

REVIEW OF UK HEALTH RESEARCH: RESPONSE OF THE UK STROKE RESEARCH NETWORK

Introduction

This response to the Review of UK Health Research is submitted on behalf of the UK Stroke Research Network Directors and Local Research Network Leads. Our response is focused on consideration of how a single ring-fenced budget to support UK health research and development could improve future stroke research activity and best meet the needs of stroke patients and their carers.

The recent UKCRC report analysing health research spend and earlier publications by Rothwell indicate that the current funding structures have failed to adequately fund research to reduce the burden of stroke. Although the UKCRC report does not specifically report stroke, our own calculations from Fig 5 of the UKCRC report (*proportion of combined spend on health specific categories compared with DALY rates*) and WHO source data indicate that stroke receives research expenditure amounting to 25% of its contribution to disability adjusted life years whereas cancer receives 180%, cardiovascular excluding stroke 75%, and infection 280%.

Another key concern we have in the new proposals is that it will be difficult to join the Devolved Nation R&D budgets with the new fund since the Health Budgets are devolved. Thus the new ring-fenced fund joins one UK fund (MRC) with a single nation Health Budget (England). Any attempt to bring all devolved nation funding into a central single fund would run the risk of disregarding differences in health provision between the devolved nations and impact on local priorities and research support resources needed to conduct national research. Assuming the Devolved Nation budgets remain independent, any effective structure such as a Board or Institutes established for coordinating UK research will need to include the Devolved Nation R&D departments.

Preferred Model

Our preferred model is the creation of a joint fund for translational research and the establishment of Institutes to oversee the strategic development of biomedical research. In view of the importance of stroke as the leading cause of adult acquired disability and third leading cause of death in the UK, the importance of both neuroscience and vascular science to stroke, we suggest that if Research Institutes are created a stroke Research Institute is required rather than it being included within a Neuroscience or Cardiovascular Institute.

- 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?**

We consider there are problems with the balance of funding across the system in relationship to diseases (e.g. stroke compared to cancer), settings (secondary compared to primary care) and type of research (basic vs translational vs applied).

MRC Strengths and Weaknesses

Major strengths are its track record in delivering high quality research outcomes relevant to patients. Weaknesses are that until recently stroke was neglected and poorly represented within the Neuroscience Board. However MRC has in recent years taken measures to address this by holding stroke strategy workshops, which had significant influence on thinking about networking within the stroke community prior to the establishment of the UK Stroke Research Network.

NHS R&D Programmes Strengths and Weaknesses

Strengths of the NHS R&D Programmes have been in Health Services Research and support of systematic evidence reviews. The main problem identified by many observers is that the main Support for Science funding streams provided as annual payments to Trusts have increasingly been used to support clinical services. We strongly support and commend recent changes for transparency and performance management of this income stream through BRBH changes which we consider will significantly improve research outputs from the NHS.

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?

We consider the major organisational challenges facing UK Health research in the next decade are:

2.1 Involvement of health care staff in research:

Involvement in research is not seen as an active part of health care professional training and as legitimate activity for non-academic NHS practitioners. Participation in clinical research needs to be part of the Quality Outcome Framework for primary care and a key performance indicator for SHA's and primary care and hospital Trusts. As the independent sector becomes an increasing provider of health care in the NHS, participation in research needs to be included in performance targets of these new providers. Managers also need to be engaged in research and we support the recent requirement for managerial involvement in the NIHR Programme Grants. Evidence of contribution to (not leadership in) research should be made a key component of promotion and progression of all NHS staff. Recruitment to academic posts remains difficult and current RAE research metrics overly favour independent research or leadership of multi-centre trials over collaborative working.

2.2 Engagement of patients and the public:

The engagement of patients and the public in biomedical research lags behind involvement in other areas of the health system. NICE has demonstrated considerable achievements in this area and some of their models of working, such as the Citizen's Council, might usefully be considered for development to provide a public voice in areas of health research policy.

2.3 Improving access to data:

See comments Q11.

We believe the Government's principle objective for health research should be to reduce the burden of disease and disability in the UK through most effective coordinated use of available R&D resources to develop new treatments and means to implement them effectively through the NHS. Achieving this requires R&D resources to be targeted to conditions which account for significant disability adjusted life years and where there is a reasonable likelihood of effective new treatments being developed within a time frame relevant to the type of research (applied research - short-term; clinical - medium-term; basic - long-term horizon).

