

Response to Sir David Cooksey's Review of UK Health Research from the Association of Medical Research Charities (AMRC)

Introduction

The Association of Medical Research Charities (AMRC) is pleased to respond to the Cooksey Review of UK health research in the context of the Government's ongoing commitment to UK science and research set out in its Science and Innovation Investment Framework 2004-2014.

AMRC and its member charities believe the move towards 'a single health research fund' is an opportunity to build upon, and maximise the potential of, the UK's current assets in health research – the strength and quality of the medical research charity sector, the international reputation and excellence of the Medical Research Council (MRC), and the advantages for research offered by the National Health Service - by developing a more coherent vision and strategic framework. However, our concern is that, if approached injudiciously, reform will irrevocably destabilise the strengths of the current system.

We also welcome the Cooksey Review as an opportunity to underline the unique and vital contribution of medical research charities - working in partnership with the Medical Research Council (MRC), the NHS and other agencies - as major funding organisations, agents for delivering health benefits from research, and as a source of public engagement and involvement in determining future research priorities. This role has too often been underplayed in the past and we hope that the Review will echo the fundamental role of charities in sustaining and growing research of benefit to patients and the public, and in delivering an overall research strategy for the UK in the future.

In putting together our response AMRC has consulted its member charities, a number of whom have also made individual submissions.

Success criteria for a single health research fund

For medical research charities the success of 'a single health fund' will rest on its ability to deliver the following:

- An environment in which medical research charities are able to maximise their impact and contribution.
- Governance and leadership of UK health research which facilitates joint-working and partnership, translational research, and policy leadership.
- A culture within the NHS in which research and development is seen as a priority and integrated as much as possible with patient care.

Our response focuses on each of these objectives, the current challenges that impede their delivery, and possible solutions for their achievement.

The contribution of the charity sector to UK medical and health research

In terms of scale, growth, vibrancy and diversity, the research charity sector is unique to the UK. Over the last five years, charities have contributed over £3.25 billion to research in England and the devolved administrations¹. 85% of charity research funding takes place in the life sciences, medicine and health. Fifteen per cent of all research and development performed in UK universities was funded by UK charities. And, over the last three years, it has become the fastest growing source of research funds after industry.

In addition to funding specific projects, medical research charities:

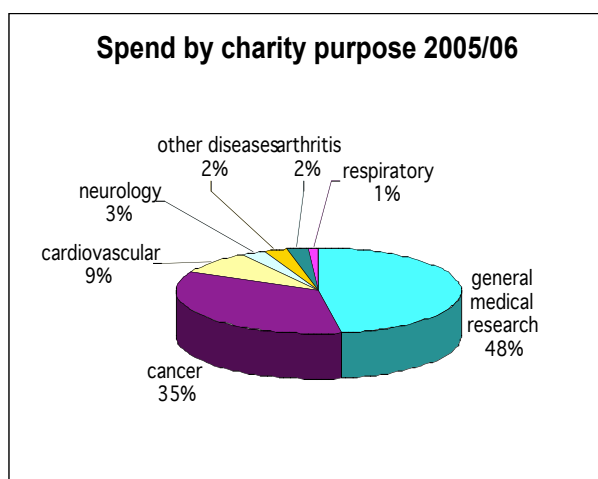
- Support the best people and encourage career development
- Fund the best teams and specialist centres
- Invest in infrastructure and equipment
- Strengthen research resources i.e. tissue banks, knowledge base
- Have close associations with patient groups
- Deliver health benefits by supporting the translation of research into practice

Often forgotten is the wider indirect and direct social and economic impact of research charities – from contributing significantly to the excellence of the biomedical sciences in the UK, which underpins our strong pharmaceutical and biotechnology industries and brings considerable economic benefits to the UK, to its role as a growing source of indirect and direct employment. We hope that the Cooksey Review will recognise this wider impact in its recommendations, particularly in view of the ongoing review of the Third Sector being conducted by the Treasury.

The appendix to this document provides further detail on the nature and diversity of the medical research charity sector in the UK.

