



# The Royal College of Pathologists

*'The science behind the cure'*

20 July 2006

## Review of UK Health Research Funding – The Cooksey Review

*Comments from the Royal College of Pathologists.*

### ***Our viewpoint and background***

The Royal College of Pathologists is charged by its Royal Charter with maintaining and improving the standard of practice of pathology, for the benefit of patients. It is a charitable body and does not enter into discussions on the terms and conditions of employment of its members.

The RCPATH has over 8000 members, involved in all aspects of laboratory medicine. All are senior professionals, typically employed at NHS Consultant level or equivalent.

The principal divisions of pathology are clinical chemistry, clinical and molecular genetics, haematology, histopathology, immunology and microbiology. Within each of these areas, the activity of our members spans the entire spectrum from “blue skies” basic research through transitional and clinical research to implementing service delivery for the benefit of patients. Many have considerable commitments in undergraduate and postgraduate teaching and training.

The work of many of our members thus includes a combination of research, teaching and service delivery. We believe that this diversity of roles benefits the development of pathological sciences and thus benefits patients, but such ‘multi-tasking’ has come under increasing pressure in recent years for various reasons, notably including changes in funding driven by the research assessment exercises. University-based staff are increasingly expected to maintain research grant incomes sufficient to cover their own salaries, which is unlikely to be practical for a researcher who also has an NHS diagnostic commitment.

The pressure on university staff imposed by the research assessment exercises, the pressure on NHS staff to deliver service provision and increased demands for financial accountability have combined over

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recent years to diminish the close collaborative links between NHS and University departments of pathology, to the detriment of research productivity in both.

If a single funding stream could be engineered to promote collaborative working between NHS and university departments (as well as collaboration with commercial interests) this would be a benefit; but there is a danger that competition for funding could drive separation still further.

Problems with recruitment and retention in clinical academic medicine in general have been widely recognised and a number of initiatives have been devised to resolve the problem, as yet with only limited success. The fall in clinical academic staff numbers in pathology has been recognised by the Council of Heads of Medical Schools to be particularly severe. This is already having adverse consequences for training across all sectors of medical education, especially of UK medical students, particularly in their understanding the processes underlying disease. It is also inhibiting research in laboratory medicine, especially those forms of research which demand the involvement of scientists who also have clinical knowledge and responsibilities. Declining appreciation of the scientific basis of disease processes and their management will have a significant impact on both the treatment of diseases and the development of innovative therapies throughout the UK.

### ***General comments***

The review appears to assume that reform can produce better outcomes for the money spent on medical research in the UK. This is a logical starting point for a review, but we note that in terms of several outcome measures (such as peer reviewed research publications) the output of medical researchers in the UK in relation to their funding level is already amongst the best in the world.

However, the number of medically-trained doctors engaged in academic research has fallen to disastrously low levels, such that the vast majority are now no longer participating in research. Current numbers are below the critical mass necessary to sustain and develop active programmes of viable first-class medical research in the UK.

We note that the total funding is described in the 'Invitation to submit comments' as 'worth at least £1 billion per annum'. Our understanding is that the total current spend on research from the sources identified is considerably more than £1 billion. We hope that this represents an approximation in the text of the invitation to comment rather than a plan to reduce research funding.

The core proposal is to merge all sources of medical research funding into a single management structure.

### **But the aims and uses of MRC funding and NHS R&D funding are very different:**

- MRC funding is aimed mainly at supporting large, nationally important research projects, mainly in basic science but also in relation to large clinical trials. MRC-funded training is aimed at a relatively small number of individuals who aspire to carry out such projects in the future.
- NHS R&D funding is, in practice, more concerned with smaller projects and in training much larger numbers of staff (including medical students) in research methods at a rather simpler level. This supports recruitment of staff to research of the type funded by the MRC. It emphasises translational research more than basic science and it includes areas of research funding which, although often very important, the MRC would not consider. It provides much basic infrastructure on which many types of biomedical research depend. On many occasions it bridges

the gap where it is difficult to define a specific activity or expense as research or service delivery, but where failure to bridge that gap would lead research productivity and / or patient care to be damaged.

As a result no single method of assessment can legitimately be used to assess the productivity or efficiency of both funding streams.

As an organisation whose members include those with MRC funding and NHS funding we are concerned that the proposal to merge all funding streams risks generating imbalance. There are individuals and organisations whose research is funded by each source who will argue for more generous funding, each to the detriment of the other.

