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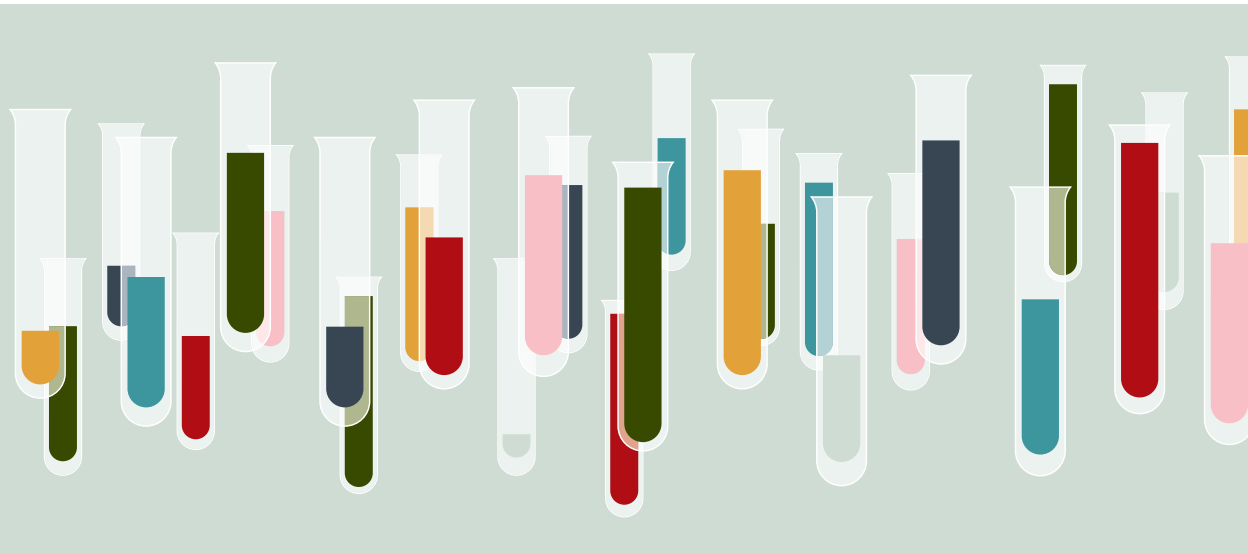
EVALUATION OF IMPACTS OF MEDICAL RESEARCH



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EVALUATION OF IMPACTS OF MEDICAL RESEARCH

Dr David Cox, Susan Cozzens,

Gerrit van Ark, Laura McAuley, Peggy Borbey

EVALUATION OF IMPACTS OF MEDICAL RESEARCH

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PREFACE

Governments around the world are facing increasing demands of accountability and efficiency of their investment of public funds into research. There is also an increased demand on research councils to evaluate the effects of the research funded. In order to retain credibility and confidence amongst the public and politicians, funding organizationsneed more accurate ways to show that their funding policy is evidence-based. To achieve this, there is a need tocompare and develop methods in measuring the impact of medical research on society in an international perspective. This report presents such an effort.

In November 2007, the Scientific Council for Medicine within the Swedish Research Council brought together an international group of evaluation practitioners, funding organisations, policymakers and researchers for the first of a series of workshops on this topic in Sigtuna, Sweden. The first Sigtuna workshop, *Economic Returns of Medical Research*, reached two conclusions: Firstly, evaluators need more accurate ways to estimate economic returns, and secondly, greater international collaboration is required to advance knowledge on crucial issues.

As a result of the workshop, a core working group was set up, led by Dr David Cox of the UK Department of Health. The working group was tasked with creating a roadmap that defines key questions to explore and possible approaches to take. The other members of the group were Dr. Gerrit van Ark at ZonMw, Netherlands, Dr. Peggy Borbey of the Canadian Institutes of Health Research, Dr. Martin Buxton at Brunel University, UK, Dr. Per Carlsson at Linköping University, Sweden, Dr. Susan Cozzens at Georgia Tech, USA, Dr. Jonathan Grant of RAND Europe, UK, and Dr. Toni Scarpa of the National Institutes of Health, USA. Former Secretary General for the Scientific Council for Medicine, Dr. Håkan Billig, initiated the workshops and was instrumental in the process.

In May 2009, the second Sigtuna workshop, *New Frontiers in Evaluation of Impacts of Medical Research*, took place, which moved the debate forward. Now the questions addressed were how research funding agencies and stakeholders can better understand agency performance and what is the key to better strategy development and implementation. The workshop focused on what issues can be addressed now, using current evaluation practices and what conceptual and methodological questions should be top of the agenda for future work.

In this report, the core working group presents their conclusions. Views presented in this report are those of the authors. In addition, the Swedish Research Council has also published two conference proceedings from the workshops in 2007[1] and 2009[2]. The work of the core working group, as well as the discussions at the workshops, show that it is not an easy task to measure the outcome and impact of medical research. But that does not make it less essential and it is important for the Scientific Council for Medicine and Health and other stake holders to continue the efforts of the first two Sigtuna Workshops.

