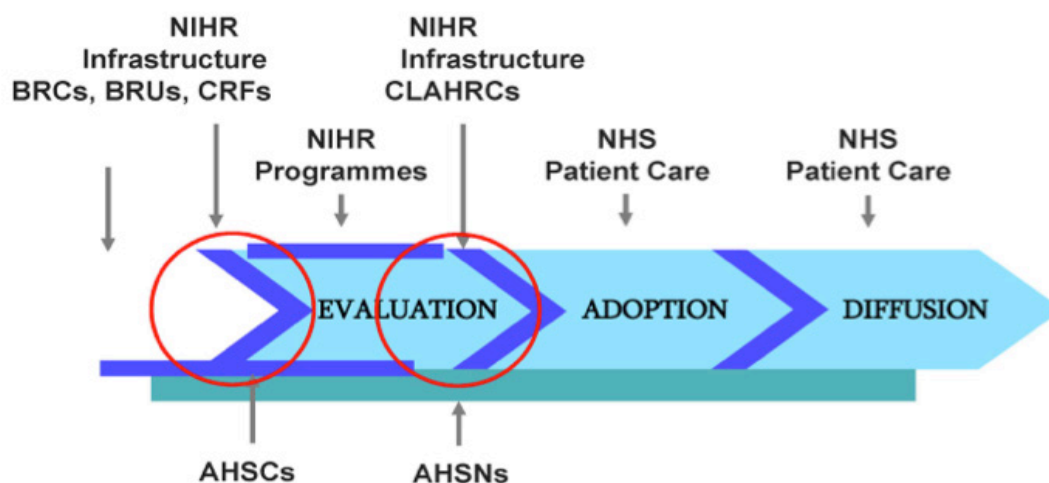
The NIHR already has achieved much by creating a health research system, as shown in Figure 2, replacing an outdated and inefficient ad hoc approach. Treasury has been convinced enough of NIHR's value to continue to fund it. Perhaps most exciting is that the NIHR has developed a new cadre of researchers who work within the system and benefit from its funding.

Infrastructure is critically important. The role of NIHR funding in shaping and maintaining that infrastructure is summarised in Figure 4. This figure may seem overwhelming, with all the acronyms, but the concept is clear: a managed clinical research infrastructure that bases spending on desired outcomes and holds researchers responsible for producing results.

The NIHR Research Infrastructure provides world-class research facilities, staff and resources to support research funded by other sources, including industry, charities and other public (non NIHR) research funders. The NIHR funds infrastructure through open competition. Following the recent open competition, the NIHR has designated and funded a third round of BRCs within 20 of our leading NHS and University partnerships to drive progress on innovation and translational research in biomedicine into NHS practice. These NHS/University partnerships, receiving NIHR BRC designation and funding, are those which have a substantial portfolio of world-class biomedical research, existing critical mass, a significant number of research leaders, and a wide range of underpinning facilities.

