The Academy of Medical Sciences

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Medical research: assessing the benefits to society

A report by the UK Evaluation Forum, supported by the Academy of Medical Sciences, Medical Research Council and Wellcome Trust.

May 2006

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Foreword

The UK Evaluation Forum was first conceived at a roundtable meeting hosted by the Academy of Medical Sciences in June 2003. Attendees at this meeting, who represented Government, Parliament, the Medical Research Council, the Wellcome Trust and the Association of Medical Research Charities, agreed that research funders should do more to co-ordinate activity in determining the socio-economic benefits of medical research. Engagement with other stakeholders was considered a priority and a Steering Committee with broad representation from the UK medical research community was convened in July 2004 (see Appendix I).

The Evaluation Forum Steering Committee identified two strategic objectives, to be undertaken by a Working Group:

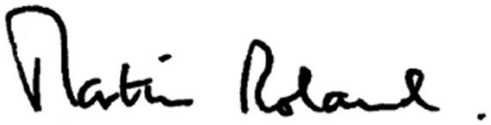
1. To examine how member organisations carry out their own evaluations; to establish what information has been generated; and to consider how this has been presented.
2. Subsequently, to establish the lessons that can be shared within the UK, identify gaps in knowledge, research international evaluation practices and highlight challenges and opportunities for the future.

I chaired the first meeting of the UK Evaluation Forum Working Group in October 2004 (see Appendix I). Forum members were generous in sharing their evaluation experiences and were keen to learn how their methods could be improved. It was quickly decided that an international symposium would provide a valuable focus for the Forum's activities and generate further information on the strengths and weaknesses of current evaluation approaches. We are extremely grateful to the symposium speakers and attendees, whose expertise and experience has provided an invaluable source of evidence for this report.

I thank Dr Robin Fears (Academy of Medical Sciences), Dr Liz Allen (Wellcome Trust), Dr David Cox (Medical Research Council), Dr Margaret Bryant (Medical Research Council) and Dr Helen Munn (Academy of Medical Sciences) for their considerable time and efforts in organising the symposium and helping to draft this report. I also thank those who provided very useful comments on the draft document (see Appendix I).

It is important to emphasise that this report does not represent the final output of the UK Evaluation Forum, which will continue to provide a hub for member organisations to share knowledge and co-ordinate activity. Rather, the Working Group considered it an appropriate point at which to share its conclusions and recommendations, based on the information learned so far.

Finally, I thank the Academy of Medical Sciences, Medical Research Council and Wellcome Trust for their generous and on-going support for the UK Evaluation Forum.



Professor Martin Roland CBE FMedSci
Chairman, UK Evaluation Forum Working Group

Summary and recommendations

Medical research plays a key role in improving national health and prosperity. Data from the UK Department of Trade and Industry testify to the excellence and efficiency of UK medical research. However, in recent years the medical research community has recognised a growing need to demonstrate the wide range of socio-economic benefits that result from investment in medical research.

Researchers and research organisations are accountable for their use of funds to a range of public, charitable and commercial sources. Evaluation of how and why medical research delivers benefits is therefore crucial to research stakeholders, which include Government, funders, industry, regulatory bodies, patients and the public. The process of evaluation enables funders to identify successful research and development (R&D) practices and improve the design of future research strategies. It must also take account of the uncertainty surrounding innovative research and the contribution of both 'successes' and 'failures' in advancing scientific knowledge. Developing better evidence through evaluation will help to build a dialogue with both politicians and the public and will ultimately support the case for investment in high-quality medical research.

There have been several recent initiatives attempting to develop an evidence base in this area. Despite significant activity in quantifying the inputs and outputs of research, there are few examples where the broader outcomes and impact of research have been assessed, particularly in terms of the socio-economic benefits. The UK Evaluation Forum was set up by the Academy of Medical Sciences in 2004 to address this.

The Evaluation Forum includes representatives from a range of UK funding organisations, including the public, charitable, academic and commercial sectors. It aims to explore how different organisations assess the outputs and outcomes of their investment in research, to share good practice and knowledge about research evaluation methods, and to explore the opportunities for coordinating UK activity to demonstrate the broader impacts of medical research in the future. This report presents an overview of the evaluation methods and frameworks that have been used by UK and international organisations and identifies opportunities for further development and improvement.

We conclude that there is no one 'best' method of evaluating research. Rather, various evaluation methods are complementary and different organisations and their stakeholders may employ different evaluation methods at different times. Similarly, research funders need to adopt evaluation methods that are appropriate for their research; different methods and their associated metrics need to take account of the often long, risky and incremental nature of medical research. These methods also need to recognise the value of negative findings in adding to knowledge, but also the risk that such results may be selectively under-reported. Overall, we believe there to be clear opportunities for the UK research community to develop improved evaluation methods, gain consistency in evaluation practices and demonstrate research achievements more actively.

Our recommendations are based on four premises:

1. **Medical research produces a wide range of socio-economic benefits.**

2. **There is a growing need for the UK research community to develop better methods to capture, evaluate and demonstrate these benefits.**

3. **Different stakeholders in the research process have different drivers and requirements for research evaluation and require different methods at different times.**

4. **UK research stakeholders should be more active in demonstrating the benefits that arise from medical research and making the case for continued investment.**

The UK Evaluation Forum recommends that:

- **The research community should consider how it can better demonstrate the value and benefits of medical research to all its stakeholders, through improved use of existing evaluation tools, greater sharing of good practice and the development of new approaches where required.**

- **UK research funders should work together to develop an evidence base for demonstrating the impact of research. This should include identifying opportunities for greater consistency of data collection and analysis across funding agencies. An initiative of this type in the UK is likely to be supported across Europe.**

- **Research funders should identify and fund further research into evaluation methods with a rigour and quality equivalent to other research fields.**

- **UK research funders should support research to assess the economic impact of UK medical research, which should include critiques of existing economic approaches.**

- **The research community should consider how it can stimulate a more active and informed dialogue with policy makers and the public about the achievements, applications and broader societal implications of medical research.**

Report outline

The UK Evaluation Forum was set up by the Academy of Medical Sciences in 2004 and comprises a Steering Group and Working Group (Appendix I). The broad remit of the Forum is *'to explore how member organisations might share information and co-ordinate activity in evaluating and demonstrating the outcomes of research relevant to human health'*. Following an initial mapping exercise of evaluation practices in member organisations, a central part of the Forum's activity was the organisation of an international symposium, held in June 2005. The symposium was designed to:

- Bring together UK research stakeholders to discuss their evaluation needs and expectations.
- Help to build the interface between these expressed needs and what the research community can deliver.
- Review what has already been attempted in demonstrating the socio-economic impact of health research in the UK and in other countries.
- Clarify the strengths and limitations of existing research evaluation methods, including prospective assessment.

The symposium has provided a significant source of evidence and material for this report and we are grateful for input from both the speakers and attendees (see Appendix II).

The issues discussed in this report are relevant to a broad range of research activities, from basic science through to clinical and health services research. The report is intended for policy makers and research funders, as well as researchers and other stakeholders.

- **Chapter 1** identifies the stakeholders of research and describes their perspectives in more detail. It describes the need for research evaluation and some of the associated challenges.

- **Chapter 2** describes the range of available evaluation methods and how they have been used by stakeholders in the UK and internationally.

- **Chapter 3** describes a range of economic approaches to evaluating research and the evidence they have generated.

- **Chapter 4** describes several frameworks that can be used to assess the breadth of benefits gained from medical research, giving examples of how these have been applied.

- **Chapter 5** discusses ways in which the benefits of medical research might be made available to the public and key decision-makers to ensure continued support for medical research in the UK.

1 Introduction: opportunities and challenges

Summary

- *Medical research increases the health and wealth of the nation.*
- *There are increasing demands on the research community, in the UK and internationally, to demonstrate the benefits of medical research in order to justify future investment.*

1.1 Research stakeholders

The stakeholders for medical research include the funders, users and beneficiaries of research, as well as the researchers themselves. In this way, Government, the NHS, charities, patients, public, media, industry, universities and the research community can all be considered research stakeholders.

In recent years there have been substantial increases in funding for UK medical research across all sectors. With such increases come demands from stakeholders for information about the outcomes delivered by research. At an early stage of its activities, the UK Evaluation Forum began asking the questions:

- What benefit do stakeholders want to see?
- What information do they need?
- What do they consider to be useful indicators of success?
- Is the information currently being produced satisfactory?

It quickly became clear that stakeholders have very different drivers for evaluating the impacts of medical research. Their evaluation needs may also differ greatly in terms of the quantity and quality of information required and the timescale involved. Some of these differing needs are outlined below.

1.1.1 UK Government and the Research Councils

The Government's Science and Innovation Framework (HM Treasury, DTI and DfES 2004) makes the case that innovations in science and technology have driven the increase in living standards in developed countries over many years, and that investment in research has a consistently positive impact on long-term national productivity and growth. This position is supported by increases in funding across all areas of research over the last decade. Since 1997, the UK government has invested, through its eight Research Councils, around £7 billion across 130 Higher Education Institutes and intramural research centres, and an additional £2.6 billion on research infrastructure funding through its partnership with the Wellcome Trust.