AMRC

Established in 1987, AMRC is a membership organisation of the leading medical and health research charities in the UK. Its 112 charities fund research to tackle diseases including heart, diabetes, and rarer conditions like cystic fibrosis and motor neurone disease. The following shows the distribution of this funding by charitable purpose:



In 2005/6 AMRC member charities contributed over £700 million to UK medical and health research. Four charities – Arthritis Research Campaign, British Heart Foundation, Cancer Research UK and the Wellcome Trust together spent £615 million in 2005/6 and accounted for approximately 86% of the total

¹ Figures taken from Office of Science and Technology, SET statistics. The latest figures are for 2003-4.
<http://www.ost.gov.uk/setstats/index.htm>

UK medical and health research funding from AMRC charities. It should be noted that the majority of AMRC members spend less than £1 million on research but that many of these charities play a critical role in sustaining research on neglected or rare diseases.

AMRC supports and represents the sector in a number of ways: setting standards for research practice; providing information, guidance and support; and influencing and lobbying Government in the UK and EU. AMRC membership is increasingly used as a 'kite-mark' of quality in the sector and its peer review principles – one of the fundamental requirements of membership – were used by the Treasury when establishing criteria for the Charity Research Support Fund (CRSF) in the higher education sector.

AMRC is currently undertaking a strategic review of its future role and direction in supporting the sector. The review includes an extensive consultation exercise with our member charities which will provide an in-depth insight into key issues and concerns confronting charitable organisations supporting medical and health research. AMRC will be happy to provide the Cooksey Review team with headline conclusions from this consultation in due course.

An environment in which medical research charities are able to maximise their impact and contribution.

In considering the 'single health research fund' proposal, our member charities have underlined the following conditions necessary to engineer the right environment for UK health research going forward:

- Reform in which the priority is to preserve and build on current strengths
- Strong and effective governance and leadership
- An open and transparent culture in which the process for making both strategic and operational decisions is clear to all partners, and politically neutral
- The equitable involvement of charities in the setting and implementation of research strategy and priorities
- A balanced research portfolio for the UK in terms of basic, translational and clinical research but also the critical nature of research into rare and neglected diseases as well as those that are recognised as major causes of disease and ill-health
- The ongoing development of a strong public and patient involvement (PPI) ethos within the research community
- A research culture which is outcome focused in terms of health benefits and wider economic prosperity
- A research culture which is attractive and inclusive to all scientists and researchers at all stages in their career.
- A focus on ensuring that there is sufficient infrastructure support for research to be carried out in the NHS, built on a belief that all patients should be able to benefit from access to research as part of their treatment.

Governance and leadership of UK health research which facilitates joint-working and partnership, translational research, and policy leadership

We are aware that various institutional models have been suggested for the new 'single health fund' organisation. In our response we do not prescribe a preferred model in any detail. Our concern is that in any institutional model, the onus will be on the following:

1. Developing strong and effective governance and leadership of a single health fund: an independently chaired board – charged with ensuring that the necessary mechanisms are in place to identify research priorities, key areas of overlap, engineer a greater unity of purpose and culture, and determine future institutional arrangements. Lines of accountability and responsibility with and to Government must be clear and Haldane principles enshrined.
2. Fostering a more collaborative approach to determining and implementing research strategy including the setting up of appropriate cross-cutting forums and fostering new ways of working and communication that enable the involvement of all partners, including charities.

The potential here is to break down traditional organisational and cultural barriers and ensure that the research community, including patients and the public are working as one in support of a common agenda. Charities, along with others such as industry, should be seen as key stakeholders whose research expertise, independence and closeness to the donating public can bring legitimacy to the new organisation.

The UK Clinical Research Collaboration (UKCRC) model of working is instructional here with its recent UK Health Strategic Analysis of Research supported by the main funders, a significant example of what can be achieved through partnership working.

We also believe strongly that appropriate mechanisms embracing this model of working need to be adopted at the level of the devolved countries and also at regional level without disrupting the strengths of the current institutional models already in place.

