

Response to the Cooksey Report

Responding Organisations: The Society of Academic Primary Care (SAPC, UK), the NIHR National School for Primary Care Research (SPCR, England), and the Heads of SAPC Departments Group.

This response has been prepared by the academic organisations which represent all of the university departments of primary care and general practice based within the United Kingdom Medical Schools. The draft was initiated by Hobbs (Chair, SAPC HODs Research Working Group and Deputy Director of NIHR SPCR), edited by the HODs Research Working Group, SPCR and SAPC Executive Leads, with comments contributed from the wider SAPC membership. This report is structured in accordance with the twelve questions raised by Sir David. Recommendations and key points are italicised

Background

In an unanticipated and fundamental change in UK research funding, the Chancellor of the Exchequer announced a new single fund for health research in his recent Budget Statement.¹ The single fund will be jointly held by the Secretaries of State for Health and Trade and Industry and will be worth at least £1 billion per year. The funding is intended to encompass the full spectrum of health research starting from fundamental biomedical research, through translational research which links laboratory and other science with the science of treating or preventing illness, to applied research which looks at the application of new discoveries to 'front-line' health services, including technology assessment, public health and social care research.

Pooling all public sources of funding, this new scheme encompasses research funded by the MRC and the new National Institute of Health Research (the NHS R&D Programme in England and its counterparts in the Devolved Countries). It also includes some research funded by other research councils, including the BBSRC, EPSRC and ESRC. The review of the scheme involves a wide consultation exercise, which started 4 May, to take into account the decision to create a single research fund of at least £1 billion (*it is worth noting that the current combined total of these separate funding streams exceeds £1.3 billion*), and the way this relates to the new NHS priorities of the Clinical Research Collaboration (UKCRC) and 'Best Research for Best Health'.

General Comments

1. We welcome the opportunity to influence this important review from a primary care perspective *and would be pleased to meet Sir David to amplify our response*. We see potential within a unified budget to foster not only research in the basic sciences, but also in clinical areas and health services, and the flow between these areas and on into practice and policy. The proposal sits well with the unified approach embodied in the UKCRC. Already initiatives such as the joint UKCRC funding of a national prevention research initiative managed by UKCRN has shown the way to begin to foster the set-up of new research teams addressing important questions in an underfunded area.

Within the current research strategy we welcome the courageous attempt to move the NHS components of the funding (over 50% of the total) out of the NHS budget. There it could not survive the public approbation in relation to NHS service cuts, especially in clinical staff. That change alone could argue for the new arrangements. However, this potential gain needs to be reflected in the degree of influence that might be exercised by the Secretary of State holding the new

budget, and the situation of an organisation dealing with large service cuts while developing a research infrastructure dependent on a strong service wing and partnership for success. The potential for non-scientific influence on health research strategic investment and an imaginative attempt to avoid perverse outcomes of well-intended actions is an important issue for the Cooksey Review.

2. The research investment in applied and primary care research is at a relatively low level. Perverse outcomes in the more applied clinical research areas will be hard to avoid when investment in the research wing of the organisation is occurring at the same time as constraints in the service hosting the research. The emergence of primary care commissioning and foundation hospitals is eroding the sense of partnership in provision of services for a local population, and commanding attention with an inevitable opportunity cost for activities such as hosting clinical research. In primary care, general practitioners remain independent contractors with the NHS and their hosting of research cannot be assumed if the immediate opportunity cost is at all high.

Organisation of the new funding stream to protect and encourage innovation in clinical and applied research will be very difficult in these circumstances. Yet it is a worthy aspiration to strengthen the ability of health related R&D to generate improvements in health outcomes as well as basic scientific knowledge of cellular mechanisms. Key to achieving this will be the investments in the primary care research infrastructure and the management of the service support for science which must more than offset the effort required by service partners if they are to agree to host research.