The Science and Innovation Framework is seminal in several respects: it takes a long-term view of performance, it represents a coherent strategy across Government departments and it makes a powerful case for investment in research. The opening words of the summary reveal the political imperative:

'Harnessing innovation in Britain is key to improving the country's future wealth creation prospects. For the UK economy to succeed in generating growth through productivity and employment in the coming decade, it must invest more strongly than in the past in its knowledge base, and translate this knowledge more effectively into business and public service innovation.'

The Government's target is for overall levels of public and private R&D spending to reach 2.5% of GDP by 2014. However, given the competing pressures for funding within Government, it cannot be assumed that the Treasury will continue to invest in research without evidence that the research is providing broad socio-economic benefits. Policymakers and the taxpaying public need to know what benefits arise from investments in medical research in order to make decisions for sustained or increased funding in the future.

1.1.2 Department of Health and the NHS

The status of research as a front line NHS activity was emphasised by Dr John Reid, then Secretary of State for Health, in March 2004: *'To us, science and research constitute a front line service, as they too reduce distress and pain and save lives.'* The Department of Health is a major research funder in its own right: in 2005/6 the total spend on NHS R&D programmes and new funding for the UK Clinical Research Collaboration (UKCRC), in addition to hosting research funded by external agencies such as the Medical Research Council (MRC), the research charities and industry, will be at least as much as that spent by the MRC.

Research is a long-term investment that can be difficult to balance against the day-to-day needs of the NHS. Evaluating and demonstrating research impact are therefore central to NHS R&D strategy, yet the importance of research in the NHS has previously been underestimated. In the past, NHS R&D priorities have been criticised as insufficiently focused on the public interest (Harrison and New, 2002; Wanless, 2004), with the design and delivery of health services research receiving particular criticism (Lomas, 2003; Dash *et al.*, 2003). Poor links between researchers and policymakers have previously resulted in delays in the adoption and development of research outcomes into policy and practice.

The recently published NHS R&D strategy sets out research goals for the next 5 years with the aim of creating a research environment that contributes to the health and the wealth of the nation (Department of Health, 2006). From an economic perspective, health research supports NHS reform through the provision of new ideas, new evidence, new products and improved efficiency. It also underpins economic growth through a healthier work force and by providing an attractive environment for investment by pharmaceutical and biotechnology companies.

The new NHS R&D strategy aims to reverse the recent trend in which the NHS was perceived to have become a difficult place in which to conduct research. The NHS now aims *'to provide world class support to those who conduct and participate in health research for the benefits of patients in the NHS and the wider public'* (Department of Health, 2005). There is a particular emphasis on establishing an environment that is attractive to industry and the medical research charities. The development of a national electronic patient record offers a major new opportunity to create an NHS research environment that will be unique in the world. Furthermore, the development of the UKCRC, and proposed changes to the management of the NHS R&D levy, present an opportunity to increase the profile of R&D in the NHS, and to provide more transparent information about how NHS R&D is conducted.

The decision to bring together research funding for the MRC and the NHS, announced by the government in April 2006, is likely to present a number of new challenges for evaluation. There are likely to be a range of general and specific requirements for accountability, stewardship and evaluation of a combined budget of over £1bn per year.

1.1.3. Not-for-profit and charity sector

The not-for-profit and charity sector in the UK is sizeable. Government Science, Engineering and Technology[1] (SET) statistics suggest that the not-for-profit and charity sector contributed around 14% of total SET R&D in the UK in 2003–04. Although these statistics are based on R&D across all science areas, medical research accounts for most of the charitable research investment.

There has been a drive throughout the charity sector for better demonstration of the outcomes and benefits of the research it supports and several charities are developing new methods for gathering and evaluating information on research outcomes. Charities have a range of stakeholders interested in ensuring that charitable funds are put to their

1 http://www.ost.gov.uk/setstats/5.htm

best use, including their trustees, researchers, donors and the public, as well as the UK Charity Commission (which requires that charities document their aims, objectives and outcomes in an annual Summary Information Return).

1.1.4 Industry

Industry differs from other research funders in that it needs an economic return on research investment, i.e. research should ultimately produce profitable products. For research intensive companies such as those in the pharmaceutical sector, the share price is heavily influenced by the market's evaluation of the number and potential of new drugs in development. Shareholders expect such companies to be investing heavily in R&D. Indeed, the high share price of many smaller biotech companies reflects their investment in R&D, even though they may have yet to make any profit. Some of the economic approaches used specifically by industry are discussed further in Chapter 3.

In many other respects, the needs of industry are closely aligned with those of the public sector. The Bioscience Innovation and Growth Team (BIGT) report identified industry's interest in creating a health care system that is supportive of innovation, and the vested interest that the pharmaceutical and biotechnology industries have in improving health care[2]. From an economic perspective, industry investment in research is seen as a driver of UK economic productivity and global competitiveness, and it has been argued that resources used in the pharmaceutical industry produce greater economic benefits than if they were employed elsewhere, for example in manufacturing[3].

The public and commercial sectors have often played complementary roles in medical research. The traditional view of this relationship has been that the public sector focuses on basic scientific research, while industry applies this science for the development of novel products. However, many pharmaceutical companies have also invested in basic research (for example, in genomics) and in the early stage discovery and validation of novel drug targets, as well as in the later developmental stages in the R&D pipeline. There is likely to be continuing change in the dynamic balance between activities undertaken in the larger pharmaceutical companies, smaller biotechnology companies and the public sector. Although analysis of the collective benefits accruing from this spectrum of R&D should not be overly generalised, it can be deduced that there is now much closer alignment between the goals of the private and public sectors. For instance universities increasingly value partnerships with industry and start-up companies for their income generation potential and as a means of ensuring that research is translated into patient benefit as quickly and effectively as possible. Furthermore, recent changes to R&D policy within the NHS specifically acknowledge the need for the public sector to create an environment in which commercially funded research can thrive.

1.1.5 The public

Surveys of public attitudes suggest that, in the area of medical research, people are most concerned about issues that affect them personally[4]. Nevertheless, research funders play a key 'brokering' role, managing funds channelled into research from taxation and donations to research charities. Funders are increasingly developing ways to effectively and responsibly engage with society to better inform research strategies and priorities. This engagement is particularly important where there is a focus on the introduction of new technologies in research, for example the use of reproductive technologies, or around emotive subjects, such as the use of animals in medical research. The interests of the wider public, be they patients, carers, parents or taxpayers, are not uniform; a responsible research community must work with these different groups to understand the concerns and value systems that influence attitudes to medical research.

2 http://www.bioindustry.org/bigtreport/downloads/exec_summary.pdf
3 http://www.advisorybodies.doh.gov.uk/pictf/pictf.pdf
4 http://www.mori.com/polls/2004/pdf/ost.pdf

1.2 Challenges

The previous sections show that research funders are subject to a range of internal and external stakeholder demands to evaluate and demonstrate the impact of research. These varying, and sometimes conflicting, requirements are not always clearly defined or addressed. A focus on one particular stakeholder can imbalance research objectives. For instance funders may become overly risk averse if they concentrate on satisfying their internal audiences and support only research that can more easily attain short-term objectives. While the internal and external drivers are clearly related, this report focuses on how funders might better make the case for medical research to society.

It is clear that it can be difficult to identify the impacts of medical research in what may be a complex, slow and incremental process to eventual heath benefits. Broadly speaking, these difficulties include:

- The significant time and resource demands of expert peer review.
- The difficulty of factoring in negative results (including the risk that such results may be selectively under-reported), non-incremental developments and 'blue-skies' research.
- The time-lag between research and tangible outcomes.
- The complexity of tracing the role of individual research contributions over the developmental life cycle of a new product, technique or service.
- The collaborative nature of research and the difficulty of evaluating the relative contribution of different funders, research groups or countries.
- The relative paucity of information about how research impact should be assessed.

UK researchers and funders are not alone in their desire to evaluate and demonstrate the benefits of medical research. In June 2005, the European Science Foundation[5] held a meeting to discuss how the value of scientific research could be assessed to inform European decision-making and research budget setting. The European Research and Technology Development Evaluation Network[6] has also been working with the Research Evaluation Network in Washington[7] to discuss the development of common evaluation methods, and the Australian National Health and Medical Resarch Council[8] has been experimenting with new methods of capturing research outcomes, having previously assessed inputs and outputs in more conventional terms (e.g. bibliometric analysis, counts of research studentships).

In 2003–04, the Heads of International Research Organisations (HIROS) convened a Working Group to consider evaluation practices across organisations and identify opportunities for benchmarking. The HIROS Working Group concluded that:

- Research funders differ in the degree to which they focus on outcomes of research. Those that do not currently evaluate outcomes wish to do so more in the future.
- Evaluating outcomes is challenging: the path from discovery to impact can be long and unpredictable, and may depend on the activities of several funders.
- Government requests for evidence on the outcomes of research increasingly emphasise quantitative targets.
- There is a continuing tension between short-term quantitative measurements and the long-term benefits which research brings.