Figure 4. NIHR Research Infrastructure and the Innovation Landscape

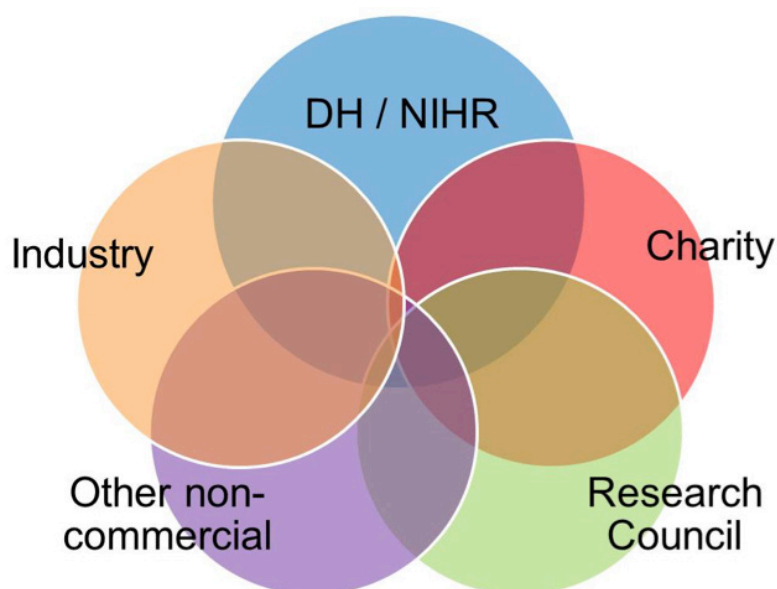
Bridging the gaps



AHSC: Academic Health Science Centre; AHSN: Academic Health Science Networks; BRC: Biomedical Research Centre; BRU: Biomedical Research Unit; CLAHRC: Collaboration for Leadership in Applied Health Research and Care; CRF: Clinical Research Facility

Figure 5 shows the sources of infrastructure spending and the importance of the portion provided by the NIHR. As an example, the NHS cost of research funded by charities comes from the NIHR. Managing such research is expensive. The Research Councils also rely on NIHR infrastructure spending, as do non-commercial entities other than charities. The life sciences industry provides funding and benefits as well. We have progressed through many stages with these networks, but at each stage their capacity and capabilities have improved.

Figure 5. NIHR: A Health Research System



The Clinical Research Network (CRN) was an NIHR innovation. NIHR's CRN began with six discrete networks focused on specific topics, which were chosen by the ministers. Although this arrangement did produce results, about five years ago the groups were reorganised into 15 Local Clinical Research Networks (LCRNs). The LCRN boundaries now align with those of the Academic Health Science Networks (AHSNs), allowing a more flexible deployment of resources. Budget allocations for each of the LCRNs are based on both the amount of activity supported, including complexity, and on the population of the catchment area.

The extent of activity in just 2014-15 in the CRN is exceptional; the following metrics illustrate this.

- The 618,000 patients recruited in 2014/15 exceeded the 604,000 recruitment for 2013/14. In 2015/16 Guy's and St Thomas' NHS Foundation Trust led the national annual league for recruitment to clinical research with 27,813 patients in studies, a 20 percent increase over the previous year. Ranked first in London, the Trust was second nationally only to Newcastle hospitals for the number of studies hosted—nearly 500. The Trust was one of eight in London that made the top 20. This process is proving to be an extremely effective approach for stimulating health research; every hospital Trust in the country now participates. Recruitment, while increasing and remaining high, is not rising rapidly. The reason is due in part to the growing complexity of studies; those that involve personalised medicine, for example, require screening more patients and fewer are accepted into the studies.
- Nearly 35,000 participants enrolled in commercial contract studies in 2014/15. Acceptance of commercial studies gradually has increased as understanding of their importance and contribution has grown; they also bring economic benefit to the health system. The number of Trusts participating in those studies has steadily risen, reaching 78 percent in 2014/15. Moreover, 41 percent of general medical practices have put patients in NIHR studies, a proportion that also is increasing steadily.
- The process is moving faster: across all study sites, 83 percent of studies received NHS permission within 40 days. This is in part due to NIHR's work with the Trusts to incentivise best practice, improve transparency and use league tables to create competition among them.
- Finally, 52 first global patients and 20 first European patients were recruited in the last two years. That was not happening at all ten years ago.

In 2016, KPMG delivered a report for the NIHR CRN that quantified the economic impact in 2014/15 of research supported by the CRN (KPMG, 2016). It estimated that the gross value added (GVA) from non-commercial research supported by the CRN was £396 million for NHS Trusts and other care providers, and £382 million for universities and lead investigators. In the Trusts, 11,593 FTEs were created and 6,747 FTEs in universities. This is a significant impact

and the analysis will be useful in coming comprehensive spending reviews.

