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RESPONSE TO THE COOKSEY REPORT

Barts and The London Queen Mary's School of Medicine and Dentistry
and
Barts and The London NHS Trust

We welcome the recognition of the importance of health related research for its contribution to:

1. Improving healthcare
2. Supporting success in the UK healthcare related industry
3. For its important role in medical training.

We welcome the merger of the Medical Research Council (MRC) and NHS R&D budgets and the commitment to an integrated approach to fundamental, transitional and applied research. We note that the guaranteed budget of at least £1 billion per annum is less than the current total of NHS R&D funding plus MRC funding.

Q1. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?

MRC
The strengths of the MRC have been its independence, its rigorous peer review and its support to institutes to pursue medium and long-term goals, such as the MRC tuberculosis unit. Certain areas are under funded in relation to the importance of the clinical problem in the UK.

The weaknesses of the MRC are that strategic errors (cooperative grants) and financial exigencies have sapped the morale of UK researchers. MRC funding is seen as irrational and it does not encourage young researchers to enter medical research when they see world-leading figures repeatedly fail to get support.

The focus of the MRC on a relatively small number of disciplines that have temporary popularity (e.g. Genetics), or a high political focus (e.g. Cancer) profoundly affects researchers in less popular, but nonetheless important clinical areas (e.g. Mental Health). Researchers in these areas have a reduced chance in this environment to advance their careers or obtain funding for their work. It is also the case that the more popular areas tend to have access to large pools of charitable funds, to support their work. Funding from blue-chip organisations impacts on how universities are funded by Higher Education Funding Council for England, based partially on an evaluation of external income. Groups

facing MRC/Charities funding drought are likely to be rated low in the periodic Research Assessment Exercises, missing out on infrastructure support from the funding council. In effect those researchers who work in the less popular fields that suffer from external funding drought need to be supported from secure and stable central funding if the UK is to succeed in addressing clinical needs in all but a few clinical disciplines.

It is important to recognise that many advances in biomedical research occur because of improved analytic techniques related to physics and chemistry. Examples include development of electron microscopy. These new technologies often lead to exciting new insights into disease. They are expensive technologies and can crowd out other important areas. An example of this would be the focus in the last few years on genetic research. The funding of fundamental biomedical research should be encouraged to migrate to a situation where the funding in different areas approximates to the size of the clinical problem and mechanisms need to be built in so that when an expensive new technology becomes available it does not necessarily squeeze out other important research areas.

NHS R&D Programmes

The change from the historic methods of allocating national DoH funds under Best Research For Best Health (BRFBH) have caused deep concerns amongst both NHS and Academic researchers, particularly with regards to the virtual exclusion of the universities and non-clinical researchers from the strategy. The pace of change in BRFBH is challenging and there must also be concerns that centrally-dictated priority areas will fail to deliver tangible benefits.

Historically the problem with NHS funding has been the perceived level at which funding has fed through to front line researchers. Clearly the NHS has spent funds on research activities and the results have impacted on care. For example Support for science has enabled trusts to finance the labour, service support and treatment costs of academic research (funded by the MRC, charities etc) by covering costs that these organisations do not fund e.g. lab. Costs, imaging and other patient related costs. BRFBH selectively allocates costs to specific programmes and initiatives, dictated by the DoH, concentrating funding on a small number of what are perceived by the DoH to be organisations with international reputations. This will have the effect of:

- Reducing the total volume of research carried out in the UK by disenfranchising many research active trusts, through the reduction or removal of research funding.
- Severely reducing the financial capacity of many large Teaching and Research trusts to support research by removing infrastructure funding (in terms of overheads and service support costs) from networks and programmes and other BRFBH initiatives.
- Increasing massively the bureaucracy involved in obtaining R&D funds, as evidenced by the application process for Biomedical Research Centres and Technology Platforms. This is particularly contradictory given that one of the objectives of BRFBH is to reduce bureaucracy.
- Remove the incentives for academics to undertake NHS research.
- Reduce the capability of trusts and universities to develop their own research objectives and themes, given the need to follow DoH or MRC determined inflexible, priorities.
- Breaking the link between full cost funding arrangements for service activities (Payment By Results) and research, through the removal of overheads and service support costs from BRFBH funding streams. In effect financial planning over more than a one year period is impossible under the new funding regime, leading to financial uncertainty in trusts that house R&D activities.
- The DoH drive to eliminate the cross-subsidisation of activities will fail if different costing methodologies are applied to different activities (teaching, research and service). In actual

fact it is likely that the current position, where some believe research funds are subsidising service in the NHS, is likely to be reversed, particularly as BRFBH implementation plans leave no time for trusts to plan effectively for what could be very large reductions to their R&D funding.

If the MRC and NHS R&D merge, the structure needs to be changed to firmly embed the universities and medical schools into the system.