1.3 Conclusions

The need to devise, test and implement tools that can more directly measure the socio-economic impact of research has been highlighted by the Director of the Office of Science and Technology Policy in the USA in an effort to

5 www.esf.org
6 www.cordis.lu/fp5/monitoring/rtd_evalnet.htm
7 www.wren-network.net/
8 www.nhmrc.gov.au. A recent publication (Kingwell and co-workers, 2006) describes the experience gained in evaluating NHMRC-funded research in terms both of knowledge outputs, and health and wealth gains.

elaborate a new 'science of science' policy (Marburger, 2005). This new science is designed to offer more compelling guidance for policy decisions and credible advocacy to develop the evidence base needed to help answer policy questions. This US strategy resonates with recent UK policy questions around how much a nation should spend on science, what kind of science should be funded and how investment should be split between private and public sectors.

In short, there are increasing demands from stakeholders for improved evaluation of medical research to demonstrate more effectively its societal benefits. The medical research community, both in the UK and abroad, has begun to respond to these demands, although there are significant challenges to be faced. The following chapters explore existing research evaluation methods and frameworks, with a view to identifying promising areas for development and routes to improvement.

2 Methods of evaluation

Summary

- *Several methods can be used to assess the value of medical research.*
- *Methods of assessing the outputs and outcomes of research include bibliometric analysis, retrospective case studies, surveys, peer review, micro-economic and macro-economic analysis.*
- *Different methods of evaluation will suit different organisations at different times.*
- *Examples are given of the ways in which each of these methods have been applied.*

2.1 Introduction

UK research funders are experienced in a range of methods of research evaluation and most funders use more than one approach. Different methods will suit different organisations at different times, but collectively these efforts can help to demonstrate value to their stakeholders. This chapter provides an overview of non-economic methodologies, whereas Chapter 3 focuses on the economic approaches to research evaluation that are currently producing significant international interest.

In 1993, the US Government introduced the Government Performance Results Act (GPRA) to help improve effectiveness and accountability among federally funded agencies.[9] To help those agencies that support research, the US National Academy of Science's Committee on Science, Engineering and Public Policy (COSEPUP, 1999) developed a taxonomy of the techniques that can be used to evaluate research. This 'evaluators toolkit' provides a useful overview of techniques. It has been adapted by several organisations (NHS Executive 2001/Wellcome Trust; Wooding *et al.*, 2004) and is further adapted in Table 1.

2.2 Bibliometric analysis

The science of bibliometrics, involving analysis of publications and citations, is based on the premise that a researcher's work has value when it is judged by peers to have merit and is therefore made available in a 'peer-reviewed' journal. Bibliometric approaches describe outputs in and across research areas by assessing the volume and estimating the 'quality' of publications. Its quantitative and systematic methodology allows for comparative and repeated analyses.

Bibliometric approaches have mainly been used to assess the contribution of scientific research to *knowledge creation*, rather than to determine *socio-economic benefit*. Bibliometric data have been used to estimate scientific impact (citation analysis), technology development (patent citations) and health services impact (citation of research in clinical guidelines).

Bibliometric approaches have weaknesses and there are plenty of critiques of the methods used (e.g. Chapman, 1989; Seglen, 1997; Adam, 2002). These weaknesses fall into three broad areas:

(a) Multi- and inter-disciplinarity
A focus on *numbers* of publications provides little indication of actual importance and applicability. As indicators of quality, citations based on journal impact factors (JIFs) may be a reliable way of assessing work in single disciplines but are unsatisfactory as a means of comparing across disciplines and in dealing with multi-disciplinary research. For these reasons, while publication output is clearly an important indicator of research activity, complex bibliometric analysis has now been rejected by the Higher Education

9 http://govinfo.library.unt.edu/npr/library/misc/s20.html

Funding Council for England (HEFCE) as a method of research evaluation in the UK Research Assessment Exercise.

Analysis of the publication outputs of research, using bibliometric methods, has greater utility for considering the

Table 1: The Evaluator's Toolkit[10]

Method	Pros	Cons
Bibliometric analysis	• Quantitative: measures volume of output • Can be used to indicate quality of output • Enables analysis of global trends • Suited to repeated analyses • A number of new bibliometric indicators, such as the H-index and Y-Factor, are being developed (Ball, 2005; Ball, 2006)	• Estimates of quality by citations and journal impact factors (JIFs) can be misleading • Use of JIFs can obscure the impact of individual articles • Data are difficult to compare across research fields and disciplines • Analysis complicated by the introduction of electronic publications and open and public access journals • No consideration of the value of 'grey' literature
Case study analysis	• Provides in-depth analysis of the process of discovery • Can demonstrate pathways from basic science to application in health services • Information useful for a range of purposes (e.g. reporting to stakeholders, media)	• Selection bias: cases chosen may not be representative • Often difficult to track and interpret the history of scientific discovery • Problems of recall bias • Method can be highly resource intensive
Systematic peer review	• Well understood component of research management • Widely accepted by the research community	• Time consuming for experts • Concerns about objectivity and variability of judgements and lack of transparency
Surveys and consultations	• Can identify outputs and outcomes associated with particular pieces of funding/ research • Provides qualitative analysis of outcomes, e.g. quality of trained researchers, business/academic interactions.	• Dependent on contact details being available, e.g. for past award holders • Poor response rates can lead to biased responses
Economic rate of return (a) Micro-economic analysis	• Can be applied to variety of sectors • Case-based studies provide a rich source of data e.g. HTA contribution to national guidelines • Can be used comparatively, e.g. contribution of cost effectiveness studies	• Involves subjective decisions around attribution of what's involved and therefore what to 'cost' • Difficult to put financial value on many influences involved
(b) Macro-economic analysis	• Quantitative • Provides big picture and context • Demonstrates likely directions • Potentially powerful political tool	• Depend on monetary valuation of non-monetary goods (e.g. quality of life) • Difficulty to identify contribution of individual funder/sector/country

10 After COSEPUP, 1999 and NHS Exec, 2001

outputs associated with more basic medical research, where an estimation of the contribution to knowledge is required. To estimate the impact of medical research with a more clinical and/or health focus, analysis of scientific publication output can have less relevance and value.

(b) Attribution

Many funding bodies attempt to track the publication output of researchers they support, though this can create difficulties around attribution. First, pieces of research (and the publications that describe the outcomes of this research) are often the product of multiple funders and researchers. Second, researchers may simultaneously hold awards from a range of funders. Third, medical research (and research in general) increasingly involves collaboration between researchers and across disciplines. This collaboration is reflected in the increasing number of authors on research publications, making it difficult to identify which piece of the research puzzle can be attributed to a particular funder (Wellcome Trust, 1998). In recognition of this, research funders are moving from positions of 'claiming' to 'celebrating' contributions towards particular lines of research.

(c) Gathering information

Research funders face considerable technical difficulties in simply gathering information on publications as they emerge. While there are several online databases that provide access to publications (e.g. Medline; PubMed; and Web of Science), for a high proportion of articles the full text is not available for scrutiny. Furthermore, there is no standard way in which researchers acknowledge their funder (e.g. no listing of the grant reference), despite it being a grant condition for most. Analysis by the Wellcome Trust (1998) and Webster and Lewison *et al.*, (2004) found that only two thirds of bio-medical publications acknowledge a funding source at all, with clinical papers much less likely to include acknowledgement of funding than basic science papers. As mentioned above, even if the names of the funding source could be easily extracted from the acknowledgements, the relative contribution of each individual author (and therefore the funder) is often difficult to decipher.

A number of funding organisations, including several of the UK Research Councils, have developed more proactive strategies to encourage researchers to inform them about research publication output associated with their support. The Natural Environment Research Council (NERC), for example, requires individuals whom they support to provide details of research outputs and outcomes as they emerge and for a designated period following the cessation of funding. This has benefits for both the funder and the researcher; the funder has details of outputs to which it has contributed and the researcher has details of their track record readily available should they wish to submit an application in the future.

Despite these issues, bibliometric analyses can be used to identify trends and features of the research process that cannot be elucidated by other means. For example, research on the sources of references contained in UK clinical guidelines show they selectively include UK research, demonstrating the use the NHS makes of its local science base (Grant *et al.*, 2000a; Webster *et al.*, 2004). Papers cited in guidelines tend to be relatively recent and have a high proportion of citations from industry-based authors, probably because many guidelines deal with the cost-effectiveness of new drugs. Further analysis of these data (Grant *et al.*, 2000b) found that guidelines tend to cite primary research rather than

systematic reviews, even though the latter might be a less biased source of information (Chalmers, 2000). However, this situation may be changing: other analyses (Patsopoulos *et al.,* 2005) suggest that meta-analysis is now cited in research publications more frequently than other forms of evidence.