3. Ensuring transparency: With ever greater emphasis being put on public accountability and demonstration of impact – whether health, social or economic - it is imperative that the 'single health research fund' should work in an open and transparent way and be inclusive of the many interests involved in supporting science and research. We believe there are already useful models (such as NICE) for the ways in which priority setting can be made more explicit. Our member charities would welcome greater openness over funding decisions that a 'single health research fund' might deliver.
4. Providing policy leadership: It is clear that there are a number of policy developments and trends impacting health research – the increasing regulatory burden, issues concerning patient data, Connecting for Health – where policy leadership is often fragmented, if not lacking entirely, across various government departments and structures. For member charities, as we suspect for many parts of the research community, it is not clear where the lead for resolving these issues is placed. We believe that, provided it has sufficient infrastructure, the new 'single health research fund' body could be a powerful arbiter for negotiating with other parts of government and resolving such issues in a way that will benefit patients and researchers.
5. Be adequately funded: Achieving the Government's goal of increasing innovation will require requisite funding. It is also crucial that the new 'single health fund' has a clear sense of the year-on-year funding environment so that it can set clear expectations with its partners. More difficult will be a funding settlement for the devolved administrations which ensures continuity with the way research monies are currently apportioned by the NHS and MRC.
6. Patient and public involvement: It is critical that patient and public involvement (PPI) is integral to the workings of 'a single health research fund' including the way in which it sets research priorities and makes funding decisions. This will help ensure accountability and responsibility and also that monies are allocated according to greatest need. Admittedly, there continues to be debate about the most effective ways of achieving PPI which can impact positively on research outcomes. Many different models are being explored by research charities, many of which are also patient bodies, involved in the delivery of health and social care as well as providers of patient information and education.

A culture within the NHS in which research and development is seen as a priority and integrated as much as possible with patient care.

In 2005, AMRC introduced a requirement that all member charities have a published research strategy to ensure that their stakeholders and partners understand better the way that charities will fund research and what types of research they will support. It has led many members to consider their approaches in more depth and AMRC has detected a growing trend among members to emphasise more clinical research in their long-term plans as they align their research priorities closer to the needs of their supporters and patient groups.

Charities accept and fund applications across the spectrum of clinical research and a range of conditions and diseases - everything from understanding the genetics of diseases, to developing new surgical procedures, from small trials to test the effects of different types of therapy to large multi-centre randomized controlled trials to determine which drugs work best. Many projects are led by clinical academics in close collaboration with non-clinical colleagues and the interaction between NHS Trusts and academic centres provides an important link between basic and applied research.

Clinical trials are often considered to be the preserve of the big pharmaceutical companies, for testing the effects of drugs. However, a third of AMRC member charities have funded clinical trials and two thirds of these are to test the effectiveness of non-drug interventions, such as different types of surgical procedures, screening for disease, approaches to counselling patients or different types of physical therapy, such as exercise. Although, clinical trial funding by AMRC members represents less than 4% of their total spend, charities provide a unique source of support for both drug and non-drug trials, their role is growing and ready access to the NHS infrastructure is becoming ever more critical.

NHS R&D

Against this background, and in terms of the NHS, AMRC believes that the 'single health research fund' provides a real opportunity to build upon the measures already laid out in 'Best Research for Best Health: a new national health research strategy' and ensure appropriate prioritisation is given to R&D throughout the NHS – from a strategic level at the Department of Health to an operational level within NHS Trusts.

The NHS provides a ready-made clinic for the application and assessment of new treatments, the potential of which has never been fully realised. One reason for this is the historic difficulties in ensuring that NHS R&D monies are spent according to their allocation. The reality is that a significant proportion is used to fund NHS care services locally. Furthermore, clinical research infrastructure is not always co-located with the best and most relevant research. AMRC and its member charities therefore welcome the decision to ring-fence NHS R&D monies. However, we are concerned that the transition to ring-fencing is done carefully to avoid a detrimental knock-on effect on those services it has previously been used to support.

In addition, AMRC believes that the 'single health research fund' must build on this move to greater openness and transparency by providing better incentives to NHS Trust Boards for prioritising R&D and improving ways by which charities and other organisations can partner with the NHS at Trust level. Our experience is that the linkages between member charities and the NHS are often personal, as opposed to organisational. Charities could be powerful allies in assisting local Trust management to engage local public support and accountability for R&D expenditure and ensuring that it is seen as part of their 'core business.' Yet real change in the degree of priority given to R&D at Trust level will only happen if strategic leadership is provided from within the Department of Health.

Research into Practice

A key disappointment with the research programmes of the Department of Health and MRC, as they currently operate, is that they do not have a single mindset or agreed approach to translational research and ensuring that new treatments and ideas are delivered into the communities where patients will benefit. Previous attempts such as 'Research into Practice,' have failed to make the hoped-for impact in this area, principally because insufficient strategic priority has been applied to it.

AMRC believes that moving to a 'single health research fund' could maximise the potential of bench to bedside research, by facilitating more joined-up working across the research disciplines; enabling partnerships between organisations; providing greater incentives for clinical research and in encouraging greater cost-effectiveness.