Q2. What do you believe are the key scientific and organisational challenges facing health research, and underpinning training in the UK over the next decade? How might the UK Government best help address those challenges? What do you believe should be the Government's objectives for health research, and why?

The key challenge is to re-invigorate clinical and non-clinical research and researchers. MMC and new blood clinical researchers are a useful start in this direction. However, this should only be part of a broad portfolio of support for talented researchers, and government must ensure that support is available for those who follow the research path.

The government could help medical research by reducing the huge amount of bureaucracy in ethics, governance, GCP and animal research which is stifling innovation.

The choice of metrics to inform objectives for government health research is difficult, with the unique nature of the NHS distorting international comparisons. Publication in international journals and citation of published works is however easily done. Thus, if an innovation in the NHS in treatment or clinical practice is adopted world-wide, it can be considered a success.

The following key principles should be incorporated into the UK plan for research over the medium term:

- Focus on clinical need and funding it appropriately
- Training
- Relieving bureaucracy
- Smoothing out anomalous funding patterns
- Providing adequate funding to deliver the UK research agenda
- Introduce change at a measured pace, in line with current and future research patterns
- Develop infrastructure to ensure that researchers in all disciplines and career paths (medical, nursing, scientific and Allied Health Professionals) can gain adequate access to research funding.

Q3. What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources, what can it lower in order to release the necessary funds?

Prioritisation

Basic Research

Prioritisation of basic research is always difficult, particularly when a new mechanism or pathway is being investigated since it is often very difficult to know if it will be important or not. Major determinants of priorities are to keep the funding of basic research roughly aligned to the importance of the diseases they are investigating and to look for excellence and innovation in proposals.

Translational Research

For translational research, prioritisation is often somewhat easier as it is determined by new treatments and investigation of the importance of mechanisms discovered by basic science.
The UK has always had an excellent record in translational research but this record is currently under serious threat. Translational research was often pursued by medical practitioners who combined clinical care and research. The competing pressures of a target driven clinical culture with decreasing hours and the Research Assessment Exercise, which militates against clinical research, has led to a serious squeeze in translational research capacity. There should be encouragement of research active medical practitioners combining research and clinical care and the individuals should link with basic research departments. The value of clinical research in the Research Assessment Exercise needs to be reconsidered with contributions to change in practice and the longevity of the research findings or citation papers being considered important.

Applied Research

For applied research, evidence based clinical guidelines, like those developed through the Health Technology Assessment programme, can provide a mechanism for prioritisation as guidelines will frequently provide knowledge of where there are gaps in the evidence base. This approach has been successfully used in a number of disease areas.

Consideration should be given as to whether an independent body made up of representatives from DoH, Hospital trusts and University Medical Schools should be established to oversee the implementation of BRFBH. Clinical academics with research training, higher degrees, a proven record of output of grant income, should be an integral part of the management process.

Q4. How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base; and, the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgements about this balance?

The performance record for government priority-led targets for research is mixed. The UK has a highly talented and innovative group of researchers who are seriously under threat. Focus on basic and translational research will re-invigorate this group of people and will reap benefit in the long-term. There is also the huge economic benefit of investing in basic and translational work in terms of intellectual property and a knowledge-based economy.

Moving from a demand led to a targeted provision will be difficult to manage without a close relationship with the research community. It will be necessary to target new research areas as they arise and provide reactive funding, at reasonable rates, to ensure that trusts and medical schools can properly resource its research activities.

Research and evaluation should be built into services provisions, rather than bolted on to service. If this mechanism were used NHS research could be delivered more cost effectively.

Investigator Led vs. Priorities Led Research

Priorities led research is well suited to applied and health service research where important questions to improve healthcare can be identified from guidelines as discussed above. For translational research the prioritisation will depend on the importance of the disease area and availability of new treatments or diagnostic techniques. Prioritisation of basic research is more difficult and much more of this research will, by its nature, be investigator led. However, where there are obvious gaps in basic research that need to be addressed.

Q5. In your experience, how have the results of publicly funded health research in the UK been used, both in the development of new treatments and to influence/change wider policy and healthcare practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?

Results of Health Research
The use of basic research to develop new treatments depends on either the willingness of the pharmaceutical industry to pursue an area, or investigators setting up new start-up companies. The latter has been less successful in the UK than in the USA although the situation is improving.

With regard to translational research, the record of turning translational research findings into a change in clinical practice has varying levels of success. The UK has led in some seminal work in ischemic heart disease, but in other areas, clear outcomes still elude the clinical fraternity, in spite of considerable investment through national research initiatives.
Health services research has been rather less successful in changing methods of delivery of care. This is sometimes because the method of healthcare delivery in research is not universally applicable. There is also a problem that changes in service delivery models of care, i.e. NHS Direct or Community Matrons, are introduced without any prior evaluation and those active in health service research frequently complain that their studies are overtaken by events and changes in service design which are not evidence based.