There will naturally be tensions about the point of balance to be achieved in funding between basic and applied clinical research in the UK. However, perhaps the biggest risk will be a temptation to reduce overall research expenditure through the 'efficiencies' of merging budgets. This temptation should be resisted since the UK probably has the most cost efficient and effective global health research investment (UK health research tops the world league for papers per \$ expended and citations per \$ expended and is fourth ranked for papers per researcher.¹ Perhaps unsurprisingly therefore, 55% of returned staff worked in top international ranked 5 or 5* departments in RAE 2001.²

Maintenance of research investment is essential if the UK is to retain this status – *delivering 9% of the world's research effort for 4.5% of the world's research expenditure in a high cost economy seems precarious.*

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?

Balance of research funding by type of health research

The MRC has traditionally been the major UK funder of 'underpinning' or 'aetiology' research, as defined in the recently published UK Clinical Research Collaboration Health Research Analysis.³ Such research in the UK particularly focuses upon normal biological development and functioning (84% of all Underpinning Research activity in the UK between 2004/05), and investigation of biological and endogenous factors (64% of Aetiology Research) and factors relating to the physical environment (16% of Aetiology Research).

Underpinning and aetiology research represent the main elements of 'basic clinical research' and between them consumed 68.6% of the total UK health research expenditure in 2004/05. The MRC are very significant supporters of the basic research effort and currently commit 80% of their total budget to basic science.

Research that has a more immediate clinical application has, traditionally, received much less funding from the MRC (and, importantly, from medical research charities also). These areas of the clinical research endeavour, described as applied research, include prevention (2.5% of total UK health research expenditure), detection, screening and diagnosis (5.2% of total UK research spend), development of treatments and therapeutic interventions (8.5% of total spend), evaluation of treatments and therapeutic interventions (8.1% of total spend), management of diseases and conditions (2.3% of total spend), and health and social care services research (4.8% of total spend). The MRC has traditionally invested limited research funding within these more applied clinical research areas with 2.9%, 4.5%, 5.6%, 4.5%, 1.2%, and 1.6% of the overall MRC budget going into these six areas during 2004/5. By contrast the NHS R&D programme has, from its inception, been one of the very few funders of health research that have invested significantly within the more applied clinical research areas (this is also true of Scotland and Welsh Health Departments, although the Northern Irish Government Department unusually commits around half of its budget to basic research). During 2004/5, 31.4% of the NHS R&D budget was committed to support evaluation of treatment, and 29% to health services research, with only 12% of the budget to basic clinical research.

International significance and importance of all health research areas

This emphasis for NHS R&D funding on more translational and applied clinical research has been of major significance in partially redressing UK health research investment to funding that has a more continuous investment from the laboratory to patient setting, and back again. Indeed, even now, one might debate the relative balance between basic to translational and finally applied research, given the continued near 70% of UK medical research which is invested in the basic science funding. Such research has major significance to international science and may, ultimately, impact significantly upon the NHS and other health systems. However, the application of better knowledge of cellular function and disease aetiology into practice and policy is of equal importance: how such knowledge can be used to prevent disease, when possible, or delay the onset of disease, where possible, and the most effective and efficient methods for alleviating the impact of disease where it occurs. Such applied research can have major impact on patient well-being ;for example the research validated practical tools that improve warfarin INR monitoring to reduce the incidence of embolic stroke in patients with atrial fibrillation and minimise the risk of bleeding. This work is, of course, crucial in helping to configure the most cost effective healthcare systems at a time where most developed economies are spending between 8– 20% of their entire GDP on delivering healthcare to their populations. Such research can importantly also feed back to basic science ; for example the clinical observations that aspirin appeared to reduce thrombo-embolic disease being fed back to basic research on platelet function and the repeat cycle back into clinical trials of drug technologies that reduce platelet adhesion. Basic and applied research are at least of equal importance to a thriving health economy and too often basic discoveries in this country have been exploited elsewhere to the benefit of other peoples and their economies. The enhanced status of basic research is certainly associated with greater investment and more international prizes, which are in turn determined by subjective assessments by selected sections of the scientific community.