2.2.1 The use of bibliometric analysis in Public Service Agreement (PSA) targets

Bibliometric analyses can be used to compare national levels of research activity, specialisations and strengths, and bibliometric indicators are core components of the Public Service Agreement (PSA) targets develope in 2003 by the Department for Trade and Industry for the UK research base (Box 1).

Box 1: PSA target metrics for the UK research base[11]

Inputs
Public expenditure on R&D

Outputs
Publications and share of world publications
People, e.g. PhD awards and share of Organisation for Economic Co-operation and Development (OECD) PhD awards

Outcomes
Research recognition, e.g. citations and share of most cited papers
Training
Research quality

Productivity – financial
Outputs and outcomes per input

Productivity – labour
Publications and citations per researcher

People
Availability of skilled people and proportion of population classified as researcher

Business expenditure on R&D

A large set of research indicators has been selected to reflect differences in performance between scientific disciplines, the interaction between inputs and outputs, and measures of efficiency and effectiveness.

The PSA analysis conducted in 2003 concluded that the UK has considerable research excellence and the system that produces this research is relatively efficient, albeit resting on relatively low investment by international comparison. For the scientific areas covered by the UK Evaluation Forum (clinical sciences, pre-clinical and health-related sciences and biological sciences) the UK's overall share of citations is second only to the USA, though there may be some indication that this position is under threat (King 2004, Table 2).

The most recent report[12] of the bibliometric indicators set out in the PSA shows that the UK is maintaining its strength; while the UK undertakes 5% of the world's research, it contributes 9% of published scientific papers and has a citation share of 12% (13% of papers with highest impact), therefore retaining its position in relation to the G8 nations.

2.3 Case study analysis

A case study approach can be used to look in-depth at the stages leading from basic

Table 2: Example of the use of bibliometric analysis for international comparisons: rank order of nations based on share of top 1% of cited publications[13]

Country	Percentage 1993–1997	Percentage 1997–2001
United States	37.5	34.9
United Kingdom	9.3	9.4
Japan	8.7	9.3
Germany	8.1	8.8
France	6.1	6.4
Canada	5.1	4.6
Italy	3.7	4.1

11 Summarised from Department of Trade and Industry 2003 www.ost.gov.uk/research/psa_targets_metrics.htm
12 HM Treasury, DTI, DfES and DH 'Science and innovation investment framework 2004 – 2014: next steps' March 2006
13 From King, 2004

scientific discovery to the implementation of new treatments for patients. Various approaches have been used to assess the impact of medical research and to identify the origins and influences on particular bodies of research and practice. This in-depth approach enables cause and effect to be determined with more certainty. However, by their nature, case studies present unique situations and therefore have particular value in generating, as opposed to testing, hypotheses.

2.3.1 Examples of the case study approach

In a classic and much quoted study, Comroe and Dripps (1976) used citation analysis to identify the critical pieces of research that led to several clinical advances in cardiovascular medicine. They concluded that 60% of all research judged to be essential for clinical advances in cardiovascular medicine could be defined as basic research. This study provided seminal information in helping to underline the importance of basic research to clinical advances. However, the methods used had several limitations. In particular there is no *a priori* reason why the contribution of basic research to cardiovascular disease should be similar in relation to different medical advances, or necessarily appropriately represented by citation counts.

Several studies that have attempted to replicate Comroe and Dripps' retrospective, bibliometric case study approach show that the path from scientific discovery to clinical application is lengthy and unpredictable (Contopoulos-Ioannidis *et al.*, 2003). For example, a recent study of publications underpinning clinical advances in neonatal care estimated that the contribution of basic research was much lower than that suggested by Comroe and Dripps, ranging from 2% to 21% (Grant *et al.*, 2003a, b). This work did, however, reveal other valuable insights into the process by which research is translated into benefits for patients (Hanney, 2005), including delays in getting findings into clinical practice (see Box 2).

2.3.2 Narrative case study approaches

Another 'case study' approach used to describe the development of medical research and its associated benefits has been adopted by the Wellcome Trust. Drawing on methodology developed by the Institute of Contemporary British History, the Witness Seminar[14] approach has been used to bring together a range of experts to discuss the key influences on the development of a particular innovation or research field. To date there have been over 20 Witness Seminars, covering topics as

Box 2: Corticosteroids and preterm labour

In the late 1960s, Liggins was doing research to understand how preterm labour might be prevented. After using corticosteroids to induce labour prematurely in ewes, he noticed that some of their immaturely born lambs had inspired air before they had died (Liggins, 1969). This led to the hypothesis that prenatal administration of corticosteroids might reduce complications resulting from preterm birth in humans. Within three years, Liggins and Howie (1972) showed in a large randomised trial that pre-natal administration of corticosteroids produced important reductions in neonatal respiratory distress and death. Many other controlled trials were done during the subsequent 20 years, but most of them were too small individually to obtain statistically reliable evidence. The strong evidence of the benefits of corticosteroids only became clear when the results of all these studies were reviewed systematically and consequently it was not until the 1990s that this highly cost-effective treatment became more widely adopted. This case also shows the importance of systematic review and meta-analysis in identifying effective treatments and reducing duplication of research; indeed the logo of the Cochrane Collaboration incorporates the meta-analysis of the first seven trials of steroids in preterm labour. The issues surrounding this case are discussed in more detail in a recently published report of a Wellcome Witness Seminar (Reynolds and Tansey, 2005).

14 http://www.ucl.ac.uk/histmed/publications/wellcome-witnesses/

diverse as Obstetric Ultrasound (Tansey and Christie, 2000), Genetic Testing (Christie and Tansey, 2003) and Environmental Toxicology (Christie and Tansey, 2004).

Research funders are increasingly drawing on narrative approaches to help them identify the key developments and outcomes of the research they have supported. Both the US National Institutes of Health (NIH) and the National Science Foundation (NSF) currently use narrative case studies to profile their funded research, using 'stories of discovery' and 'research nuggets' respectively. These case studies complement the more quantitative requirements of the GPRA.

2.3.3 Limitations of the case study approach

Case study approaches have a number of limitations, including the difficulty of dealing with large volumes of information, long time-lags between discoveries and their application, uncertainty about the critical steps in innovation, and variability in expert assessment of impact and attribution (Hanney *et al.*, 2003). Perhaps the greatest problem lies in the selection of cases, which may result in bias towards cases where particular benefits can be demonstrated. Nevertheless, this type of in-depth, focused approach is valuable to the particular case under investigation, and can provide effective demonstration of the impact of a piece of research.

An important factor is that negative results of studies may not be published or even submitted for publication, resulting in publication bias (Chalmers, 1990). For this reason, some major journals have now moved to compulsory registration of clinical trials at their start if the journal is to consider publication of the results at a later stage (Abbasi, 2004). This is to reduce the risk that only positive findings will be published. When using case studies to evaluate research (whether prospective or retrospective), it may therefore be important to follow a 'cohort' of research to investigate the findings and not just rely on published results.

More work is needed to identify valid approaches to case study analysis, and its role alongside other methods, and to identify common approaches across funding organisations.

2.4 Peer review

Peer review describes the process of using expert peers to assess the quality, worth and potential value of particular piece of research. It is perhaps the most traditional method of research assessment, though it is not generally used to evaluate longer term impact. It is most frequently used to inform decisions on what research should be funded and therefore relates to the application process. It is also the process used to guide the selection of research papers that appear in scientific publications.

In relation to the UK Evaluation Forum's focus on the benefits of research, peer review can be used for post-award assessment, i.e. to evaluate the outputs or outcomes of medical research. A number of organisations do routinely peer review final reports, e.g. the NHS Health Technology Assessment Programme[15] and the NHS Service Delivery and Organisation Programme[16]. Despite the limitations posed by the timing of such final reports, which are often requested within a few months of the termination of a research grant, they can, if suitably designed, provide a valuable overview of achievements and offer a rich source of information.

In the UK, formal review of final reports is not routine practice and many funding organisations do not have formal tools or approaches to enable the review of the achievements arising from research that has been supported. The Association of Medical Research Charities (AMRC) is currently working to improve this situation among its member organisations by encouraging the use of reporting tools and post-award evaluation. A number of other organisations are working to ensure that post-award achievement

15 www.ncchta.org
16 www.sdo.lshtm.ac.uk

reporting and assessment becomes a core component of management information. In addition, organisations are considering approaches to enable the longer-term impacts of medical research to be tracked, many of which, by their very nature, occur well beyond the lifetime of a particular research award.

Peer review can be very time consuming and makes considerable demands on the scientific community. Funding organisations have responded to this by adopting a range of incentives and strategies to minimise reviewer 'fatigue'. Despite uncertainties about the reliability of peer review (Godlee and Jefferson, 2003), it remains the best available method for assessing the quality of individual pieces of work. This has been recognised in the UK Research Assessment Exercise, which has so far retained peer review as the assessment method of choice following a search for less time-consuming alternatives. In 2001, the US National Academies Committee on Science, Engineering and Public Policy (COSEPUP) also concluded that: *'The most effective means of evaluating federally funded research programs is expert review.'*

2.5 Surveys and consultations

Surveys and consultations are used by funders to access research stakeholders to gather facts and views around impacts of medical research and training. For example, the holders of training awards may be traced and surveyed some years after the award has finished to see whether they have pursued successful academic careers, or whether they have continued to use skills gained during their training period.

