

## **BHF Response to the Cooksey Review**

### *Executive summary*

- The MRC has an admirable track record of achieving health, science and economic objectives
- It is much harder to identify success in any of these categories for the NHS R&D budget
- Any new funding mechanism should be directed at ensuring efficient use of NHS R&D funding to support high quality clinical research and adopting the proven operating principles of the MRC
- Those administering the single fund should have the discretion, according to transparent, agreed criteria, to move money within the fund to support the highest quality research.
- Apportionment of the single budget should not be susceptible to short-term political considerations.
- Research funding cannot be considered in isolation of current, fundamental changes in models of health service delivery that give little or no consideration to research
- The NHS has the potential to sustain the very highest quality translational research if its research strategy is linked to output from fundamental biomedical science.
- The new research environment must be conducive to training and retaining a new generation of clinical researchers
- The BHF would expect the new combined budget to maximise the opportunities for research charities to support world class basic and clinical research.

### *Background*

The BHF is the UK's leading research charity in cardiovascular disease and is an active member of the AMRC. Each year we commit some £60-70m to support cardiovascular research in UK universities and health departments. Our research portfolio extends from fundamental laboratory-based molecular, biological and genetic studies to large scale clinical trials of novel and existing preventive and therapeutic interventions. We support research through infrastructure awards for buildings and equipment, project and programme grants for research staff and consumables and, most importantly, research training and career posts for basic and clinical scientists, from PhD students through to Research Professors. Consequently, the BHF has a very legitimate interest in the UK clinical research environment.

The following comments reflect conversations and written communications between the Medical Director, BHF-funded senior researchers and senior medical academics from overseas.

In general terms we welcome the Cooksey Review into how public funding for research is distributed and administered. We particularly welcome any attempt to ensure that NHS R&D money is redirected, in a transparent manner, into clinical research. Our perception is that the MRC has an admirable, world renowned track record in funding leading biomedical research through a robust, transparent and

largely equitable process that has all too often received insufficient funds to meet high quality demand. In contrast, the NHS R&D budget has produced few if any pioneering clinical interventions and has been largely used to support hard pressed clinical services. It is essential, therefore, that **any new funding mechanism does not try to fix that which is not broken, but instead is directed at ensuring efficient use of NHS R&D funding to support high quality clinical research.**

#### *Definition of research*

In determining how a single research budget is distributed, there must be clarity on exactly what constitutes research and what the budget is expected to fund. Broadly speaking there are four basic categories of research: fundamental laboratory-based research with no immediate clinical application (previously the domain of the MRC, BBSRC and to a lesser extent other funding councils), clinically based observational and interventional research, including translational research and epidemiology (funded previously by MRC and to a lesser extent NHS R&D), health services research aimed at establishing cost effectiveness of different interventions (previously NHS R&D), and industry-led clinical research into the effects of novel therapeutic agents (mostly industry). Any new funding arrangement from a single pot will have to establish how the budget is to be allocated to support these different research activities giving due objective attention to the outcome of research spending. The main driver for this apportionment should be the quality of research being supported and **it will be important for those administering the single fund to have the discretion, according to transparent, agreed criteria, to move money within the fund to support the highest quality research.**

#### *Models of research funding*

Research funds can be distributed either in response to demand from the research community, so called bottom up or response-mode funding, or it can be pre-specified by the funder for specific initiatives – top down funding. Most ‘breakthroughs’ in medical research (eg monoclonal antibodies, stem cells, cell cycle genes) have evolved from investigator-led, curiosity-driven research (bottom up), in which the UK has played a leading role. Whilst there are times when a top down approach can stimulate new research activity (eg the Wellcome Trusts Clinical Research Facilities), it also runs the risk that funds can be allocated to projects (the best applications for the initiative) that would not have succeeded in open competition against other scientific proposals. Thus, funds are diverted away from high quality bottom up research towards poorer quality top down research. There are prominent scientists who believe this is exactly what has happened by unified research council and health service budgets in Canada. Therefore, it is crucially important that in the new funding arrangements there are sufficient funds for investigator-led, hypothesis driven research. Consequently, it is essential that **responsibility for allocation of the research budget should not be susceptible to short-term political considerations. In other words, Haldane principles must apply.**