As said before, with charities under ever-increasing pressure to demonstrate 'impact' in line with their charitable objectives, there is a small but noticeable trend among research charities in placing more emphasis on clinical research in their research strategies. As they strive to achieve this, it will be incumbent on the NHS to provide a culture and environment which is 'fit-for-purpose.'

Any concerted move in this direction will also need requisite attention paid to close-working with other public bodies such as NICE and MHRA that will need to be in a position to handle a larger and faster - flowing stream of new treatments and applications.

Conclusion

'A single health research fund' presents some clear opportunities for maximising UK health research. It also has potential risks associated with it, not least that of unintentionally destabilising areas of excellence in the current system through major structural reform. AMRC believes that the best outcome for UK health research is the development of a more coherent strategic direction and institutional framework in which:

- medical research charities are seen as integral to its delivery and are able to maximise their impact and contribution.
- there is strong and effective governance and leadership which facilitates joint-working, translational research and policy leadership.
- research and development is seen as a priority within the NHS.

We are pleased to have taken part in this Review and look forward to receiving its conclusions and recommendations in due course.

June 2006
AMRC

Appendix

The role of charities in medical and health research in the UK

Key facts about AMRC and its members

- AMRC is a membership organisation of the leading medical and health research charities in the UK
- 112 member charities
- All members use peer review to allocate their funding
- Over £700 million awarded to UK medical and health research in 2005/06
- Charities contribute approximately one third of all public expenditure on medical and health research in the UK – a situation without parallel elsewhere in the world
- Over 2,000 awards are made annually to a range of institutions. UK universities receive 70% of all the funding awarded
- Medical research charities fund an extraordinary diversity of research projects through a variety of mechanisms
- Charities have strong links with patients and carers, enabling the public to have input into the medical and health research agenda
- Through the research they support, charities also have a wider social and economic impact

AMRC's role

AMRC is a membership organisation of the leading medical and health research charities in the UK. Working with our member charities and partners, we aim to support the sector's effectiveness and advance medical research by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government.

Established in 1987, AMRC has 112 member charities that contribute over £700 million annually to research aimed at tackling diseases such as heart disease, cancer and diabetes, as well as rarer conditions like cystic fibrosis and motor neurone disease. Over the past five years AMRC charities have spent over £3.25 billion on research in the UK, contributing significantly to our knowledge and understanding in the life sciences, medicine and health.

Profile of AMRC members

The members are diverse both in terms of research areas that they fund and their histories. However, they share a common goal of understanding more about human health and disease. Some charities fund general medical and health research, others consider a broad range of organ specific or system specific research (e.g. heart or lung) while many focus on a d specific disease (e.g. diabetes, cystic

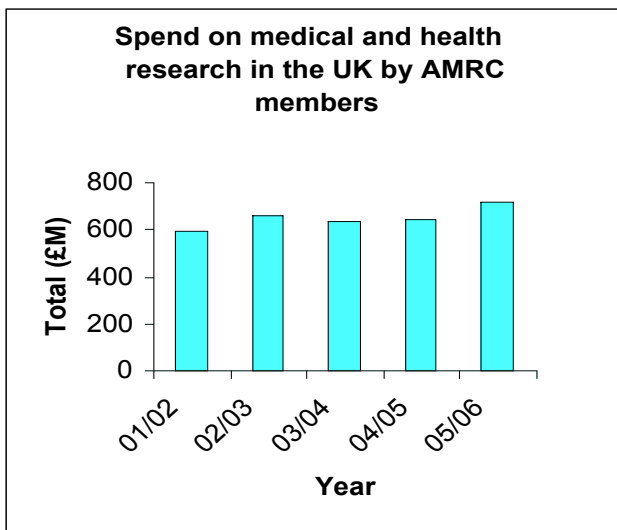
fibrosis). They may provide funding in a variety of ways or concentrate their funding through a particular scheme (e.g. fellowships).

One common characteristic of medical and health research charities is that they involve a wide range of stakeholders in their activities. Most disease areas will be of interest to several professional groups including clinicians, nurses and other allied health professions, laboratory-based scientists, computer experts, complementary therapists, carers and health service researchers and so on, as well as patients and their carers. It is now common practice for research advisory panels to include a broad base of professionals, scientists and applied researchers who can assess a wide range of proposals, as well as contributing to the overall strategic objectives of the charity. In addition, many charities are creating more opportunities for lay groups and patients to be involved in shaping their research strategies.