This type of approach is often resource intensive. It requires significant commitment on the part of the research funder and the ability to find/contact the appropriate informants. The more detailed the survey, the more meaningful the data may become. For instance, it is relatively easy to count the number of public events that a research funder organises, but the impact of such events on public attitudes to research would be much harder to assess, and requires a more detailed form of investigation and analysis.

Box 3: Assessing outputs or outcomes?

Outputs are the immediate tangible results of an activity (e.g. number of papers produced, number of research students), whereas outcomes include longer-term effects (e.g. impact on health). A focus on outputs may divert the researcher from the long-term goal of increasing scientific knowledge to improve national health and wealth. However, outcomes are much more difficult to identify, capture information on and assess. Research funders must oppose their needs for information on outputs and outcomes against the risk of introducing burdensome accountability requirements that may stifle scientific creativity and introduce perverse incentives across the research community.

2.6 Discussion and conclusions

To conclude, there is a continuing need for research on methods of evaluation to both question underlying assumptions of current methods and develop other robust and reproducible approaches. The UK Evaluation Forum found that this field of research evaluation is relatively immature and often driven by the need of organisations to monitor and manage their own operational performance. There is certainly more to be done in developing common approaches between the major research funders and in engaging the users of research.

There is no single best approach to research evaluation, and ways in which different methods may be combined are explored in detail in Chapter 4. The prospect of improved methods in the future should not prohibit a

better use of what is available now, but this does not mean that inadequate metrics should be adopted for want of anything better. The research community can protect itself from the introduction of inappropriate indicators and perverse incentives for research performance through pro-active engagement with research stakeholders about preferred evaluation criteria.

We recommend that:

- **UK research funders should work together to develop an evidence base for demonstrating the impact of research. This should include identifying opportunities for greater consistency of data collection and analysis across funding agencies. An initiative of this type in the UK is likely to be supported across Europe.**
- **Research funders should identify and fund further research into evaluation methods with a rigour and quality equivalent to other research fields.**

3 Economic approaches to evaluation

Summary

- *Macro-economic analyses suggest very high rates of return on investment in medical research. However, most of these describe research outside the UK, and the methods make a substantial number of important assumptions that may not be applicable to the situation in other countries.*
- *Further work is required to explore the use of economic approaches in evaluating the impact of medical research in the UK.*

3.1 Introduction

Several approaches have been developed to assess the economic and financial impacts of medical research. These were recently summarised by Buxton and colleagues (Buxton *et al*., 2004) into four broad areas of evidence:

1. Direct cost savings to health care systems.
2. Benefits to the economy from a healthy work force.
3. Benefits to the economy from commercial development.
4. Broader benefits to society of the health gain from medical advances.

This chapter describes some of the economic and econometric work done within these four broad categories to demonstrate the economic value of medical research. Particular attention is given to the fourth area, in view of the wide publicity given to work in the United States, which suggests that investment in medical research is returned many times over in terms of societal benefits.

3.2 Direct cost savings to health care systems

Even if medical research yielded no economic return or savings in health care costs, the moral case for undertaking research that improves health is compelling. Nevertheless, some innovations, e.g. vaccines, have been assessed in terms of their estimated impact on reducing the costs of disease treatment/ prevention. Some of the best examples of cost saving preventive measures are in the developing world, e.g. measles vaccination, vitamin A supplementation, use of insecticide-treated bed nets, and oral rehydration therapy (Salama and Roberts, 2005).

One review identified health care savings from medical research for a wide range of disease areas, including infectious diseases, childhood diseases, cardiovascular disorders, metabolic and immunological diseases, cancer and surgery (Silverstein *et al.*, 1995). It is, however, difficult to disaggregate costs incurred in different ways. For example, in many health service accounting systems, the cost of treating an influenza epidemic cannot easily be distinguished from the cost of an influenza immunisation programme. There is a further problem of attribution, with different countries 'claiming' the research behind particular medical advances, for example the identification of helicobacter and the development of lithium treatment (Buxton *et al.*, 2004).

3.2.1 Health Technology Assessment (HTA)

Micro-economic approaches have been used to identify the benefits of research in terms of the efficacy and cost effectiveness of new treatments. Although these approaches do not always identify net cost savings from research, they may identify ineffective treatments that can be withdrawn, and also identify how treatments can be introduced to maximise the benefits of investment in health services.

This type of approach to evaluating medical advances is widely used by the NHS (as the *user* of new advances) and by industry (as the

provider of many advances). Health Technology Assessment (HTA) is a core part of this micro-economic approach. Rather than evaluating individual pieces of research, HTA evaluates the products of research in terms of their value to a health care system. Health technologies evaluated by this method range from pharmaceuticals to new types of professional activity (e.g. substitution of nurses for doctors). The UK has developed a major programme of HTA[17], which links to its programme of national guideline development at NICE[18]. Similar programmes of HTA have been developed in other countries, e.g. the Health Technology Assessment Programme in Canada[19], and Evidence Based Practice Centers in the USA[20].

Of course, research findings are not automatically translated into improved clinical practice. There is a continuing challenge for health care systems to act on the evidence in choosing which technologies to use, selecting the most cost-effective interventions and implementing them quickly (Canning, 2003). Research is likely to have the greatest impact on health if health professionals are able to act upon new advances. Ways of changing professional practice are comprehensively reviewed by the Effective Practice and Organisation of Care Group of the Cochrane Collaboration[21].

3.2.2 The use of economic evaluation by industry

To help health care services in identifying medical treatments of greatest value, R&D intensive companies are increasing their efforts to demonstrate socio-economic benefits (Vacani *et al.*, 1997). Economic evaluations are also increasingly required by regulators. A summary of recent US examples, provided on the website of the US trade association,[22] describes how industry considers new medicines to have saved lives, helped control health care costs and strengthened the economy.

Recent European work for the biotechnology industry summarises some major advances attributable to the first generation biotechnology-derived medicines[23]. Specific case studies reviewed recombinant vaccines, growth factors, monoclonal antibodies and other proteins. The report concluded that the socio-economic impact of biotechnology has already been high, although it is difficult to quantify this reliably in the absence of an agreed pharmaco-economic model and the relative paucity of cost-effectiveness studies.

Industry perspectives can also be instructive in understanding the possibilities for prospective impact assessment. Valuation techniques (based on estimating net present value and adjusted for assumed uncertainty in business development), 'real options' valuation, simulations and scenario analysis all provide data to inform R&D management decisions (Villiger and Bogdan, 2005). Risk adjusted net present value algorithms have also been employed in the prospective evaluation of proprietary technology platforms (Bode-Greuel and Greuel, 2005) and have the potential to be applied by other research funders. The Council for Science and Technology (2005) has specifically recommended wider use of 'Real Options Analysis' to evaluate potential outcomes from research investment.

3.3 Benefits to the economy from a healthy work force

Recognising that a focus on health care savings or provision of cost effective medicines alone is a relatively narrow economic perspective, some studies have also considered the indirect benefits to the economy associated with a more productive or longer working work force (Pardes *et al.*, 1999; Canning, 2003; Buxton *et al.*, 2004). These studies take a human capital approach and assess the value of production

17 www.ncchta.org
18 www.ncchta.org/nice/index.htm
19 www.ccohta.ca
20 www.ahrq.gov/clinic/epc
21 www.epoc.uottawa.ca
22 www.pharma.org/publications/policy/24.04.2004.983.cfm
23 www.bioimpact.org

that is no longer lost due to premature death or ill health. The approach has been criticised because it limits benefits to the working age population, but also because it makes several major assumptions, e.g. that the labour of sick people cannot be replaced from an unemployed population.

The 'lost production' approach has been most commonly used in the United States, perhaps because employers are major contributors to health care costs. However, the impact of improving the health of the workforce may be greatest in developing countries where premature mortality and morbidity may have its biggest impact on the working age population. In these countries, health systems research may be particularly important in identifying how established treatments can most effectively and cost-effectively be delivered (WHO Task Force on Health Systems Research, 2004). In addition, following policy shifts at the World Bank over the past decade, there is now an overt recognition that ill health is a major cause of world poverty. The World Bank now accepts that investments in health services are vital for the promotion of economic development, in part, through developing and sustaining a healthy workforce (World Bank, 2005).

3.4 Benefits to the economy from commercial development

Industrial innovation is dependent on public as well as privately funded research (Silverstein *et al.*, 1995; Pardes *et al.*, 1999; Buxton *et al.*, 2004), and publicly funded research makes a significant contribution to the maintenance of a healthy industrial sector. Rosenberg, for example, suggests that in the USA, 500,000 jobs in the biopharmaceutical industry *'would not exist if industry wasn't standing on the shoulders of public funding and academic performance'* (Rosenberg, 2002).