A major weakness of current UK investment in applied health research is the very limited funding available from any sponsor for 'response mode funding', namely research ideas that are developed by researchers and competitively awarded on scientific merit and protocol argued health significance, rather than research proposals that are invited to address pre-declared health priorities set by the funder. This has distorted the distribution of applied health research funded.

Equity & VFM of investment in providing the best evidence base for health

If it is reasonable to consider health research investment across this continuum of basic research through translational research to applied (health services) research as a model, with the potential for reverse travel with applied research feeding into basic science questions, then in the absence of any objective evidence, a more equitable distribution of research funding from the current 70% investment in basic research and 30% investment in translational and applied clinical research seems relevant. The creation of a new unified health research might helpfully promote a debate about the best balance of investment across this research continuum. As implied earlier, this dynamic within the MRC and NHS R&D investment strategies is particularly important since most of the other major funders of research within the UK, who will be less influenced by government, invest most of their funding in basic research.

Importance of research capacity building

A second extremely important outcome from both the MRC and NHS R&D programmes is investment in research training for basic and clinical scientists. Both organisations run bespoke training programmes which include 3 year fellowship schemes at lower grades and 5 year award schemes for more senior scientists. Naturally, a similar distribution for research training occurs between the two organisations in priority areas as for their main research funding. Therefore, the MRC funds a significant proportion of their awards within non-clinical disciplines or amongst clinicians who have interests in basic science. Only a small proportion of MRC fellowships are awarded in health services or public health areas and we are not aware of the MRC having funded senior scientist awards at the highest levels in applied areas. What can be done is illustrated by the investment in primary care research of 11 million pounds through the joint MRC/DH Primary Care research programme following the MRC Topic Review.

This has matured to inform the management of a range of painful conditions, our understanding of the better management of infections in children, and the place of preventive action in relation to chronic disease. The investment illustrates a further extremely important aspect of applied research; the production of evidence of well meaning but ineffective activities. Thus studies of preventive interventions that do not achieve the required outcomes can save significant NHS expense by reducing their uninformed implementation in practice. While the investment successfully supported a number of high impact primary care studies listed in section 5, it has not been repeated.

By contrast, the NHS R&D schemes have strategically invested in expanding the capacity for applied research across many discipline areas, both medical and non-medical. This strategic investment has significantly contributed to the expanded capacity and infrastructure for more applied clinical research within the UK. Indeed, a proportion of the current high international status of primary care research within the UK is directly related to NHS R&D investment in more applied clinical research programmes and in NHS R&D fellowship and career scientist

schemes. This is also true for departments of public health and epidemiology, departments of nursing and physiotherapy, and the growth of health economics and specialist trials units within the UK. Given that these areas have been less well developed, the NHS R&D programme has also produced research training schemes which are more focussed on growing research capacity with a more linear investment in research training from pre-doctoral fellowships, to formal post-doctoral schemes (which support individuals to some research independent status), to 5 year career scientist awards which enable newly independent researchers to consolidate their research expertise. However, the MRC clinical scientist programme provides continued support for internationally competitive researchers to maintain their ability to invest time in research at the most senior level. Such very senior awards are also provided by a number of the medical charities, most notably the British Heart Foundation, but are currently not available from the NHS R&D programmes.

As the decade of NHS R&D investment in more applied scientists matures, some mechanism to protect the senior progression of the most internationally competitive scientists in applied clinical research fields should be considered a new priority for the new unified budget, again to provide balance with that available to basic scientists. It is also critical that the current investment in junior academic career development in applied research is expanded, to reflect the more equitable balance of research programme investment justified above.

A further weakness is the lack of structure linking clinical governance and service development to research findings; the potential strength of this is demonstrated by the Quality and Outcomes initiative which has been informed by the Manchester School of primary care policy. More needs to be done to support the research and training needs of the NHS and social care, to enable service partners to better host research and deploy research findings into practice.