Q6. How might better links be forged between 'basic', translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists and social scientists.

In universities, schools of biological sciences (that are often largely biomedical) should be incorporated into medical faculties to bring basic researchers into contact with medical problems. Tranches of funding are available to bring other disciplines into biomedical sciences and these should be increased.

As regards forging better links between basic, translational and applied researchers, this is best achieved by having a multi-disciplinary campus where researchers and clinicians can meet both informally and formally to exchange ideas and opinions and form research groupings. This might be achieved, for example by arranging periods of secondment of medical researchers to basic research laboratories and vice versa, so that potential partners can understand their collaborators' challenges and the opportunities that close collaboration can bring to their research.

These types of activity need to be funded and the funding needs to be flexible, in order to meet the needs of each collaboration. Trusts and Medical Schools need, therefore, to have access to an allocation of funding attached to their organisation that will facilitate local decisions on how to resource research activities that are important to their individual organisations. Both the DoH (under BRFBH) and the MRC, tend to focus on research activities in compartmentalised research areas, that restrict significantly an organisation's ability to set its own research strategy or target areas.

Q7. How can the Government encourage translation, entrepreneurship, and innovation in health research to improve public services in the UK?

Asking clinical and non-clinical academics to be entrepreneurs while at the same time asking them to

be administrators, researchers, teachers and clinicians is not possible. The government should set up a fund to buy researchers out of the NHS or universities for 3-5 years to allow those who wish to translate their ideas into practice the space to do so. If the idea fails and most will, they can then return to the NHS or academia, but without prejudice. Asking an NHS consultant to leave his job and become an entrepreneur is unrealistic. Having said this some thought should be given to the provision of specific funds to allow trusts to release staff to participate in non-clinical education e.g. business skills etc. The funding should cover time-out costs as well as course fees.

Q8. How can UK health research funding be most effectively used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?

Infrastructure should be made available by a mixture of open competition and direct grant. Institutions that do not wish to be research led can elect to opt out of the system. UK health research should form much closer partnerships with small and large commercial organisations; the UK needs to be careful to ensure that market failures in the application of healthcare are not merely a problem of the unique nature of the NHS, rather than a failure in delivery per se.

The development of an integrated healthcare system to support research, innovation and the adoption of new `ideas', is essential. This means that research funds must be integrated more fully with service delivery and teaching funds, if innovative research is to be translated into practice. At present there is no homogeneity between these "separate" funding streams.

Q9. What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?

Centrally-led targets rarely work. Invest a higher proportion of GDP in medical research (like Ireland), invest in academics and research active consultants, think commercial and international, and the talent in the UK will deliver. Alternatively the Canadian hub and spoke model could prove attractive in that it provides for a network of leading centres, linked to smaller "feeder" providers, that covers the country. BRFBH as it is currently configured will make many parts of the UK research no-go areas, with no funding available to address even local research priorities.

Q10. In implementing the single fund for health research, to what extent should the MRC and DH/NHS R&D be merged or brought together? And to whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.

Merger of MRC and Department of Health NHS R&D

While integration of thinking between MRC and NHS R&D is to be welcomed, we feel that if there was one unified process for funding applications this would be detrimental. Even a well qualified and rigorous evaluation of research proposals can lead to rejection of novel ideas particularly if they do not conform to current thoughts about disease. Instances of this are numerous but would include the discovery of the importance of helicobacter pylori in peptic ulceration which was pioneered by independent researchers swimming against the current tide of opinion. Therefore, heterogeneity in funding streams and evaluation is helpful. The MRC systems could be used for overall control of the new Health Research budget, with an extended remit into health care delivery and accountable to the DoH. The MRC's problems have in large been due to lack of money so they cannot support the

excellent applications they receive from academics.

Q11. To what extent does the success of recent innovations in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?

Connecting for Health

A better patient database of diseases, such as the system that may be provided by Connecting for Health, would be a huge advance in clinical research. The database could potentially provide enormous opportunities for epidemiological research. For both academic and pharmaceutical industry sponsored clinical trials, one of the greatest problems and cause of higher costs is slow recruitment. If it was possible to use the database to identify suitable patients for trials this would be hugely helpful, however, at present there are significant problems with regard to access to databases and consent. These would have to be dealt with for the full potential of Connecting for Health to be realised.

Q12. Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximise the health and economic benefits to the UK?

Both basic research and applied research need a mixture of central coordination and a facility for local objective setting in terms of the national research strategy. Funding should be on a local level as well as nationally allocated budgets. Some flexibility in funding streams will enable researchers the mobility required to move around between research active organisations.

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