The UK Government's Science and Innovation Investment Framework argues that *'harnessing innovation in Britain is key to improving the country's future wealth creation prospects'* (HM Treasury, DTI and DfES, 2004). To be successful, this requires the operation of partnerships and networks involving both public and private sectors. The particular value of the UK science base in supporting the UK pharmaceutical and biotechnology industry was a major theme in a previous report of the Academy of Medical Sciences, *Strengthening Clinical Research* (*2003*) and of the Bioscience 2015 (BIGT, 2003) report. This has also been a key element in Government initiatives to support innovation in the UK and across the European Union.[24]

Within the UK, there are increasing pressures to demonstrate the economic impact of research and development at the regional level. Each Regional Development Agency in the UK (and their equivalents in the Devolved Administrations) has a remit to promote local competitiveness and to monitor local research impact in terms of industry collaboration, the creation of university spin out companies and inward investment, as well as proxy impact measures such as patenting and licensing. In nearly every case, medical research is seen as a priority for these agencies.

Quantification of the specific contribution made by science to Government economic objectives and to policy making is difficult. Various attempts have relied on proxy data such as patents and surveys, with industry managers exploring the contribution made by academic research. Buxton *et al.* (2004) review several econometric studies that have related R&D spending to commercial innovation and GDP growth.

R&D has also been used to underpin the development of pharmaceutical companies in middle-income countries, with the additional benefits of creating employment and reducing local drug costs (Gadelha, 2000; Kettler and Modi, 2001).

24 UK initiatives include the Pharmaceutical Industries Competitiveness Task Force (2001), and the Biosciences Innovation Growth Team (2003). A corresponding initiative at EU level was led by the G10 Medicines Group (2002;http://europa.eu.int/comm/health/ph/key_doc/key08_en.pdf)

3.5 Broader benefits to society of the health gain from medical advances: 'Exceptional Returns'

Buxton *et al.* (2004) refer to the broadest type of benefit to society from health-related research as 'the intrinsic value' to society. In many ways these benefits are the most difficult to estimate, especially in terms of their economic value. The best-known attempt to describe the value of medical research to society in economic terms is a US study sponsored by the Lasker Foundation called 'Exceptional Returns' (Funding First, 2000). This work involved a collaborative effort by economists and life scientists to determine the major contributing factors to the increasing life expectancy of US citizens over recent decades. Improvements in health were found to account for almost half of the gain in American living standards in the past 50 years. Better health care has also been a major source of the increased life expectancy and welfare in the UK (Canning, 2003).

The Exceptional Returns study uses national income accounting and individual 'willingness to pay'[25] criteria to calculate the economic value of increasing longevity, and subsequently relates this gain to the imputed cost of the medical research. The results of this type of analysis are striking; it was estimated that the decline in deaths in the USA between 1972 and 1992 from cardiovascular disease and stroke was worth more than $1.5 trillion per year to the US economy. Assuming that only a third of this gain came from medical research, the return on investment ($500 billion per year) was 20 times greater than the annual spending on medical research (Funding First, 2000). Using similar 'willingness to pay' assumptions, Murphy and Topel (2003) estimate that, for the cancer field in the USA, an investment of $100 billion in research would yield $935 billion in societal gain (excluding health care costs).

One of the attractions of the Exceptional Returns approach is that it aggregates all of medical research, and therefore can be applied to both basic and applied science. In some of the other methods discussed in this report (e.g. citation analysis, cost-effectiveness studies), it is much easier to relate health care benefits to research that is nearer the implementation phase, e.g. clinical trials and systematic reviews.

There is considerable interest from other countries in how the approach might be replicated in other economies. For example, the Australian Society for Medical Research used a similar technique, resulting in an estimate of between a one and fivefold annual return on R&D expenditure in Australia, when combined economic gain from reduced mortality and morbidity are included.[26] The Australian study extended methods used in the USA by including disability-adjusted life years (DALYs), as well as overall mortality, in their calculations. The Canadian Institutes of Health Research[27] has also explored the application of macro-economic approaches although such work has, to date, focused more on commercial development endpoints (for example the creation of new companies based on medical research discoveries). While the work of the Lasker Foundation has generated considerable interest from developed economies, the potential value of this type of analysis in less developed countries may be even greater. Using the macro-economic approach, current and future medical research can be expected to continue to have major economic impact, with growing elderly populations and rising income levels in developed countries.

While the Exceptional Returns study has been hugely influential in the USA, there are many potential problems with its wider application. First, the research is heavily dependent on 'willingness to pay' assumptions, which derive monetary values for a range of non-monetary benefits based on the price individuals would be willing to pay for them. Second, potential gains must be

25 Willingness to pay assumptions derive monetary values for a range of non-monetary benefits based on what people are willing to pay for them.
26 www.asmr.org.au/general/Except.pdf
27 www.cihr-irsc.gc.ca

offset by increases in health care costs; new advances in treatment may be increasingly expensive and less cost effective. Prediction of future benefits is therefore dependent on a range of factors, including the productivity of the pharmaceutical sector, health care costs and disposable societal income. There are also substantial difficulties in attributing advances to research in a particular country, since research is an international endeavour and the product of many different actors working over a period of time.

Moreover, demonstrating a high rate of return on the overall investment does not necessarily facilitate understanding of the marginal rate of return on additional investment, nor whether there is a consistent relationship between spending and outcome across all fields of medical research. The technique is most suitable for examining the overall benefits of medical research, and may not be easily adapted to help prioritisation between new areas for research. From an economic perspective, there is also an issue that public funding may be most valuable in areas where industry is unable to draw a significant return on its investment, for example in epidemiological research, health services research or in clinical trials on agents without patent protection. Any attempt to use this type of economic approach to help set priorities between research streams requires further work to resolve its methodological limitations. Nevertheless, information on the overall economic benefits to society of medical research would be useful for all stakeholders in research.

3.6 Discussion and conclusions

Much work has been performed in the past decade to refine micro-economic methods of analysis, e.g. incorporation of costs into trials. However, there has been no attempt to present an analysis of the broader macro-economic impact of medical research from a UK perspective. Given the demands for information around the benefits of medical research, it is time to consider how this approach might be applied to the UK. Current work being pursued by the Health & Social Care team at the London School of Economics in this area is therefore extremely welcome. Limitations with macro-economic approaches would be addressed by more research to yield better value of life calculations, life expectancy data, disease-specific data, and causal links between health outcomes and the research base. In developing the 'Exceptional Returns' methodology for the UK, several methodological and policy issues need to be considered, including:

- When can extension of life expectancy be considered productive? How should the negative consequences of increased longevity, e.g. increased spending on pensions, be taken into account?
- How should the economic value of a reduction in morbidity be captured?
- How should the attribution of benefits of research in individual countries be assigned?
- How can economic methods be extended to include developing countries, in particular to assess the impact of health systems research?
- The potential economic gains from medical research are large but need to be considered alongside the rising costs of health care associated with an ageing society with increased longevity.
- The costs associated with health care are difficult to predict; they may increase over time (e.g. new treatments) but they might also decrease through the development of new types of preventive treatment (e.g. vaccines).

We recommend that research funders should support research to assess the economic impact of UK medical research, which should include critiques of existing economic approaches.

4 Bringing together the evidence

Summary

- *Any overall assessment of the value of research should take into account the life cycle of research and avoid assessing research impact prematurely. This is particularly important for basic scientific research.*
- *Several frameworks have been developed to bring together evidence around the outcomes of medical research to paint a broader picture of overall impact.*
- *Two frameworks are described; the 'payback model' is described in detail.*

4.1 The research life cycle

4.1.1 Timelines for evaluation of research

A key reason for employing a range of methods to evaluate research is that the outputs and outcomes available for assessment depend on where in the research life cycle the evaluation is undertaken. This is of particular importance in evaluating basic scientific research, where the gap between investigation driven by scientific curiosity and clinical application may be years or even decades. The following examples illustrate the length of time between research and its direct application to improve human health:

- Basic research identifying monoclonal antibodies was done in the MRC Laboratory of Molecular Biology in Cambridge in the 1970s by Milstein and Köhler, who were awarded a Nobel Prize for their work in 1994. However, any potential application to patients required the additional step of humanisation of the antibodies. As little as four years ago, there were doubts about whether monoclonal antibodies had commercial potential (Gallagher, 2005). Now, more than 100 drugs based on this technology are in clinical trials, and monoclonal antibodies may account for one-third of the biotechnology health care market by 2008 (Stacy, 2005) with potential applications in oncology, inflammation, organ transplantation and infection and immunity.
- In 1950, major case–control studies by Doll and Hill in the UK and by Wynder and Graham in the US provided the first clear evidence implicating tobacco smoking in lung cancer deaths. In 1951, Doll and Hill initiated their first large cohort study, investigating the smoking habits of British doctors. Within 3 years, Doll had confirmed that smoking habits predicted lung cancer risk. As the prospective study of mortality among doctors continued, more diseases were shown to be related to smoking, and their 40-year follow-up showed that the habit would kill about half of all persistent smokers. These findings were of profound public health importance and paved the way for preventative measures that have been implemented in countries worldwide, most notably recent UK legislation restricting smoking in public places.