#### *The research environment*

Second only to its principal researchers, the UK’s greatest asset in clinical research is its NHS-based patient population. It is becoming ever harder to undertake clinical research in a target driven, payment by results health service where research is considered a dispensable and expensive luxury. Furthermore, the shift from a specialist-led, hospital-based clinical service towards a community-based service

provided by multiple providers threatens to complicate the ability to undertake clinical research still further, particularly in the absence of a robust IT system - Connecting for Patients still looks a long way off. It should be a fundamental principle of all service provision (regardless of who is the provider) that it budgets for, and has the capacity to, support clinical research (and training). **There is a complex interaction between the clinical service environment and the ability to carry out first rate research that must be considered whenever changes are being considered.**

Much is made of the need to provide an environment conducive to the delivery of large scale, industry-driven clinical trials. However, it is unlikely that any changes in the UK environment will make it sufficiently cost effective for big pharma to stop looking overseas where governance bureaucracy and running costs may be lower, patient recruitment rates higher and end points more numerous. Instead, the UK should perhaps focus on delivery of smaller scale, high detail, translational clinical studies on new and emerging technologies that can be supported by the rapidly increasing network of clinical research facilities in centres of clinical and research excellence around the UK. What has been missing from the current research funding model is any direct link between MRC and NHS R&D funded research. Currently there is no means by which results of MRC (or BBSRC) funded research can be directly fed into patient based clinical research. In other words the translational element is missing. **The NHS has the potential to sustain the very highest quality translational research, but will only do so in the future if research activity is given appropriate priority and research strategy is linked to output from fundamental biomedical science.**

A major issue facing the UK at the moment is the dearth of clinicians willing to consider a research-based career, particularly in cardiovascular medicine. Where the UK once led the world, we now follow. This unfortunate anomaly will only be corrected if young physicians and surgeons can foresee a stimulating and rewarding future in research. The MRC and the NHS have both committed resources to research training, but have failed to create an environment that attracts and retains the most able clinical researchers. Any new research funding arrangements must consider this a priority and ensure that initiatives like Modernising Medical Careers are given the best opportunity of succeeding. **Thus, training and retaining a new generation of clinical researchers is paramount.**

*What does the BHF need?*

The BHF receives all its income from public donation. Therefore, if it is to continue to spend the bulk of its money on research (and it has no absolute obligation to do so), it requires an environment that facilitates and maximises research opportunities. The BHF does not commission research, but provides funds, on request and following peer review, to help academic and health service staff carry out research that they otherwise cannot afford to do. The public, rightly or wrongly, expect the state to provide the basic infrastructure for both research and clinical practice through publicly funded universities and the Health Service. Donors to research charities do not expect their money to provide services that they believe they have already paid for through their taxes. In other words, the BHF should provide the icing on the cake and not the whole cake. Consequently, we need an environment that facilitates this role and doesn't increase unduly either the administrative hurdles or the financial

costs of supporting research. There are huge opportunities for charities like BHF to collaborate with the publicly funded sector to great mutual benefit. In this regard our history of collaboration has been much better with the MRC, who make clear cut financial commitments, than with NHS R&D which is apt to change its level of commitment according to prevailing financial pressures.

As a UK wide charity, the BHF has to work with the increasingly different research environments across the UK. We would strongly urge that a commonality of approach is adopted across the devolved administrations. **The BHF would expect the new combined budget to maximise the opportunities for research charities to support world class basic and clinical research across the UK.**

*BHF's vision for a unified budget*

The BHF would like to see the same level of rigor, peer review and transparency that currently applies to MRC funded research applied to the NHS R&D budget. We would not wish to see investment in basic biomedical research prejudiced and we would like an environment that facilitates interaction between the NHS and AMRC charities. We believe this would be best achieved if a unified budget is the responsibility of an independently chaired governing body that reports to the two secretaries of state and has responsibility for apportioning the budget largely to two councils, one modelled largely on the current MRC, the other on NHS R&D, but incorporating the same values and standards as the MRC. However, in addition there should be an overlapping subgroup of these two councils whose particular responsibility is to ensure rapid translation of basic biomedical research findings into clinical research to ensure that the NHS R&D budget is primed to take rapid advantage of new basic research findings. Importantly, representatives of the new governing body should also take a leading role in determining and shaping reforms in the health service to ensure that research remains a fundamental component of UK health services.

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