As secondary objectives we consider that the Government should increase multidisciplinary working across Universities, the NHS, pharmaceutical and device manufacturers and patient groups to achieve the above, and that every patient in the NHS is able to contribute to research to improve future health.

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 SRN welcomes the recent focus of both MRC and DH to increase funding of translational research. However it is important that the outputs of translational work are taken forward into clinical trials which result in change in practice across the NHS. Funding translational research alone is insufficient if the clinical services and clinical research support are inadequate to support the clinical research that follows on from translational research outputs. Funders and networks need to develop mechanisms and links between basic/translational researchers to ensure the outputs of translational work are taken forward and that there is a clear strategy and agreement at the funding stage of translational research as to how this will be achieved. Two specific examples of failure of this process in stroke are:

- a) the current lack of availability and access of acute stroke patients to CT angiography/perfusion and MR imaging which has prevented the undertaking of interventional trials of thrombolysis and neuroprotection in patients with a salvageable penumbra.

and

- b) the lack of therapists in stroke services to allow novel rehabilitation interventions such as constraint therapy to be evaluated in large multi-centre trials.

We cannot identify any broad areas of stroke research where funding should stop. Our suggested approach would be for a more rigorous evaluation of the likely outputs of basic, translational and applied clinical research before funding. Such evaluation should involve the perspective of patients and health care commissioners. In general the research agenda should focus on areas associated with major causes of death and disability. Funding of research into rare diseases, contributing little to the UK's health burden, should occur but only if:

- a) the outputs are likely to have clear relevance to other disease mechanisms and therapies
- b) the research has a high likelihood of delivering new therapies which will reduce disease burden

- c) the disease could become a major cause of premature death and disability in the future e.g. HIV and vCJD.

The average age of stroke patients presenting to the NHS will increase during the next 25 years due to ageing demographics and improved primary prevention delaying the onset of stroke, with possibly half of patients admitted as stroke patients aged over 80 years. Research into ageing relevant to stroke and clinical trials including very elderly stroke patients is required to improve management of these patients.

- 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?**

Strategic vision is needed to ensure an appropriate balance between investigator-led and priority-led research. Priority-led research is only required when skilled investigators have failed to address significant health care opportunities. Funding bodies should require an explicit link between the level of funding and potential health care benefits. We favour a greater role of patients and clinicians in decisions about the balance of funding.

- 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 publicly funded research changing practice of stroke (carotid endarterectomy (MRC), thrombolysis (NIH NINDS trial), BP lowering (MRC), aspirin (MRC), cholesterol lowering (MRC). However in comparison to drug therapies, many surgical or interventional procedures, changes in service delivery and new models of providing care are introduced into the NHS without adequate evaluation in randomised or other high quality designed trials.

To improve implementation, better audit data are required on the uptake and outcomes of new treatments adopted by the NHS. For example there are no data on the use of intra-arterial thrombolysis in acute stroke and patient outcomes in the NHS whereas for intravenous thrombolysis the establishment of a European wide phase IV database (Safe Implementation of Thrombolysis Study) has led to valuable data on use of the treatment in the UK and confirmed that outcomes as good as those in the original clinical trials are being obtained.

- 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?

Significant progress is being made in linking basic, translational and applied research. However we consider this could be considerably improved for stroke and that the Stroke Research Network will play a useful facilitatory role in this process with the key funders (MRC, Wellcome, TSA and BHF). The question about forging links across disciplines is a more interesting one and this approach could lead to new developments in R&D relevant to stroke patients. Research groups in both Universities and NHS have a tendency to be insular through the need for focus. The Biomedical Research Centres and Clinical Research Networks could be encouraged and funded to forge such broader interactions. We see the provision of funding for research scientists employed within the NHS with clinicians as a key development with similar Follett type employment arrangements as for clinical researchers.

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

The DH could offer incentives to Trusts that innovate and implement new research findings. Recent changes in NHS management structures and commissioning have made it more difficult for innovation to thrive at the 'grass roots' level. For example implementation of thrombolysis for stroke in the UK has been held back by Trusts and commissioners not funding this service development in the absence of a specific target or NICE recommendation. Research networks play a key role here with their aim of improving research for patient benefit. For example the Stroke Research Network has established links with other groups such as the Institute for Innovation & Improvement and English Stroke Strategy Group to help implement best practice identified through research. Improved publicity and communication of 'what works' and 'what's new' in research to managers and commissioners is required.