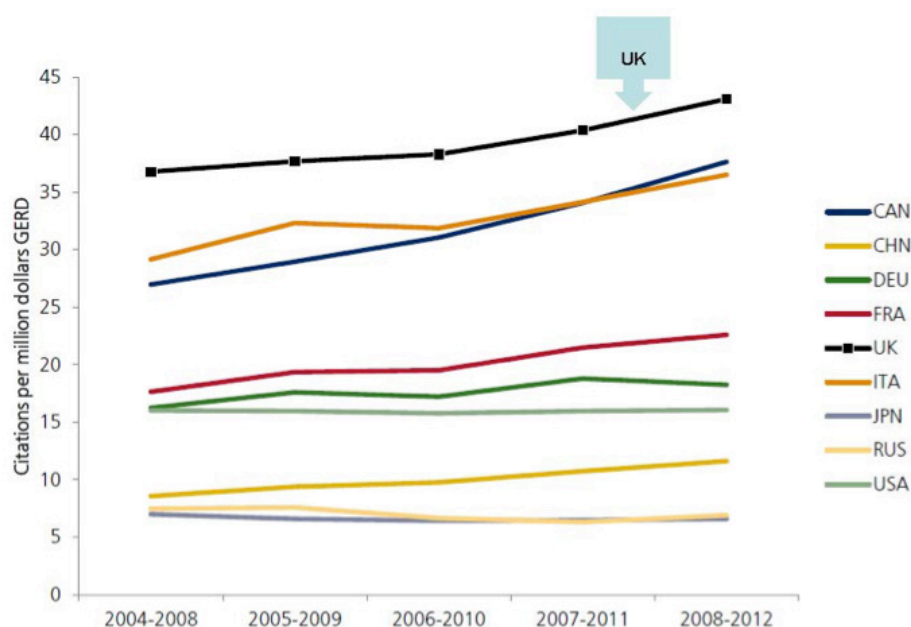
The KPMG report also assessed the impact of commercial clinical research actively supported by the CRN. GVA for NHS Trusts and other care providers was £137 million, and £1.5 billion from investment by sponsor companies and contract research organisations (CROs). Importantly, the employment impact was estimated at 20,755 jobs in the UK economy in 2014/15. This includes over 10,000 direct FTEs in sponsor companies and CROs, and with another 8,000 in indirect and “induced” jobs (KPMG, 2016).

NIHR, then, clearly has had a positive economic impact on the NHS, universities, and life sciences companies in the UK.

5. Keeping the UK Punching Above its Weight

NIHR has a positive impact on the UK’s prominence internationally in research productivity. Figure 6 is based on OECD data and taken from a study by Elsevier for what was then the Department for Business, Innovation & Skills (BIS, 2013). Figure 6 shows citations per unit of gross domestic expenditure on R&D (GERD). The top line represents the UK—which leads the world. To express UK leadership another way: with only 1 percent of the world’s population, we have 16 percent of the world’s most highly-cited articles (HM Treasury and BIS, 2014). This is particularly striking because, of the G7 countries, the UK spends the smallest proportion of its GDP on research. I would very much like to see the industrial strategy increase spending on science and research overall; and particularly more for the Research Councils to support the basic research that contributes both to health and the UK’s leadership role.