In terms of **basic medical research**, efficiency increasingly demands the development of smaller numbers of large, well-funded units which have the critical mass in terms of personnel, skills and equipment to compete internationally in an expensive, high technology field. We believe that the pattern of funding provided by the Medical Research Council has appropriately driven the development of basic science in this context and has contributed to the laudable efficiency of UK medical research, as noted above. However, it is of fundamental importance that adequate financial support remains available for small local research programmes to attract and engage potential young medical researchers and to provide them with the necessary training in research methods before they become irrevocably embedded into strictly clinical careers.

**Translational and clinical research** can sometimes fit the MRC model, but not always. Translational research and research into diagnostic methods are particularly poorly funded by the MRC.

It is frequently the case that no single institution will have a sufficient number of patients suffering from the disease under study to produce an adequately powered clinical research project, so collaboration between multiple clinical centres becomes essential to permit progress. Where such collaborative research demands coordination by a large dedicated research team, the MRC model of funding works well. But it demands appropriate support from local NHS units.

Historically, pathologists in the UK have held an internationally pre-eminent position in research into diagnostic methods, such as the identification, classification and evaluation of cancer. With the recent development of large scale genomics, proteomics and other new ways of investigating tissue samples, our efforts in such diagnostic research should be redoubled. Unfortunately the MRC has a very poor record of funding diagnostic or translational research. In that context, we note that the NHS provides a potential resource for research which is unique in the world. Because of its size, **the NHS could theoretically permit the co-ordination of studies involving very large numbers of patients even in relation to very rare diseases.** This potential is currently under-utilised.

**There are numerous aspects of smaller scale research and research training which would not occur if large-scale MRC funding was the only model available.** Such projects are of no interest to the Medical Research Council, but their potential value is illustrated by the 2005 Nobel Prize for Medicine, awarded to Warren and Marshall for the discovery of *Helicobacter pylori* as the cause of gastritis and peptic ulceration. This was small scale, low budget, curiosity-driven research which could never have attracted MRC funding. The immense benefits which have flowed from this discovery illustrate the

importance of maintaining capacity for small-scale research projects, undertaken by staff with legitimate access to relevant clinical material.

**The recent decline of clinical academic pathology** has inhibited small scale, curiosity-driven research. The inhibition has been exacerbated further by recent changes in research regulation. Onerous research ethics regulations are now applied even to small projects using limited numbers of anonymised tissue samples, where the specimens would otherwise be incinerated and there is no direct involvement of the patients. The introduction of potential criminal sanctions for using human tissue in research without appropriate consent (Human Tissue Act 2004) has further deterred NHS pathologists from undertaking or even facilitating research using tissue samples. It can be argued that, if *H. pylori* had not yet been discovered, its discovery today would be impossible in the UK as a result of the stifling bureaucracy surrounding research.

NHS Pathology departments hold huge archives of meticulously documented tissue samples which, if co-ordinated and made available for research, could allow the UK to be a world leader in the application of modern techniques such as genomics and proteomics to the diagnosis and treatment of disease. There are problems in achieving this goal, notably in relation to the current lack of a co-ordinated system for ascertaining the wishes of all patients in relation to research using their residual tissue samples. But the Human Tissue Act 2004 does include provision for permitting research on residual samples without consent under some circumstances. **The NHS could therefore provide the most powerful research tissue bank in the world, if appropriate co-ordination mechanisms were put in place.** This is not currently an MRC or NHS priority.

Historically it has been universally accepted that **good training in medicine, and especially in laboratory medicine, should include hands-on exposure to research work**, at least at some basic level. In the past, the majority of biomedical science graduates would have had such an experience. Very occasionally such small-scale projects result in a major breakthrough, as illustrated by the discovery of *H. pylori*. Far more commonly, it engenders an understanding of research methodology and a capacity for the interpretation of published results which we believe is vital to the optimal development of health service provision in the future.

**It is becoming increasingly difficult to undertake such small scale and “training” research projects** in the current funding climate and target-driven NHS culture. The NHS no longer has the spare capacity to support research, even if such support is cheap and obviously beneficial. Of specific relevance to the Royal College of Pathologists, many pathology departments are unable to translate development of novel and potentially promising biomarkers into clinical application through lack of local expertise to develop or interpret the particular technique and lack of funding within very tight diagnostic budgets.