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?

Chronic disease burden and prevention

Probably the biggest challenge facing healthcare is how to most effectively implement the advances of medical research within health systems that will be increasingly constrained by the rising costs of delivering ever more complex healthcare.

Even this general statement, however, is likely to be overshadowed by the rapid increases in the population prevalence of adverse risk factors for some of the more important chronic diseases facing societies. For example, the rapid increases in proportion of the population who are sedentary and overweight is driving rapid rises in the proportion of people with clustering of multiple risks for diseases such as diabetes and cardiovascular disease and, crucially, at ever earlier ages. This dynamic relationship between the human genome and the environment suggests that much greater efforts are needed in understanding how to most effectively implement prevention of disease strategies (only 1% of UK health research expenditure was focussed on primary prevention of disease in 2004/05) and better understanding of how lifestyle relates to expression of disease (phenotype), especially in areas where much of disease aetiology is already known.

This shift from acute illness to chronic, often multiple, disease becoming the most important causes of death and disability in the world has been recognised by the WHO for all countries. Better research in disease prevention in the UK will, therefore, have increased relevance and possible applicability to developing as well as developed health economies. A higher proportion of UK health research expenditure in translational and health services research is therefore a priority.

Research relevance for clinical teams and multi-professional expertise

One further important advantage of greater investment in applied research is that, as in clinical practice, such research is essentially more multidisciplinary and team based. It is difficult to research an area that is delivered by varied practitioners (such as nurses, physiotherapists, and doctors) that does not include research expertise within respective disciplines. Investment in health services research in the UK over the last decade has produced legitimate and fruitful academic collaborations that are multidisciplinary in nature. This secondary consequence of investing in health services research has important strategic benefits to the UK health research endeavour to better balance the historical disproportionate investment in clinical and basic scientists with relatively limited prior investment in other disciplines that are non-medical. This model has the further advantage that investment on multidisciplinary scientists is on the basis of organic and successful collaborations rather than on quotas that may be non-sustainable.

NHS relevance

The huge costs of providing universal healthcare require that a larger proportion of the UK health research budget in future must have a more immediate influence on guiding investment and dis-investment in services, preferably on the basis of empirical evidence from translational and applied research rather than pragmatic or dogmatic policy. Given that most health systems are becoming more similar to the NHS in terms of the managed care model, then UK applied research increasingly has international significance.

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?

Balanced health research investment, linked to short and long term evidence needs of service delivery

Based on the points raised in the last section, greater investment in the prevention or delay of disease onset and alleviation of chronic disease, both in terms of improved quality of life as well as extended life, are government priorities. Indeed, the risk of ignoring these issues at a time of rapid increases in clustering of adverse risk factors within the population could spell financial ruin for the NHS if such chronic diseases express full disease states in ever younger people. Again this would argue for a greater UK investment in translational and health services research, with a commensurate reduction in expenditure in basic research.

Other priorities should be health areas that are not well served by medical charities because of lay perception or lack of charismatic leadership, such as the limited charitable funding available for health issues for young people (sexually acquired diseases, unplanned pregnancies, youth drinking), or mental health, or stroke (in contrast to cardiovascular disease). In this sense, the medical charities,

crucial though they are, have a distorting influence on the generic UK health research environment which is the responsibility of government funding to balance. Importantly, primary care research has made significant contributions to science in many of these less well resourced areas (such as depression,⁴ psychosis,⁵ and suicide risk research).

Ever greater expectations of the public have also driven a greater desire for services to be based as locally as possible wherever possible. Better research on the implementation of new ways of configuring services is essential to determine whether such packages of care are worth investing in across the NHS. It is just as important for health systems to know what doesn't work, so that services can be disinvested in, as what seems to work well.

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 judgments about this balance?