Figure 6. Citations per unit of GERD for UK and comparators, 2008-2012



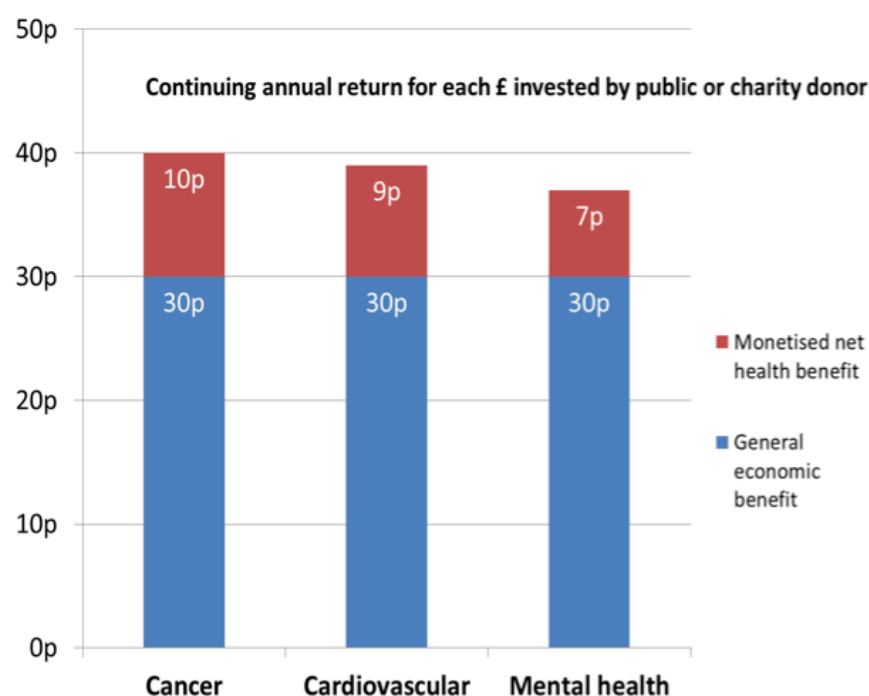
Source: BIS (2013), p. 82

The Research Excellence Framework (REF) is the new system for assessing the quality of research in UK higher education institutions, replacing the Research Assessment Exercise. The REF results published in 2014 offer another indication of the value of the NIHR. Panel A focused on health and life sciences. An analysis of the panel report underlined the major role of NIHR funding (see Kamenetzky, et al., 2014): 92 percent of case studies had regional or national impact, 41 percent had a direct effect on patients, and 45 percent influenced changes in international practice. The reach of NIHR is extensive and important.

Referring again to the KPMG report, our research network alone generated £2.4 billion of GVA and nearly 40,000 jobs in the UK. The monetary benefit to Trusts was also calculated in that report: for each patient enrolled in a commercial study, Trusts receive on average £6,658 and save on average £5,250 per patient on pharmaceuticals. In total, the NHS in 2014/15 received an estimated total of £176 million in commercial income and £16 million in pharmaceutical cost savings across the commercial CRN portfolio (KPMG, 2016). This is a significant amount of money.

An idea of the magnitude of return on investment in research was first estimated in a 2008 study in which OHE participated (HERG, et al., 2008). The methodology has been further refined since and in 2014 additional research was funded. Figure 7 shows results for cancer, cardiovascular disease and mental health: every pound invested produces a net benefit, in perpetuity

Figure 7. Continuing Annual Return for Each £ Invested by Public or Charity Donor



Source: RAND Europe, et al. (2014), p. 3

NIHR has worked to change the system and we have evidence that it is paying off. We achieved results by eliminating unnecessary bureaucracy; encouraging and supporting the researchers of the future; engaging and involving patients, the public and carers through our programme called INVOLVE; finding an appropriate balance between collaboration and competition; working effectively with industry; and stimulating effective interplay in the UK life sciences ecosystem. Our contribution is increasingly recognised. For example, George Freeman, then Minister for Life Sciences, made a point in March 2015 of presenting the NIHR to Parliament as an engine for growth.

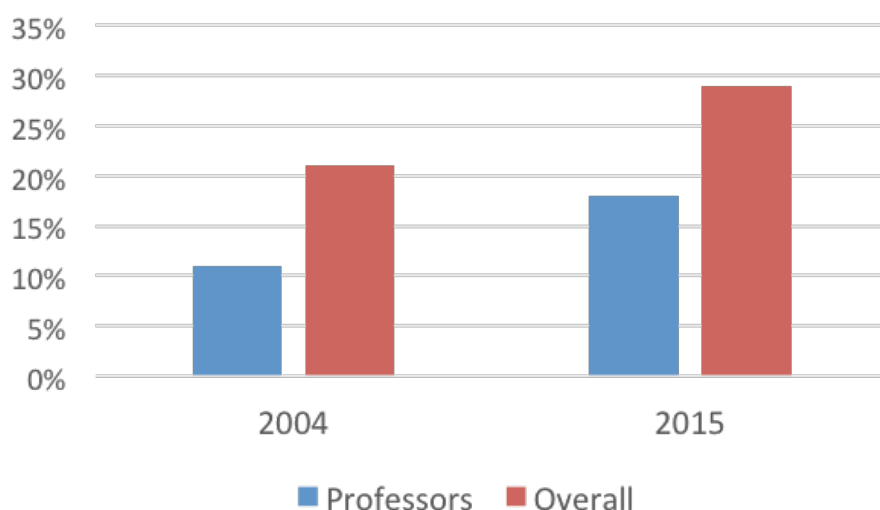
To celebrate the NIHR's tenth anniversary in 2016, RAND Europe produced a report on our impact over the past ten years and into the future. It identifies and celebrates 100 examples of positive change the NIHR has created. The study's key findings show that NIHR is: improving the health of the public nationally and internationally, making the UK's health care system more effective, cost-effective and safer; helping put patients and public at the centre of research; and supporting a robust research infrastructure in the NHS (Morgan Jones, et al., 2016).

