Clinical research in the United Kingdom: a new era

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UK initiatives to increase clinical research capacity hold lessons for Australia

The historically unmatched boom in medical science knowledge in the past few decades has steadily increased the opportunities for clinical research. Examples include research into biomarkers and diagnostics, evaluation of potential therapies, and particularly translation of breakthroughs in basic medical science into clinical medicine.

Traditionally, it has taken many years to evaluate and validate new treatments, and there is a global need to improve both the capacity and efficiency of clinical research to ensure maximum community benefits in a reasonable timeframe.[1] In the United States, several senators have proposed developing a new umbrella organisation that links pharmaceutical and health care industries — a centre for clinical cure.[2] A program to support clinical and translational science awards has also been launched. In Canada, there is a proposal to develop a taskforce to review the mission and mandate of the country's academic hospitals.[3]

One of the most ambitious responses to the need for increased clinical research capacity has occurred in the United Kingdom. Like Australia, the UK has a splendid tradition in basic medical research, but has been much less successful than the US in translating this work into clinical advances or in building an environment within the National Health Service (NHS) that attracts major clinical trials. The UK Government's 10-year framework on science and innovation investment includes an ambition to turn the NHS into a world-class collaborative research engine and a preferred host for multicentre trials with and for industry.[4] A recent publication, *Best Research for Best Health: a new national health research strategy*, set out the potential NHS contribution to health research in England.[5] The document that largely drove change in the UK was a report by businessman David Cooksey, which looked at the best structure for publicly funded medical research in the UK, with a clear aim of improving translational outcomes and clinical research capacity.[6] It is one of the most influential documents in the UK medical research scene to be published in the 60-year history of the NHS, and it led to the transformation of the NHS research and development division into a new National Institute for Health Research (NIHR). Its recommendations, now implemented, include:

- ring fencing the NHS research budget of almost £1 billion for audited research programs, many of them new;
- closely aligning the new NIHR (which is responsible for clinical research) with the Medical Research Council (MRC; which is responsible for basic research), and giving both agencies shared responsibility for translational research; and
- creating a new overseeing office to coordinate publicly funded medical research, focused on outcomes, around major areas of national need — the Office for Strategic Coordination of

Health Research, chaired by Professor Sir John Bell, Regius Professor of Medicine at the University of Oxford.[7]

An early example of this cross-agency collaboration is the development of the new Efficacy and Mechanisms Evaluation Programme, which is funded by the MRC but managed by NIHR. This program has the specific remit of supporting clinical trials that have a major innovative component aimed at gaining new biological insights, elucidating new scientific principles or developing new methodologies.[8]

A broad series of initiatives has been set in train by NIHR, with major investment in hospital- and community-based clinical research. This includes the establishment of a small number of comprehensive and specialist biomedical research centres, selected after evaluation by an international jury, at which world-class translational and clinical programs are planned or in place. These centres will be the UK equivalents of the Mayo Clinic and Johns Hopkins. A new NHS program is now underway to consolidate some of these centres into university/hospital trust consortia, where research and teaching functions are jointly owned and developed to create academic health science centres, similar to those in North America.[9]

Although several models are evolving, they have two common principles. First, the university and affiliated hospital sector will jointly own and plan research and teaching. Second, clinical programs will be academically aligned, with the belief that research and teaching excellence will underpin better clinical outcomes for both hospital patients and communities. This might be a good approach for some partnerships between Australian universities and teaching hospitals.

Other initiatives developed by NIHR include the development of an extensive clinical research network.[10] The aim of this is to ensure that health care professionals and patients throughout England can participate in and benefit from clinical research. Programs established within the clinical research network include an extensive primary care research network; six topic-specific networks, covering cancer, mental health, child health, diabetes, stroke, and dementia and neurodegeneration; and several other comprehensive clinical research networks. Another program is devoted to national technology platforms, the first being centred on imaging technologies.[11] In addition, a number of biomedical research units have been established, covering cardiovascular disease, deafness, gastrointestinal and liver disease, musculoskeletal disease, nutrition, and respiratory disease.[12] Resourcing to develop or extend similar national networks and centres would be a sensible step for Australia.

Total UK funding for basic and clinical research will increase from £1 billion (about A$2.4 billion) in 2006 to £1.7 billion by 2010.[13] Basic medical research in the UK was recently given a major boost through the institution of full economic costing for research council funded projects, which meets true infrastructure costs, and the ambitious and well funded programs discussed here are on the way to establishing world-class infrastructure for clinical research. A national structure has been set in place to ensure that the UK takes a leading role in the development of effective new therapies over the next decade. Australia, like the UK, has separate funding streams for clinical care and for research and innovation, and clinical research has been under long-term pressure. The National Health and Medical Research Council (NHMRC) introduced schemes in the early 2000s to fill the gap, such as the Centres of Clinical Research Excellence Scheme, Practitioner Fellowships, and Fellowships for both the early research career stage (eg, the Peter Doherty Australian Biomedical Fellowship and the Neil Hamilton Fairley Overseas Clinical Fellowship) and the more senior postdoctoral years (Career Development Awards) (Professor Warwick Anderson, Chief Executive Officer, NHMRC, Canberra, personal communication). However, what is currently lacking in Australia is a significant new research and development funding stream from the national health budget to fully develop translational clinical research capacity. Such funding would ensure that patients receive the newest treatments, developed in the most beneficial way.

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