Some funders are explicitly taking these timelines into account in their evaluation. For example, the Australian Health and Medical Research Council has performed a ten-year retrospective outcomes study, studying research grants completed in 1992 and 1997. The measures of impact considered, and the methods used to collect data, varied according to the nature of the research and the time from completion of the research. So, for example, influences on policy over this timescale were tracked for health services research but not for basic research.

4.1.2 Timelines for evaluation of research careers

Training awards also require a long timescale for evaluation. Many funders track the

immediate career destination of individuals following the completion of a training award (e.g. a PhD). Few funders follow these up long term to investigate, for example, how many have become principal investigators, or how many who chose NHS careers have become research leaders within NHS trusts (e.g. providing a lead in clinical trial recruitment). One example is a survey of MRC Clinical Fellows whose awards began during the period 1983–1985, which showed that nearly 90% continued to have some involvement in research. Over 40% were spending more than half their time on research, 44% were in senior academic positions and a further 14% held senior positions in the private sector. Just over half were 'high achievers', defined as group heads holding external grant support of at least £100,000, holding senior positions in industry, or publishing frequently in top journals.

A recent report from the Academy of Medical Sciences, *The Freedom to Succeed (2005)*, recommends that UK research funding agencies should collect and disseminate information on research fellowships in a consistent format to facilitate strategic appraisal and monitoring of career development.

4.2 Organising the evidence: framework approaches

In Chapter 2, a range of methods for assessing research outputs and outcomes were described. Each individual method has its strengths and weaknesses, and most members of the UK Evaluation Forum have experience using one or more of these methods. However, it can be difficult to derive a clear picture of the information gained from various forms of research evaluation, and difficult to know how to take account of the research life cycle described above. To address these problems, several frameworks have been described that attempt to bring information together into a coherent whole.

The simplest typology identifies four broad areas:

- inputs, e.g. research funding;
- process, e.g. evidence of peer review, quality of research environment;
- outputs e.g. publications, trained researchers;
- outcomes, e.g. impact on health, benefits to the economy.

Much traditional evaluation of research is restricted to the first two, i.e. descriptions of what has been funded and the process of selecting the research that was funded. However, a greater focus is needed on the second two areas, i.e. the outputs and outcomes of research. It is to address these last two that evaluation frameworks have been developed to help funding organisations clarify what the impacts and benefits derived from their support are likely to be and to guide how such information can be assessed.

4.2.1 Framework 1: the payback model

One framework for evaluation that focuses on the outputs and outcomes of research is the 'payback model', developed by Buxton and colleagues at Brunel University over the past 10 years (Buxton and Hanney, 1996).[29]

Box 4: Research Payback Model[28]

- Knowledge production – including publications and patents.
- Research targeting and capacity building – informing future research, developing research skills.
- Informing policies and product development – including clinical guidelines, government policies, development of new therapeutic products.
- Health and health sector benefits – including health gain, cost savings, service improvements, and gains in equity.
- Broader economic and social benefits – including commercial exploitation and the economic benefits of a healthier work force.

28 Adapted from Buxton and Hanney (1996)
29 A list of associated publications is available at www.brunel.ac.uk/about/acad/herg/publications/payback/

The model was developed to describe the wide range of benefits that may result from medical research. Five broad categories are identified (see box 4).

The first category in the payback model includes traditional research outputs in the category of 'knowledge production' and ways of measuring these have been described in Chapter 2. However, the strength of the framework is that it highlights the wider benefits of research, all of which can be described, but not all of which can be quantified. The framework also illustrates several economic benefits to research, some of which have been discussed in more detail in Chapter 3.

An understanding of the 'research life cycle' is implicit in a comprehensive approach to evaluation. Some indicators can be assessed as part of the award making process, while others may take some years to be determined. Taking a broad perspective on evaluation will lead funders away from a focus on short-term evaluation of individual awards. One of the important interfaces described in the payback model is that between research and policymaking. Ongoing contact between the political, policymaking and scientific community is essential if the benefits of scientific research are to be understood in the wider community.

The categories in the payback model are not mutually exclusive. Previous methods have tended to focus in an *ad hoc* manner on a single aspect, e.g. knowledge generation, cost saving, linkage to policy. Using the payback model encourages a more comprehensive and consistent approach to research evaluation. The next section includes an example of how the model has been used to describe the 'payback' from research funded by one major charity.

4.2.1.1 Application of the 'payback model' by the Arthritis Research Campaign

The Arthritis Research Campaign (ARC) has used the payback model to evaluate its own research funding (Wooding *et al.*, 2004). The impetus to do this work came from patient and supporter feedback, which indicated that some of ARC's past research was considered to be too esoteric and lacking in practical application. By embarking on a retrospective evaluation of its research, the charity hoped to identify the most effective research fields and so better define research priorities in line with its stakeholders' expectations.

The payback model was applied to 16 case studies selected as representative of the range of Arthritis Research Campaign funding (from 556 candidate grants awarded in the early 1990s). The work included a review of archive material, interviews with the researchers and analysis of published outputs. A consensus expert scoring system was used to build a single profile as a pentagram 'footprint' comprising the five categories of payback. This footprint was used to examine issues of practical importance to the charity, such as the relative impact of basic or clinical science, the relative contribution made by high impact publications, the importance of supporting individual researchers in the translation and application of their own research, and the importance of flexibility in the administration of research.

The first conclusion of the investigation was that ARC funded research produced a wide range of paybacks, which would not all have been identified without a structured approach to the case studies. Secondly, developments of practical value to patients depended on the conviction and personal networks of individual investigators, as much as on the funding stream or bibliometric impact of individual publications. Thirdly, project grants appeared to provide value for money that was at least as good as longer-term funding streams. This was an important conclusion that could not have been reached by separate evaluation of individual awards. In this cohort of case studies, one particular topic (development of anti-tumour necrosing factor as a therapeutic

agent) produced much greater payback than the others, illustrating the point that even a systematic survey may be dominated by one important case.

The ARC is now starting prospective evaluation of the research it funds. This prospective evaluation will be compared with retrospective evaluation at the end of the grant period and 10 years later to establish whether it is possible to predict outcomes of particular types of research funding.

Inevitably, in pioneering work such as this, there are concerns about potential sampling bias in the selection of case studies, the problems of timescale in application of basic scientific research and whether the lessons learned can be generalised. The study has also highlighted problems in attributing payback, and issues relating to the reproducibility of the scoring system used. Nevertheless, the study was important in terms of demonstrating what could be achieved using a broad framework for evaluation.

4.2.2 Framework 2: Royal Netherlands Academy of Arts and Sciences

In the case of applied research, the Royal Netherlands Academy of Arts and Sciences has developed a framework designed to assess the output of an institution (e.g. department or research centre) against five domains of societal impact (Smith, 2001; Van Weel, 2002). This initiative sought to broaden traditional criteria for assessing research impact by describing achievements in five domains:

- Scientific knowledge: peer review of claims of knowledge production.
- Education and training: the training of researchers or generation of skills.
- Innovation and professionalism: the production of knowledge to gain a competitive advantage.
- Production of knowledge for public policy purposes.
- Collaboration and visibility: internally within the institution, and externally.

In contrast to the very labour-intensive application of the payback model described above, these reviews are designed to be performed by a visiting team in a relatively short period of time, and the Royal Netherlands Academy has published guidance on how the indicators should be assessed. However, in the initial stages, these criteria are being introduced for self-assessment[30] and there is concern that the long list of potential impact indicators lacks power to discriminate and identify research work of highest quality and greatest impact (Smith, 2001).

4.3 Discussion and conclusions

One of the aims of improving evaluation methods is to target future investment more intelligently. However, this is particularly difficult for basic research, where it may be impossible to predict which fundamental science advances will eventually produce benefits to human health. Anderson and Fears (1996) argue that a linear approach to predicting scientific development needs to be *'put to rest'*, and that science more frequently advances through sudden discontinuities or paradigm shifts. They also point out that of the five biggest classes of drugs developed over the previous decade, all were at some stage thought to have no commercial potential. There have been attempts to use a more systematic approach to predict how information needed to solve health problems can be gained more efficiently (e.g. Claxton *et al.*, 2001), but these have to be regarded as experimental at present.

Overall, it is clear that there is no single best way to evaluate research outcomes, and any indicator or framework must be able to deal with the unpredictability of research. Some momentum has now been established to demonstrate the benefits of medical research, and there are some instructive examples of

30 www.knaw.nl/publicaties/pdf/20021098.pdf

how to do it. The UK has growing evaluation capability due to the expertise developed in university health economics research groups, RAND Europe, the MRC and the Wellcome Trust among others. The UK Evaluation Forum hopes that this report will encourage closer working between and across organisations in this area.