In many units, **NHS pathology departments are involved in the provision of patient investigations which are relevant to on-going research projects led by non-pathologists**, especially clinical trials. It is often very difficult to disentangle whether an individual laboratory test is being performed for patient benefit or because of the patient's involvement in a trial; often the answer is both. In many areas this problem has been addressed crudely by support to pathology departments from the NHS R&D budget, which is not analysed to the level of individual laboratory tests.

Historically, the allocation of NHS R&D funding has not been subject to peer review. In many centres, particularly as research activity waxes and wanes over time, current allocations are clearly inequitable. However, to dismantle such arrangements requires care; it risks further increasing bureaucracy and further separating research from clinical practice, with a consequent inhibition of the collaborative

working which is vital to translational and clinical research projects. In some institutions money which in reality has always been used for service provision has been identified inappropriately as research funding. This is to be deprecated, but in practice the continued stability of NHS service provision can in some areas be dependent on these arrangements, so adjustments must be made carefully and with full cooperation of NHS service providers if problems with service provision are to be avoided.

**These points underline the dramatic difference between the historical and current objectives of MRC and NHS R&D research funding.** If the present funding streams are to be combined, it will be vital that there is a clear mechanism to identify how these differing priorities shall be resolved. Research funding should continue to flow to areas of genuine research excellence and need, free from political interference. "Ring fencing" proportions of the budget for different types of research may seem a simple and attractive option, but with time the proportions allocated to different areas will demand adjustment, and powerful vested interests will lobby for adjustments in specific directions.

The Royal College of Pathologists, having members involved in broad areas of research and clinical practice, is concerned that a mechanism to maintain appropriate and equitable funding under such diverse driving forces will prove very difficult to devise. It is important, and it will be difficult, to avoid generating a bureaucracy which stifles rather than facilitates research.

## Specific questions

**1. 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?**

The MRC provides an appropriate model for evidence based funding of basic biomedical research and large multi-centre clinical trials. But its contribution to translational research is weak and its support of research into new diagnostic methods is minimal.

MRC training programmes are of high quality but are limited to relatively small numbers of dedicated research staff.

The NHS R&D programme provides lower-level training in research methods for much larger numbers of NHS staff. It facilitates small curiosity-driven projects, translational research, social care research and it underpins many of the basic services provided to larger studies, including MRC projects. In reality some of the NHS R&D funding contributes to the provision of NHS service care.

The strengths and weaknesses of the two systems are radically different because they are driven by different short term aims; although all the aims are important to the long-term improvement of health care.

**2. 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?**

In laboratory medicine, the most important basic scientific challenges currently relate to unlocking benefits from knowledge of the human genome and applying new methods of biological investigation such as large-scale genomics and proteomics. There is a simultaneous need to maintain and stimulate the natural curiosity of potential young researchers so that they will seek a fulfilling career in medical research.

At a basic science level these challenges require large well funded research teams and are well suited for development by the MRC model. However, such developments are of no value to patients unless they can be translated into clinical practice. This translation requires coordination between research and NHS service provision, with NHS staff who are appropriately trained to assist and understand the relevant research processes. The current "target culture" in the NHS provides short term imperatives which do not facilitate such translational work. Fear of amongst pathologists of the criminal sanctions of the Human Tissue Act 2004 and the weight of bureaucracy associated with any involvement in research are further inhibitory factors.

**3. 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 of support, what can it lower in order to release the necessary funds?**

The Government should not only maintain the pattern of basic research funding which is currently supported by the MRC but should also further develop the exposure of young investigators to good local programmes of quality research, thus stimulating their involvement.

However, the benefits of new knowledge will generate improvements in clinical medicine rather more rapidly if the patient-orientated translational research is conducted in the NHS environment.

Furthermore, if the patients of the NHS, most of whom are keen to assist with medical research, could be coordinated better to function as a single coherent research unit then the NHS itself could represent a research tool more powerful than any organisation elsewhere in the world. For this reason we urge that the Government does more to facilitate the involvement of staff, patients and (in the context of pathology) tissue samples from all NHS sites. This will, we hope, be facilitated by the appropriate development of "Connecting for Health" and we are saddened by the problems which currently beset that programme. Consideration should be given to reducing the current levels of bureaucracy imposed on research work, notably by GAfREC and COREC, and reallocating the resources into systems which can put researchers into contact with clinicians responsible for patients with relevant conditions.