Balancing health research investment

It will be self-evident from earlier questions that we believe that the balance of investment is currently too skewed towards basic biomedical research. (One might argue, it is almost unethical to continue to research for new discoveries that might impact on healthcare if there isn't a clear mechanism for translating that discovery into cost-effective health care strategies and their implementation rapidly into clinical practice.) Therefore, a unified UK health research structure that is more "joined up" and capable of evaluating the most cost effective way of implementing new health discoveries and engaging policy makers and practitioners is a structural priority for UK research funders. It is important to repeat that, in terms of applied research, many of the examples of good research in the UK have international applicability to many other healthcare systems and therefore has both international status and relevance.

A more balanced investment in health research areas also provides natural synergies with industrial partners, both pharmaceutical industry and diagnostics industry, into what are the most efficient ways of both diagnosing disease but then introducing evidence based interventions that improve quality and longevity of life. It would be interesting to consider the current distribution of research investment by the pharmaceutical industry in the basic discovery of compounds and research into providing the best evidence for the application of their technology in which contexts, among which people, at what dose, and quantifying what health outcomes (both benefits and dysbenefits) ensue. Clearly, the limitations of patent require the most rapid uptake of new drug technologies as possible based on the marketing of licensed applications. The uptake of cost effective health care interventions across the NHS has a similar imperative.

Unified health research budget

Bringing together the MRC and NHS R&D budgets into a single fund should, of itself, provide a mechanism to make judgements on the balance of secondary research investment. Indeed, one early positive outcome from this consultative process over the proposed single health research budget is to stimulate this debate. However, this balance would only occur if the advisory structures which

develop once the budgets are merged are adequately representative of the clinical research continuum. Inevitably, organisations that have a higher proportion of scientists from any given area will make secondary investments more within those areas.

If there is a completely polarised response to this consultation in terms of how health research investment should be balanced, then the Government might consider a more systematic review of the evidence base for the relative impact of biomedical and applied research investment to date to guide its deliberations. It might also consider opportunities to apply the less politically driven MRC culture to the more generalisable areas of clinical research and health services research. A simple MRC/basic and NHS/applied funding solution will be unhelpful. It will risk losing the genius of defining the key soluble problem that comes from the top performing applied research groups, linking what needs to be known to what can be currently discovered in just the same way as in more basic science.

There must be investigator led research in the applied sciences as well as in the basic sciences. Most importantly, if the most weighted responses to this review support the continued level of investment in basic sciences and in the way MRC allocates resource (which is a reasoned argument), then the absolute imperative to invest more funding in applied research (to which there can be no reasoned argument) leads to the obvious conclusion that the new Health Fund needs to be much greater than the £1 billion proposed (probably over £1.5 billion) to avoid damaging what is sustainable to support what is newly essential.

Public participation on health research investment

At some stage, it might also be sensible to engage in a more public debate about these issues. This might be more appropriate at a time the public was better informed about the wider potential for health promotion and disease prevention rather than the “magic bullet” of rescue medicine when catastrophic disease occurs. However a debate now could do much to enlist the public in the research endeavour and assist us to be more realistic in terms of the nature of informed consent and data access than is currently the trend

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?

There are many examples of health research impacting on health practice. Some of the best examples involve public research funding of how to identify who has most to gain from an effective intervention which was initially commercially developed.

One example is the discovery of statins to reduce LDL cholesterol, one of the three main risk factors for generation of cardiovascular disease. US and UK publicly funded research has identified the main risk factors for cardiovascular disease based on very long standing epidemiological research.⁶ These data drove the pharmaceutical industry to discover drugs that influence a number of these risk factors, most notably blood pressure and cholesterol. The discovery of statins created dilemmas as to who would most benefit from using the drugs and when and in what doses. Most of these questions have now been answered, through a mix of commercial, publicly funded or partnership research: examples include studies based in UK general practice populations, such as WOSCOPS⁷ and the

MRC, BHF, NHS R&D, and industry funded Heart Protection Study⁸. Such research, mostly conducted in primary care, has identified the most effective ways of identifying individuals in the community who have most to gain from a statin and has further helped design practical tools (such as cardiovascular risk calculators) that clinicians might use to identify those most at risk but without current disease (primary prevention).