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 sector? 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?

Response mode funding NICE guidelines currently identify key research topics but there is no process or commitment of the NHS to prioritise and address these. The success of pharmaceutical industry research is in contrast to failure to develop and deliver effective non-pharmacological interventions such as prevention strategies and rehabilitation technologies or to initiate 'bedside to bench' research likely to be highly productive. For example the most effective treatment intervention for stroke in terms of DALYs saved is Stroke Units and yet little research has been undertaken to determine why stroke units are effective. Industry funded trials designed to address regulatory body needs do not always answer the right question. For example nearly all BP lowering trials have compared specific drugs against placebo or other agents and not answered the more general question facing practitioners about what is the optimal BP target. The Topic Clinical Research Networks have an important role in identifying and shaping the 'right' question. Consideration should be given to applying this model to basic and translational science through expansion of the clinical study groups in the existing clinical research networks and/or through establishment of new networking groups.

We have some concerns about multiple initiatives in the implementation of research and best practice into healthcare. For example a number of groups are looking at future Stroke care delivery in England including the DH Stroke strategy group, NICE stroke guideline, and the Institute of Innovation and Improvement. Clear structures need to be established to ensure an appropriate, coherent applied research agenda emerges from these groups.

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?

We consider some lessons can be learnt from the experience of other countries particularly North America. Effective joint working between Universities, Health services and industry has been critical in the success of most internationally successful institutions. Recent BRBH initiatives have encouraged and facilitated close working but need time to determine whether they will deliver.

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.

Because we consider it unlikely the devolved country NHS R&D budgets will be included within the single ring-fenced budget we see the MRC and NHS R&D programmes will need to continue to operate independently but with a redefinition of roles and the creation of a joint fund for translational research. A merger of the English NHS R&D with MRC budgets without merger of the devolved country budgets would be problematic for stroke as there would be a risk of the excellent stroke research activity within Scotland being marginalised.

In terms of funding research NHS R&D should focus on clinical (non translational) and applied research and MRC on basic science. MRC has funded many of the important UK stroke trials that have changed clinical practice, and recently funded three major multi-centre clinical stroke trials. Although we question whether both MRC and NHS R&D should fund large clinical trials it could be argued that it is more appropriate for NHS R&D for clinical trials relevant to UK population, we would be concerned at the loss of MRC as a potential funder of multi-centre stroke trials. MRC's roles and responsibilities in funding clinical trials in the developing world needs separate consideration although we note the establishment of other large funders in this area notably the Bill & Melinda Gates Foundation. For translational research we consider models of joint working and merged funding such as the recent Clinical Research Infrastructure Funding Initiative should be applied to this area perhaps with the development of specific Institutes. Given stroke is the leading cause of adult acquired disability and third leading cause of death in the UK we would favour a Stroke Research Institute with joint funding budget from MRC, Wellcome, BHF and AMRC, closely linked to the Stroke Research Network. From the experience of an Institute model in other countries, the importance of both neuroscience and vascular science to stroke, and stroke being variously included in other UK Neuroscience or Cardiovascular initiatives we would be strongly against Stroke being included in either a Neuroscience or Cardiovascular Institute which would likely lead to the marginalisation and continuing under-funding of stroke research.

A joint fund for translational research would also provide specific focus on strategic decisions around the balance of funding between basic, translational and clinical/applied research. With respect to funding of clinical research support costs NHS R&D should fund these irrespective of the research funder (DH, MRC, Wellcome, or AMRC).

We consider an overarching coordinating body with representation of public, patients, clinicians and scientists is required to ensure complete coverage of research areas, clear definition of roles and responsibilities and avoidance of duplication. Irrespective of whatever structural changes are made it is vital that high quality peer review is maintained.

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?

We see the development of CfH structures as being potentially hugely helpful to clinical research but have grave concerns as to whether it will do so. At present CfH is not mature enough to provide major support to clinical research. We think there is a need to build on good local IT initiatives. Data protection legislation and guidelines have made increasing difficulties in using IT for research. Pharmaceutical industry demands for data source verification make efficient use of IT extremely difficult as data has to be double entered by research staff. Opportunities for patients to register interest in participation in research at any stage of contact with health services and for self-registration for potential trials would be a valuable development.

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?

As we discuss earlier we see this as being a key issue that the new single fund needs to address. The role of MRC in funding overseas research requires separate consideration as to how future strategic decisions will be made around this funding stream.