Maintaining standards

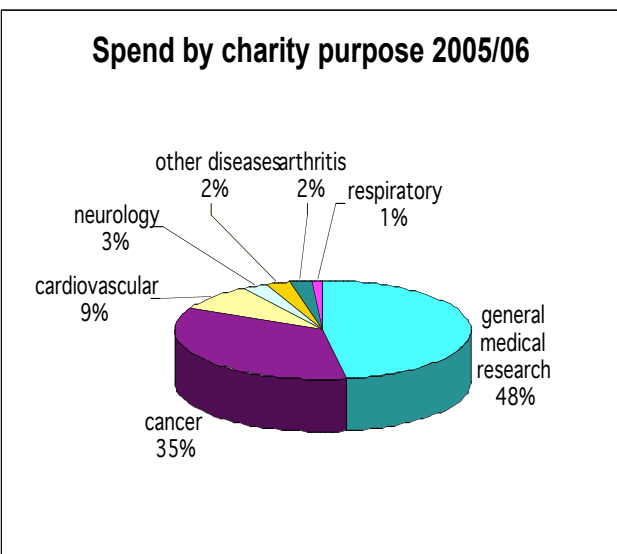
To become AMRC members, charities must show that undertaking medical and health research in the UK is a principle activity (usually defined in their objects), be registered with the Charity Commission in England and Wales, or otherwise recognised as a charity in Scotland and Northern Ireland, and meet AMRC’s criteria for a well run medical and health research charity. AMRC’s membership criteria require that charities use a method of peer review for the allocation of medical and health research grants that conforms to AMRC’s guidelines. Peer review guidelines are kept under review and members’ practice in this area is audited every few years.

Contribution to medical research



AMRC member charities allocated over £716 million to a wide range of medical and health research activities in the UK in 2005/06. This funding represents a significant proportion of the total public expenditure on UK medical and health research (approx. one third); a situation without parallel elsewhere in the world. The broad base of UK medical research, to which the charitable sector gives such significant support, has also contributed to the strong position of the UK pharmaceutical and biotechnology industries.

Four charities (Arthritis Research Campaign, British Heart Foundation, Cancer Research UK, and the Wellcome Trust) together spent £615M in 2005/06 and accounted for approximately 86% of the total UK medical and health research funding from AMRC charities. Although there is a wide spread of spending, the majority of members allocate less than £1M per annum to research.



The concentration of research funding in particular areas reflects, to some extent, public interest in those diseases. Inevitably, some disease areas receive considerably more public support than others. Cancer research, for example, has accounted for around a third of AMRC funding for more than 10 years. Support for the smaller, disease specific charities is usually drawn from those most closely affected by the condition, mainly the patients and their families, which limits the potential for fundraising. Charities representing chronic diseases, rather than those whose interest is a life threatening condition, also find it harder to compete for charitable donations.

Even when their financial contribution might be relatively small, a charity with an interest in a particular condition provides far more than just monetary support. These charities help to maintain the interest of the scientific community in the disease, so that areas of research are never quite abandoned. Many

charities which fund research also work in the field of patient support and in education. Those charities which focus on a single disease often have a very close association with those who have the condition and this helps to inform the charities' priorities, as well as providing essential insights for researchers and clinicians.

What type of research activity is supported?

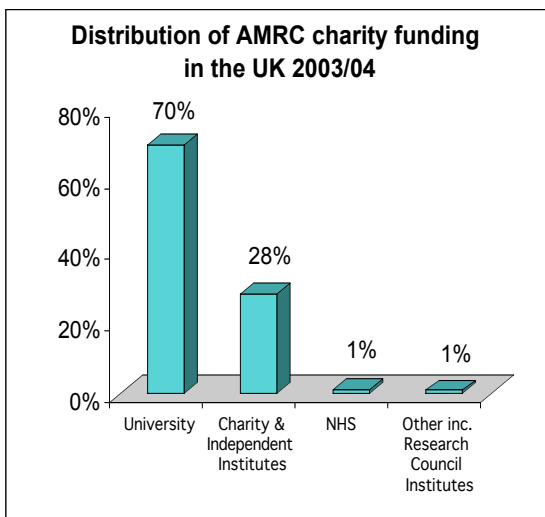
Charities support research with the aim of improving human health and well being. The purpose of the research supported by charities may be to search for a better understanding of a disease, to prevent or cure it, to improve diagnosis, treatment or quality of life for patients. As charities, their purpose in funding research must be for public benefit and not for commercial or private gain. Charities must have particular stated objectives and are therefore not free to redirect their support to other areas, even when these may be seen by some as having a higher priority. One advantage of this restriction is that charities maintain their focus over the long-term and are not distracted by changing policy demands or the latest 'hot topic'. This consistency offers a welcome sense of stability and continuity to researchers, at least for part of the funding within each scientific area. It also means that, over time, the charity is likely to have a clear understanding of the state of research in a field and be able to identify opportunities, should funding become available.