Others examples from primary care research include studies that have provided important data that have rapidly informed international guidelines include studies informing on the overall burden of important major diseases (such as heart failure^{9,10}) and of common and costly disease treatment strategies (such as for H Pylori infections¹¹ or sore throats¹²); studies of diagnostic or monitoring technologies (such as natriuretic peptides in heart failure¹³ and INR decision support packages to avoid stroke¹⁴) that have been rapidly adopted into clinical practice internationally; and validated tools to identify important disease earlier (such as meningitis in children¹⁵ or depression in adults¹⁶) or assess healthcare performance (such as GPs¹⁷ or parents¹⁸).

Applied research funding has also assisted in more rigorous methods of reviewing the evidence base available to answer some of these questions and develop the rigorous methodologies of systematic review and appraisal that have led to more reliable and valid clinical guidelines and NHS organisations such as NICE. How to best implement the generation of these scientifically produced guidelines has, traditionally, had relatively limited research investment, but has still helped guide NHS policy, most notably over the reconfiguration of approximately 20% of the entire NHS investment in primary care into an incentive led quality and outcome framework (QOF) based upon clinical indicators developed on evidence based areas, such as CVD prevention illustrated above.¹⁹ Indeed, it is not surprising that over 40% of the current QOF clinical incentives relate to clinical indicators in the area of cardiovascular disease because this has been one of the few areas of medicine where high quality research has been conducted on the application of basic science. The net result has been a very rapid improvement in the proportions of the UK population at risk of cardiovascular disease that have not only been identified to be at risk but have also been offered evidence-based interventions to reduce that risk.

There are also many examples where research has been slow to inform patient care because of the costs of implementation, or because the links between research intelligence (discussed at specialist meetings and in journals) and clinical governance are often in separate silos; the move for researchers neither to teach nor practice is a further obstacle to the free flow of new knowledge into practice.

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 what pharmaceutical companies do well – invest in people, systems, and methodologies that bridge the continuum of their interests from the laboratory to appropriate prescribing research.

Greater public investment in successful academic research teams or units that link across this research continuum presents an obvious mechanism. That has already begun to develop through the various NHS R&D funded research network

schemes (UKCRN, EPCRN), in some of the Wellcome CRF centres (such as Birmingham), and via specialised trials units. However, such collaborations need continuity and pre-protocol funding (ie programme status) since most successful groups currently have to rely on unpredictable and non-strategic project funds. The MRC Coop scheme is one (failed) mechanism that could have been used to forge better discipline links.

Inevitably, without ear-marked funding for successful groups to enhance strategic links and grow new ones, links will develop slowly and haphazardly. A dedicated new funding scheme would be one solution. The approach of the new NHS strategy towards Schools of Primary Care on the one hand and Biomedical Centres on the other will work against the symbiosis envisaged across the research spectrum, into service and back with new observations driving the cycle. Thought should be given to inducements to cross boundary working in funding proposals, and to dedicated funding streams for work at the interface between basic and applied research and applied research and practice implementation.

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

Workable and sustainable incentives for exploiting IP in publicly funded research are not well developed in the UK university or NHS sectors. This subject warrants a more developed national policy strategy.

Translation of best evidence into clinical practice, however, is better developed in the UK than most other health systems, except the US. However systems like NICE are so focussed on gate-keeping for economic reasons that they are better at stopping inefficient treatments going forward than enabling agreed ones into practice. The major gap in implementation remains the tiny fraction of health research funding that is committed to applied research – we often know *what* to do in clinical practice, but not *how* to do it. Redressing the balance of health research funding is needed.

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?