There is seduction in numbers and recent discussions about the future of the UK Research Assessment Exercise illustrate that some researchers are concerned that the UK is too wedded to quantitative indicators (Hobbs and Stewart, 2006). Evidence presented in this chapter demonstrates the value of combining quantitative and qualitative approaches in composing intelligent systems of evaluation. Evaluation practices must adapt to the different levels of aggregation (e.g. at national, institutional and programme levels) and be clear about why a particular outcome is being measured (e.g. to convince the Treasury, to inform policy development, or to communicate to the public at large). Importantly, while quantitative methods may be the most appropriate measures of research efficiency, qualitative methods may be needed to understand why a particular research area has had an impact on policy or practice.

It is also critical to ensure that new methods of research evaluation do not themselves stifle innovation, or encourage funders to pursue safe but predictable lines of research. Scientists need freedom to pursue ideas. It was the Nobel Prize winner Sydney Brenner who slightly mischievously wrote: *'It is only through the use of subterfuge such as applying for money for work already done that innovative research can be freely pursued'* (Brenner, 1998).

Gaining a better understanding of the impacts of research facilitates better allocation of resources, even if it does not automatically generate more funding. However, in developing a more sophisticated approach to research evaluation, the scientific community must be wary of self-imposed traps. There is danger in raising Government expectations that national indicators can effectively measure attributes of what is actually a global endeavour or that it is possible to demonstrate short-term benefit from research in terms of health outcomes. The research community should make Government aware about the limitations of research evidence, including the long time-lag between much of research and its outcomes, and the risks of constraining freedom of inquiry and introducing perverse incentives if inflexible quantitative indicators are imposed. The need for better communication on these issues, and the need for more general advocacy of medical research, is discussed further in Chapter 5.

In conclusion, indicators for evaluation of socio-economic impact of research must be able to:

- Capture all relevant research activity or be representative of that activity.
- Where appropriate, link outcomes and impacts to the original objectives of the funder.
- Allow for the incremental and cumulative nature of research, alongside the timescale of scientific progress and its inherent uncertainties.
- Demonstrate validity and reliability.
- Provide an efficient means of capturing information to avoid using resources that might otherwise be devoted to new medical discoveries or their application.

5 Making the case for medical research

Summary

- *The scientific community should consider how it can better make the case for the benefits of medical research.*
- *There is a need to develop an effective cadre of advocates for medical research, involving scientists and other members of the research community.*

5.1 Advocacy for medical research in the UK

This report has so far discussed ways of assessing the value of medical research. However, where the benefits of past research can be demonstrated, or benefits from future research are anticipated, the research community must consider how this information can be made available to a broader audience to help foster an environment within which medical research can flourish. This question has acquired a greater urgency since Government officials have expressed a view that the scientific community is currently not sufficiently active in making the case for medical research.

Scientists themselves are increasingly becoming key advocates for medical research and research funders are developing several initiatives to encourage and support scientists who want to become more involved in publicity and advocacy around their work.[31] However, there is some way to go and scientists are often reluctant to get involved in advocacy, either because they do not feel qualified, confident or personally inclined, or if their work is potentially controversial and may bring them into contact with more extremist pressure organisations.

At an organisational level, several bodies exist whose remit is to advocate for medical research.[32] For instance many of the medical charities have strong advocacy programmes to help them ensure ongoing funding for research around a specific illness or medical condition. In addition, several research-based organisations have actively engaged in advocacy work to ensure that the environment for research in the UK remains favourable, for example in making the case for the use of stem cells in medical research and in response to the Human Tissue Bill. Although some of this activity has tended to be rather reactive, there are examples of organisations working together on more proactive, co-ordinated approaches. For instance, the Coalition for Medical Progress brings together several research funders to promote the benefits that result from research using animals. The Research Councils UK's new Science in Society strategy also takes a multi-organisation approach to promoting the benefits of publicly funded research to UK society as a whole.

There are several broad-based science advocacy organisations in the UK: the Campaign for Science and Engineering[33] advocates for scientific research broadly across the physical and biological sciences, though there are few medical representatives among its institutional members (e.g. no medical Royal Colleges). Similarly, Sense about Science[34] is a campaigning organisation with a specific focus on addressing public misunderstandings about science, as opposed to medical research in particular.

Although evidence shows that the UK research community can successfully advocate around particular medical research issues, we consider there to be significant room for improvement in making the case for the broad-based benefits of such research. It is in all our interests to take a long-term view and better make the case for medical research. To do this, individual research organisations should be encouraged to advocate in their specialist areas and, where appropriate, to work together in developing more coordinated and holistic advocacy strategies.

31 See for example, http://www.wellcome.ac.uk/doc_WTX030830.html
32 See for example, http://www.rds-online.org.uk/ or http://www.medicalprogress.org/
33 www.savebritishscience.org.uk
34 www.senseaboutscience.org.uk/

5.2 Advocacy for medical research: the international context

Experience from the United States brings an interesting context to this debate. Research!America[35] has a mission to make medical and health research a much higher national priority. Research!America is a lobbying organisation with an institutional membership including hospitals, professional societies, industry, voluntary health groups and trade associations. Its overall goal is for greater investment in medical research, and it claims, for example, to have had significant influence in the doubling of the NIH research budget during the 1990s. Research!America makes extensive use of partnerships between scientists and industry leaders to present the case for medical research to both regional and national politicians. It also uses public opinion polling data to support the positions it wishes to advance. Often such polling is local to an individual state, for instance a senator will be lobbied with material and presentations that include the views of his or her own constituents. A similar organisation has recently been set up in Australia.[36]

5.3 Discussion and conclusions

Individual funders have their own drivers for determining the outputs and outcomes of the research they support. However, there is little information available on the benefits that the totality of this research has brought to society. The research community needs to act on this deficit and work together to better make the case for medical research.

Discussions have been held at the European Science Foundation and within the UK about establishing an equivalent Research!Europe or Research!UK. The political context and climate in the UK is very different from that in the US, and a direct translation of Research!America's approach is probably inappropriate. However, the US example does demonstrate the potential value of a more energetic and proactive approach to medical research advocacy. We believe that a change in the status quo is needed and strongly encourage a more focused debate among the UK medical research community around the need for advocacy.

We therefore recommend that:

- **The research community should consider how it can better demonstrate the value and benefits of medical research to all its stakeholders, through improved use of existing evaluation tools, greater sharing of good practice and the development of new approaches where required.**
- **The research community should consider how it can stimulate a more active and informed dialogue with policy makers and the public about the achievements, applications and broader societal implications of medical research.**

35 www.researchamerica.org
36 www.researchaustralia.com.au

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Appendix I Report Preparation

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Appendix II UK Evaluation Forum Symposium Programme

'Valuing health research – assessing the benefits to society'

2 and 3 June 2005, The Royal Society, London SW1Y 5AG, UK

2nd June 2005

14:00 Introduction
Lord Turnberg, joint Chair of Evaluation Forum Steering Committee

Session 1

Part I The views and needs of research stakeholders – what impacts of health research do they want to see?

Chair: Sir Keith Peters FRS, President, Academy of Medical Sciences

14:10 Professor Sally Davies FMedSci, R&D Director, Department of Health
A new strategy for health research – making the case

14:30 John Kingman, HM Treasury
A UK Government perspective

14:50 Professor Colin Blakemore FRS FMedSci, Chief Executive, MRC
A Research Council perspective

15:10 Session discussion

Part II Chair: Lord Turnberg FMedSci

15:30 Sir Charles George FMedSci, Former Medical Director, BHF
A research charity perspective

15:50 Sir Greg Winter FRS, MRC Laboratory of Molecular Biology, Cambridge
A research scientist perspective

16:10 Session discussion

16:30 Tea

Session 2 International Perspectives

Chair: Professor Colin Blakemore

16:45 Ms Suzanne Northcott, Executive Director, Centre for Research Management & Policy, Australian NHMRC
Laying the Foundations For Measuring The Impact Of Health Research: Australia

17:35 Session discussion

18:00 Close

18:30 Dinner

3rd June 2005

Session 3 Approaches to capturing the impacts of health research

Part I Chair: Dr Mark Walport FMedSci, Director, Wellcome Trust

09:00 Introduction
Lord Turnberg FMedSci

09:10 Professor Samuel Silverstein, CEO, Funding First, Lasker Foundation
What does economic research tell us about the economic benefits of investments in medical and health research?

09:40 Fred Carden, Director of Evaluation, International Development Research Centre, Canada
Outcome Mapping: Tracking Development Change

10:10 Professor Chris Van Weel, Royal Netherlands Academy of Artsand Sciences
The Societal Impact of Applied Health Research: Experiences from The Netherlands

10:40 Session discussion

11:10 Coffee

Session 3 Part II

11:30 Professor Martin Buxton, Brunel University
The 'Payback' Model for assessing the impact of health research

12:00 Mr Fergus Logan, Chief Executive, Arthritis Research Campaign
Evaluating arc-funded Research

12:30 Mary Woolley, President, Research!America
The work of Research!America

13:00 Session discussion

13:30 Lunch

Session 4:What should UK research funders and sponsors do next?

Chair: Professor Martin Roland CBE FMedSci, Chair, Evaluation Forum working group

14:30 Discussion

Closing remarks

16:00 End of symposium

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