Analysis of members' expenditure, shows that about half of the funding is characterised by a focus on disease specific research. Research classed as 'general medical research' is provided by non-disease specific charities, such as the Wellcome Trust, which is the main funder of generic biomedical research. There are several other smaller general charities, such as Action Medical Research, and the Sir Jules Thorn Charitable Trust which fund a broad spectrum of biomedical research.

Research partnerships

Although charities may have specific requirements regarding the area of research they will fund, they do not usually seek out researchers to do specific projects or commission research directly. Instead, they respond to requests for funding from research institutions and individuals employed by universities and hospitals who want to conduct a particular piece of research in their area of interest. This type of funding model is called 'response mode' and is the most common amongst AMRC charities. Charities believe the university environment is generally a good place to conduct research (nearly three quarters of the funding is allocated to universities) and they see this type of arrangement as a partnership with the university, enabling both to pursue the best and most timely research questions. While charities pay for the direct costs of carrying out the research, AMRC charities expect the host institutions, whether universities or NHS Trusts, to provide the underpinning funding for any indirect costs or patient care costs associated with conducting the research. The Government has endorsed AMRC's position in its Science and Innovation Investment Framework 2004-2014 when it announced the introduction of an additional stream of funding to support charity-funded research in universities. The first allocation of the Charity Research Support Fund of £135 million was made in 2006/07 and will help universities to meet the full costs of charity research. The value of the fund will increase to £180 million in 2007/08.

Where is research conducted?



The university sector is the principal beneficiary of AMRC charity funding for research, as the bar chart shows. Universities undertake a wide range of research activities relevant to medicine. Some AMRC charities fund their own institutes and these may also receive grants from other funders. Although only a small amount of funding goes directly to NHS Trusts, this does not mean that research is not being conducted there. Many of the grants awarded have more than one applicant and there is usually collaboration between researchers based in universities and those working in hospitals, with the university most commonly the lead research manager or co-ordinator. Our data identifies the lead institutions processing the grant.

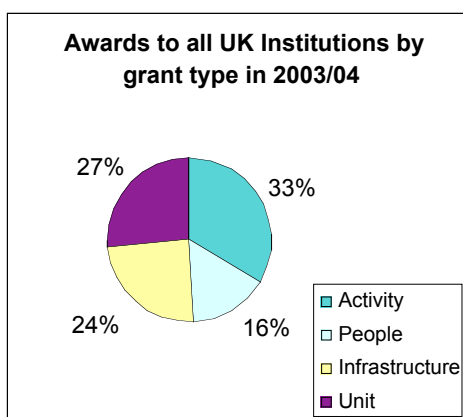
The majority of medical research charities operate UK-

wide, and will support good quality research wherever it may be conducted. Only a small percentage of the funding from AMRC member charities is restricted to particular geographical areas or to individual institutions.

What forms of support are available?

There are three broad types of research support: responsive mode funding, where individual researchers apply for time-limited funding such as project grants or fellowships; infrastructure funding where charities support longer term initiatives carried out by larger research teams or departments and which may involve supporting a unit, refurbishing laboratories or providing new facilities and buildings; and research supported in charities' own institutes. Charities are increasingly supporting longer-term programmes of research in partnership with host universities and other funders.

The breadth of methods of funding is increasing as charities respond to changing environments and the needs of their particular research areas. For example, analysis of AMRC data showed that ten years ago project grants accounted for nearly 70% of research funds, but in 2004 around a third of awards were in the form of project grants. At the same time, the proportion of funding for programme grants, unit funding and fellowships increased.