For all the reasons outlined above, the creation of a single public health research budget might act as a catalyst, as long as the investment is more strategically balanced across basic, translational, and applied fields, and the expert panels that determine strategy and what is funded are more balanced in personnel (across the 3 research areas and amongst disciplines). Without these caveats, what is likely to change?

The most powerful tools to support NICE are the GMS QOF mechanisms and practice based commissioning. Initiatives with industry will probably be best served by continued investments in specialist trials units (primary care as well as hospital based), research networks (especially UKCRN, EPCRN and MRC GPRF), and in eScience trial platforms.

It is clearly essential to health research in primary care that the new Primary Care Research Network for England (EPCRN) receives sufficient funding to facilitate recruitment to trials and other important studies. The initial level of funding of £250k per year for each hub will be insufficient of itself for the necessary level of support for practices in patient identification and recruitment, and so additional funding must come with the studies to be run on the network, in the form of Support for Science or whatever mechanism replaces SfS. In this regard, it is also essential that the funding currently provided by the MRC for the GP Research Framework is not lost to primary care research infrastructure, as the GPRF is integrated into the PCRN-E over the next few years as planned. There is a case for reviewing the current arrangements to determine whether the MRC infrastructure for primary care research should be part of an MRC Unit, part of a dual funded infrastructure economy, or moved to UKCRN control and funding. There is no case to reduce the resources available.

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?

The overwhelming requirement is appropriate risk management in research. We must move to avoiding the burgeoning bureaucratic secondary mechanisms for ensuring research governance; ethics, MRHA, and NHS governance arrangements. These remain cumbersome, time consuming, and duplicated in the UK (and therefore costly) across trusts, universities, the MRC, and other organisations. What is the value of three criminal background checks on one individual working across these sectors?. Mechanisms must be quick and efficient to implement, whilst obviously adequately protecting the public, if the UK is to compete globally for pharmaceutical industry funded studies and to limit the costs of publicly funded research.

The UK is not currently investing a similar proportion of healthcare GDP in health research as many countries with similarly developed healthcare systems (hence the high productivity of UK health researchers in global comparisons).¹

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.

On the basis of the arguments above, most or all of the budgets should be merged and probably managed by the UKCRC. It could be split into divisions of funding preserving the independent scientific culture of the MRC in the basic and translational clinical divisions, and linking the applied division to clinical governance. Joint proposals across the first two divisions will encourage bench to bedside and back flows of work. The divisions, strengthening and elaborating the current health services research board will prevent the basic science imperialism that is otherwise naturally dominant in MRC.

The accountability should not be political or similar to current arrangements with the research funders. A publicly appointed (possibly charitable) board could become the accountable body with representatives from academia, the funders (DH, DE, MRC, UKCRC), and the public determining overall strategy. Investment decisions should be based on scientific consensus in panels (such as the 26 Institutes of the US NIH). Day to day management could be modelled on the MRC

(or possibly tendered for in national competition, such as occurred for the HTA Programme).

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?

UKCRN and the components such as EPCRN are essential investments for better health research. Connecting for Health remains a very high cost (and risk) mechanism to support healthcare that may (or may not) prove useful for research. However, the greater use of e-technologies for health research is essential and therefore should not be predicated or dependent on Connecting for Health. Indeed, more focussed and greater investment in e-research is more likely to yield spin off benefits for e-health than the other way round (many e technologies in day to day life sprang from research applications, such as the internet). A proportion of the £20 billion investment in Connecting for Health should be ring-fenced with the new single healthcare fund (over and above the merged funds value) to create a new eScience healthcare research programme.

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?

Through subsidiarity, which primary care academics in the devolved nations at least would welcome. The merged budgets will only easily relate to a merged organisation in England. However, the other 3 countries may select to devolve a significant proportion of the management of their health research expenditure to a new English merged organisational structure (as similarly occurs with NHS research training posts and some of the HTA Programme), whilst retaining control of the strategic allocation of funds.

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