During the next eight years, at least 30% of the current senior workforce in each of the major pathology disciplines will retire. This means a significant loss in expertise, since scientific training was an integral part of the education of these pathologists. They are being replaced by a medical workforce demonstrably less appreciative of the scientific basis of disease processes and hence less able to lead, or to contribute to, research programmes. The type of knowledge currently being lost is of vital importance to the maintenance of an active and relevant medical research programme in the UK.

**4. 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?**

These are difficult strategic questions which will require repeated re-appraisal because they are not amenable to single permanent answers. We have doubts about the competence of any existing national body to make these decisions and we suggest that an on-going process of checks and balances would require not only professional input but also a strong voice from appropriately informed members of the public and regular publication of strategic and funding decisions. We caution against the involvement of specific interest groups, whether professional or patient-based. We are particularly against development of systems of micromanagement and bureaucracy in an attempt to enforce specific developments in translation, clinical application or basic research. Construction of a robust and well-educated basic research base will provide the researchers capable of promoting their findings in the translational arena.

**5. 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?**

We believe that historically there has been a tendency for excellent basic science results from the UK to be taken up and developed commercially elsewhere in the world, partly due to costs and bureaucratic overload in the UK and partly due to limited links and mutual suspicion between university and NHS staff on one hand and commercial companies on the other.

There are also serious limits on the implementation of new developments into UK healthcare. These are currently being exacerbated by the fragmentation of NHS decision making (e.g. into Foundation Trusts) and by the drive towards short term attainment of NHS targets overshadowing long term strategic thinking. In many situations, local clinicians and managers are unable to put together appropriate arguments to justify local developments.

For example, it is now widely accepted that the detection of genital herpes virus is cheaper, faster and more sensitive if modern molecular techniques (PCR) are used. Despite this, approximately 80% of NHS laboratories still using out-dated culture based techniques (Sex Transm Infect 2005: 81:316-7). There needs to be a mechanism, similar to NICE but faster and more flexible, which can provide authoritative advice on when and how new developments should be purchased by NHS commissioners without fear of criticism for abandoning existing methods.

**6. 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?**

This is essentially an issue of communication and motivation. The culture of the NHS has recently been driven towards maximising the efficiency of service delivery, such that informal links between clinicians and research staff have been discouraged by default. The number of clinical academic staff has plummeted, in all clinical disciplines but especially in pathology. As a result collaborative links between NHS and University staff have withered. If this is to be reversed the attitude of the NHS needs to be changed such that every member of staff recognises a commitment to facilitate appropriate research work rather than concentrating only on the delivery of the latest NHS target. The attitude of universities needs to be changed to acknowledge that clinical research is of a value which is not always acknowledged in current research assessment methods. This needs to be combined with a communication system, hopefully facilitated by "Connecting for Health", which is capable of putting researchers in touch with relevant clinical staff with a minimum of bureaucracy and expense.

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

The answer to question 6 is relevant. The communication channels described in that answer should be available to relevant and individuals and bodies outside the Health Service.

**8. 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?**

This can only be achieved by involving large numbers of NHS staff at least peripherally in on-going research projects, and requiring that some involvement in research remains an integral part of relevant degree courses. Such provision is notably absent from current MRC provision. In the short term it will not add noticeably to measurements of output such as the research assessment exercise, but its long term provision remains vital to the health of medical research in the UK.

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

As noted above, we believe that biomedical research in the UK currently provides good value for money in relation to most international models. This is not grounds for complacency, but does suggest that "lessons from abroad" should be viewed with caution.

**10. 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.**

As noted above, the priorities and benefits of MRC funding and NHS R&D funding are radically different, so although there are good arguments for better coordination between the two, complete merging risks damaging one or the other and thus NHS service provision could ultimately suffer. Whatever model is developed must involve a strong voice for suitably informed members of the public while excluding excessive influence from pressure groups. The deliberations must be open, transparent, widely published and amenable to some appropriate method of challenge.

**11. 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?**

As noted above improved communication is arguably the single greatest priority if the potential of the NHS as a clinical and translational research tool is to be achieved.

**12. 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?**

We believe that it is self-evident that, notwithstanding political devolution, researchers in all four nations should have equality of opportunity and that all patients should have equality of benefit.

The lack of a “critical mass” of investigators able to tackle large research problems is frequently a problem in the UK. Devolvement risks further reducing integration between groups of workers, thus rendering them less effective.

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