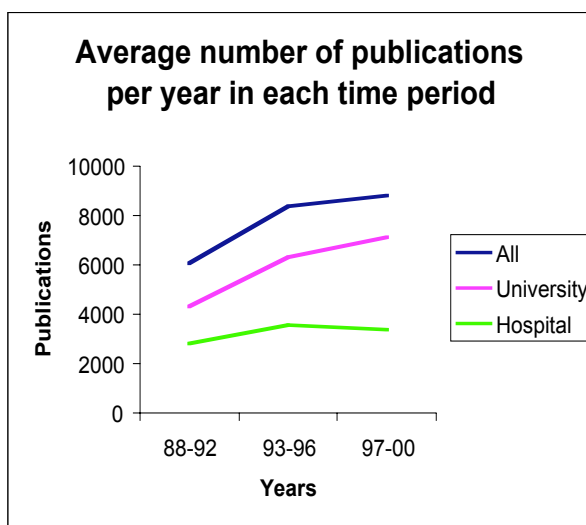
The pie chart opposite shows the spending on different types of support by AMRC members in the academic year 2003/2004. 'Activity' includes any award that supported a defined piece of research and ranged from short-term funding for proof-of-concept grants to long-term programmes of research. No definitions completely capture the scope of funding and within project and programme grants it should be remembered that salaries are provided to support people, as well as necessary laboratory consumables and small pieces of equipment. Project grants (which include awards for three years or less) represent about two thirds and programmes (four years or more) accounted for one third of the total under the 'activity' heading. 'People' includes funding for studentships, fellowships, chairs and

professorships. Such awards, aside from directly supporting the salary of the person, can also include additional funding for the research itself. 'Infrastructure' encompasses any funding for building, whether new construction or refurbishment of existing laboratories or other facilities and also stand-alone equipment grants. 'Units' receive extensive funding from the charity, often to support essential costs but are located within a university, NHS Trust or research institute, which may provide additional support.

External indicators of research quality

AMRC members must use peer review to help them select high quality research to fund. However, the results of research will not contribute to the body of scientific knowledge unless they are published and charities expect these to be published in the scientific literature. Many charities also disseminate the findings more widely to enable patients, carers, policy makers and the public to benefit. A number of AMRC members, particularly the Wellcome Trust, have been influential in supporting free public access to biomedical research papers.

Judging the impact of published results is not an easy or straightforward process, as many years can elapse between the publication of a paper and being able to measure the outcomes. Many charities are using a range of methods to monitor and assess outcomes and impact of the research they have funded.



In 2004, AMRC commissioned Professor Grant Lewison to examine the contribution of AMRC members to UK biomedical research outputs between 1988 to 2000 using bibliometric methods². Biomedical research publications were analysed using the Research Outputs Database (ROD) to determine which publications acknowledged AMRC members as funders of the research.

Between 1988 and 2000 over 100,000 publications cited AMRC members' support, compared with a little over 60,000 publications acknowledging the Medical Research Council. During this period there was an overall increase of 31% in the number of papers citing AMRC member funding. Analysis of the institutional origin of the publications revealed that about 76% came from universities and 46% were from hospitals.

Journals which publish scientific papers are themselves rated. In the system used for our analysis, journals were categorized by potential impact category, which gives an indication of the number of times other researchers quote the work of another author³. In 31 out of 32 subject areas, papers supported by AMRC members were in higher impact journals, on average, than papers with acknowledgements that did not include AMRC members. We believe that these results demonstrate the value of the peer review system used by members.

The range of stakeholders, including trustees, research assessment panels, researchers, donors, patients, carers and the public, as well as charity regulators, are all keen for charities to demonstrate that charitable funds are being used in the best way possible. The use of bibliometrics, detailed above, provides one way to assess overall outcomes and is useful for broad comparisons. However, for individual charities the long-term nature of the research process, and the fact that progress is not necessarily linear or easy to follow can make evaluation costly and uncertain. Despite these difficulties, charities are investing time and expertise in evaluating their research programmes and strategies in a number of innovative ways. Some of these have been documented in a recent publication by the UK Evaluation Forum entitled 'Medical Research: assessing the benefits to society'.⁴

² The work was commissioned by AMRC from ciber at City University in 2004.

³ This was based on mean five-year citation scores to papers in the journal published in an even-numbered year and cited from the year of publication through the next four years, and listed by the Institute of Scientific Information (ISI) in their *Journal Expected Citation Rates* file, purchased by City University.

⁴ A copy of the report is available from the Academy of Medical Sciences web site: <http://www.acmedsci.ac.uk/index.php?pid=47&prid=1>