6. Opportunities for Women Through Athena SWAN

In the first few years of the NIHR, I too often was the only woman in a room full of men. Foregoing the intellectual contribution of women seemed to me unwise, both from an economic and an equity perspective. After a rather poor response about improving gender equality in the NIHR's second BRC funding competition, we instituted a policy for future competitions for NIHR BRC/Us whereby we would shortlist an NHS or academic partner only if the entity had received at least the silver award from the Athena SWAN Charter for Women in Science. The requirement has had an impact: for the April 2017 BRC funding award, all 20 partnerships had achieved at least an Athena SWAN silver level award. In fact, 22 of our 26 universities now have reached silver or gold at either the university faculty or departmental level.

Figure 8 shows the percentage of women in clinical academic medical careers as of 2015. The percentage of female professors clearly is rising and numbers overall are improving, although progress is slow. One in three of the NIHR's own professors are women.

¹ The Athena SWAN charter was established in 2005 by the Equality Challenge Unit to encourage and recognise commitment to advancing the careers of women in science, technology, engineering, maths and medicine (STEMM) employment in higher education and research. In 2015, it was expanded to include other disciplines and gender equality overall, rather than only for women (ECU, 2016).

Figure 8. Continuing Annual Return for Each £ Invested by Public or Charity Donor

Source: RAND Europe, et al. (2014), p. 3

7. Comparisons and Lessons for Other Countries

Lessons that we might provide other countries include how to involve patients in clinical research not just as subjects, but as partners in research planning and conduct. NIHR has an excellent programme that trains patients to participate in research committees. Patients are represented at every stage of the research process, including on the financial award committees. Responses to our requests for input from patients and carers have been positive and extensive.

Recent data show that clinical research is growing much more quickly in Asia than elsewhere; Europe falls near the bottom of the rankings (KPMG, 2016). There are several explanations for this, not all quite as negative as one might suppose. However, within the UK, research has been increasing in the NIHR BRCs and BRUs, as Figure 9 shows.

Figure 9. Continuing Annual Return for Each £ Invested by Public or Charity Donor

8. Genomics and Health

Genomics is a useful catch-all term for the measurement and integration of information contained in DNA, RNA, proteins and metabolites, including cells, organs or microbial communities. Genomics and epigenetics are beginning to untangle the underlying bases of common, complex diseases. These new approaches, however, undoubtedly will raise new challenges and need to be supported by large, well-designed research studies.

The UK's 100,000 Genomes Project was launched in late 2012 to sequence 100,000 whole genomes from NHS patients and their families who have rare diseases and cancer. The NIHR was closely involved in designing this programme. We successfully suggested that the programme be run by an entrepreneurial start-up company funded by NIHR with the Department of Health as the sole shareholder. A variety of problems, of course, have appeared as the project progresses, but we are confident that our partnerships are strong and that the entrepreneurial approach was the wisest choice.

9. In Closing

Many have contributed much to ensure the growth and success of the NIHR, which in just ten years has dramatically changed the face of health R&D in the UK. The NIHR has become a model for other countries and continues to attract the best and the brightest, helping to maintain an active and pre-eminent UK science base. Its value has been proven qualitatively and quantitatively. All of us involved over the last decade can be proud of our achievements; my thanks to everyone who has been part of it.

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