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Best research

The new UK medical research strategy helps industry, but will it improve health?

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Best Research for Best Health, the UK Department of Health's research strategy launched last week, sets a new direction for the funding and organisation of clinical research across the NHS and its associated university medical schools in England.[1] The strategy's goals include making the NHS an internationally recognised centre of excellence for research and development with stronger and more streamlined governance and developing the clinical research workforce. Its two most notable features, detailed in the 16 accompanying implementation plans, are the proposal to centralise funding and the plan to control research through the establishment of a National Institute for Health Research (NIHR) and a new clinical research network for England.

Described in the document as a virtual entity, NIHR will provide the central framework for four areas of management of research: governance, staff, facilities, and infrastructure. The initial budget for NIHR will comprise all the existing budget for research and development in the NHS in England, currently £680m. Crucially, it will also include the additional funding that currently supports clinical academic appointments in the NHS. Universities and their associated NHS partners will lose control over research activity and funds and, effectively, over research strategy. Research staff from NHS and university institutions will become members of the new NIHR faculty.

Funding will be centralised by progressively disaggregating from the budgets of all 253 NHS trusts in England over three years the current funds provided for research and development. Eliminating education and research "cross subsidies" is in any case a market requirement following the introduction of private providers into NHS service provision. According to the plan, funding will then be reallocated on a competitive basis, using a "transparent, sustainable and contestable activity based funding system," something that has hitherto eluded the best efforts of the Department of Health and its management consultants. The beneficiaries of the resulting competitions for funding will include a range of new research providers, including hybrid public-private partnerships, through a plethora of initiatives ranging from clinical research programmes to new research units and centres.

The sums do not add up, however. The total allocation for the proposed new biomedical centres is £100m, compared with current funding to all NHS trusts for research and development of around £500m. Any withdrawal of the current funds will not only increase the financial instability of NHS trusts, but will extend to all of the associated universities.[2]

The two key drivers behind the strategy are the belief that economic growth in research can be achieved only by harnessing the UK strategy for biomedical research to the needs of industry, and the idea that research efficiency and productivity can be achieved only through market competition. One of the clear influences behind the strategy is the UK Clinical Research Collaboration (UKCRC), which was set up in 2004 as a forum for stakeholders in biotechnology research and which has established networks for research and development in the NHS across the UK. Its board includes representatives from the NHS, the Department of Trade and Industry, the main funding bodies, academia, regulatory bodies, patients, and industry.

The bioscience, healthcare, and pharmaceutical industries complain that too few trials are done in the United Kingdom and that UK requirements make the regulation and approval of new products too slow and too expensive. In 2005, the UKCRC commissioned management consultants McKinsey "to articulate a clear overall value proposition to industry for clinical research, supported by distinctive 'Offers' that are attractive to industry when deciding where to place clinical research."[3]

According to *Best Research for Best Health,* a core aim of the new clinical research network "is to ensure the NHS can meet the research needs of industry" by "removing barriers to research in the NHS and strengthening research collaboration with industry." The network will act as a single portal for trials, and together with the NIHR will speed the processes of approving clinical trials and gathering patients' data and other information. The document does not, however, discuss how this "bureaucracy busting" will square with the legal obligations of NHS trusts and universities to safeguard patients' interests.

The strategy also raises wider questions. Will centralisation and competition improve the outputs of research, given that the timing and provenance of most real breakthroughs are not predictable. How will research priorities be decided and what will be the

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balance between the commercial interest and patients needs. While the strategy document does speak of encouraging innovation in a range of research areas including public health, primary care, social care policy, and health systems, how are these to be secured when the strategy is so focused on industry? And what will become of drug research that is of no commercial interest to the pharmaceutical industry,[4] such as highly successful public trials of aspirin for cardiovascular disease and magnesium sulphate for eclampsia?[5] In the words of the House of Commons health select committee, "as the industry funds most of the research, it has a major effect on what gets researched, how it gets researched and how results are interpreted."[6]

Furthermore, the scientific and ethical integrity of research done by clinicians and scientists and the public interest must be safeguarded. Yet the biased selection and under-reporting of industry based research and the failure to disclose relating competing interests are well documented.[7]

Lastly, it is not clear where this new strategy will leave researchers, clinicians, patients, and taxpayers. Who will own the intellectual property generated by this radical reorientation of funding for research? Above all, how far will the curiosity, rigour, and clinical concern that have driven much medical research in the United Kingdom survive these measures?

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Antibiotics in pandemic flu

Will be essential for treating, but not preventing, bacterial pneumonia

With the continuing spread of avian H5N1 influenza a possible pandemic of human influenza becomes more likely. If a pandemic started soon no effective vaccine would be available and there would probably be a shortage of antiviral drugs. There is no evidence (yet) of the effectiveness of neuraminidase inhibitors in case of avian and pandemic influenza viruses,[1] and mortality among patients infected with H5N1 bird flu remains high, despite the use of neuraminidase inhibitors.[2] Resistance to antiviral drugs, which may even develop during treatment, might further limit the efficacy of these drugs.[3] Given that secondary bacterial infection is an important and often fatal complication of influenza, antibiotics will also have a critical role in the event of a human pandemic.

In 1918-19, when antibiotics were not available, pandemic flu caused 20 million to 100 million deaths worldwide, with an estimated case fatality rate of between 2% and 4%. There are no data on the numbers of patients who died directly from influenza, or from secondary bacterial infections that might have been prevented with antibiotics.

How should antibiotics be used in the event of a flu pandemic? And how many patients with influenza will develop secondary bacterial pneumonia? In a largely healthy population of adolescents and adults who developed acute influenza (predominantly caused by the virus H3N2) the rate of respiratory events diagnosed by doctors and treated with prescribed antibiotics was around 17%, most commonly acute bronchitis and acute sinusitis. Pneumonia was diagnosed in only 1-2% of patients.[4 5]

Can we expect a different bacterial aetiology for cases of pneumonia complicating influenza? *Staphylococcus aureus* is a common cause of post-influenza pneumonia, characterised by rapid clinical deterioration, septicaemia, and high mortality. In a comparison of pathogens isolated from patients with pneumonia during the Hong Kong influenza pandemic (1968-9) with those isolated from other patients with pneumonia during a one year period outside the epidemic, the proportion of infections caused by *Staphylococcus aureus* was more than double during the pandemic (26% *v* 11%), but *Streptococcus pneumoniae* was even more common (48%).[6] Carriers of *Staphylococcus aureus*, therefore, might be particularly at risk of catastrophic complications during a flu pandemic. Whether similar rates of complications and shifts in bacterial aetiology will occur during a H5N1 pandemic is, of course, uncertain.

Should patients with mild respiratory symptoms during a pandemic be treated empirically? General practitioners will be overwhelmed with patients who

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