Stockholm in April 2010

Mats Ulfendahl
Secretary General
Swedish Research Council,
Medicine and Health

Karin Forsberg Nilsson
Deputy Secretary General
Swedish Research Council,
Medicine and Health

[1] Lönsam forskning? Att mäta effekterna av medicinsk forskning, Vetenskapsrådet 2008

[2] New Frontiers in Evaluation of Impacts of Medical Research, Vetenskapsrådet 2009

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SAMMANFATTNING

Denna rapport presenterar olika aspekter av hur den medicinska forskningens genomslag och resultat kan mätas. Rapporten är skriven av en arbetsgrupp utsedd vid ett internationellt seminarium (Economic returns of medical research) organiserat 2007 av Vetenskapsrådets ämnesråd för medicin. Arbetsgruppen fick i uppdrag att formulera vilka nyckelfrågor som behöver ställas och vilka tillvägagångssätt som kan användas i arbetet med att utvärdera betydelsen av medicinsk forskning i samhället. Arbetet utfördes mellan 2007 och 2009 och ett uppföljande seminarium hölls 2009. I denna rapport sammanfattar arbetsgruppen sina slutsatser. Två konferensrapporter har tidigare publicerats.

Utvärderare behöver kunna uppskatta ekonomisk avkastning mer exakt, och ett ökat internationellt samarbete krävs för att förbättra kunskaperna kring en rad centrala frågor. Till dessa frågor hör förståelsen av hur innovationer blir till, hur man bäst analyserar forskningens sociala och kulturella genomslag och hur forskningsresultat kan attribueras till individuella finansiärer.

SUMMARY

This report reviews aspects of measuring impacts and outcomes of medical research. A core working group appointed at an international workshop in 2007, organised by the Scientific Council for Medicine within the Swedish Research Council, was tasked with creating a roadmap that defines key questions to explore and possible approaches to take. Their work was performed between 2007 and 2009.

Evaluators need more accurate ways to estimate economic returns and greater international collaboration is required to advance knowledge on crucial issues. These issues include understanding how innovation takes place, how to best analyse the social and cultural impacts of research and how research outcomes can be attributed to individual funders.

Attribution versus contribution

The ability to *attribute* something to someone is an implicit part of any evaluation of how well a specific organisation or system is performing. However, it is difficult to attribute overall economic impacts to the effects of a specific funder or policy, due to the number of funders over time as well as the increasingly global nature of research and development. Focusing on what a research funder has *contributed* to an achievement offers advantages such as the standards of evidence required to demonstrate a contribution are less challenging than those required to attribute a specific share of an outcome to a particular research funder. Some sort of attribution can, however, not be avoided where stakeholders wish to hold accountable a research funding agency whose funds they are providing. It is reasonable to aggregate activities and immediate research outputs (trained people, publications etc) across sets of projects or programmes funded by a single body.

Systems of innovation

Interaction among the actors in a system of innovation – firms, research organisations and government agencies – creates a network. The interaction in that network leads to learning in the form of generating, testing, and adopting new products or processes. Although the goal of a standard innovation system is economic growth or business success, it is possible to include non-commercial goals. In a health innovation system the learning

process would consist of identifying and addressing health problems and the outcome measure would be health with additional benefits for economy and society.

Social and cultural impacts

To analyse social and cultural impacts one must analyse how the health sector and general public engage with the results of health research. It is important to differentiate between activity, the various outputs of the research, and the true social and cultural impact. At present it is difficult to count or even compare social and cultural impacts of health research. However, it is essential that the medical science community becomes aware of the importance of societal impact evaluation of health research as a crucial addition to scientific impact evaluation to improve public accountability and to enhance public, private and political advocacy.

Implementing impact assessment

The Canadian Institutes of Health Research has implemented a framework based on the 'payback model' created by Martin Buxton and colleagues. Some of the projects look at impacts of a specific kind of research, others focuses more on specific categories on impact regardless of research area, such as commercialization resulting from health research.

ATTRIBUTION VERSUS CONTRIBUTION

Dr David Cox, Deputy Director - Research Faculty
Research & Development Directorate, Department of Health, UK

'Attribution' and 'contribution'

There are two schools of thought on evaluating the association between a research funder's decisions and the impact of the resulting medical research: 'attribution' and 'contribution'.

The first approach is based on the idea that achievements (outputs and outcomes) should be 'attributed' to some 'agent' (person or organisation). It implies direct association and accurate quantification. It is strongly driven by a stakeholder desire for assurance about the societal utility and relevance of the science that is funded.

The alternative approach is to adopt a less rigorously quantitative definition of cause and effect that looks at the 'contribution' an agent has made to achieving research-led change. This acknowledges the complexity of the processes by which scientific discoveries are turned into improved health care, and hence the difficulty of making a direct link (attribution) between a funding decision and a health outcome.

The standard of objective evidence required to convincingly attribute an achievement to a funding agency is very high. It is not enough to show an association between the achievement and the agent. Even a causal link between the two is still not sufficient. The challenge is to tease out those components of an achievement that can be attributed uniquely to a particular agent rather than to any other, and to quantify them. It can be difficult to do at the best of times; sometimes it is impossible.

In contrast, the standards of objective evidence needed to identify a contribution are not as demanding. As long as a contribution has been significant, there is less need to accurately quantify the unique contribution of a particular funding agency. This paper argues that, in many circumstances, this less rigorous approach can still meet stakeholder requirements for evidence on the benefits of medical research they have funded.

The US National Cancer Institute (NCI) has recognised the potential of the contribution approach. In the highly political 'hearts and minds' environment in which US public research funds are allocated , an agency that takes a robust approach to claiming achievements gains a competitive

edge in attracting funds. NCI made the reasonable assumption that if the Institute had funded any research that had contributed to a cancer breakthrough, then it was justified in highlighting that. The extent to which others had also contributed to success was not a paramount issue in the battle for funds.

This paper looks at:
- why the drive to 'attribute' developed;
- the challenges posed by attribution;
- the pros and cons of the 'contribution' approach;
- when to use either approach.

Why does attribution matter?

In a strictly logical sense, the ability to attribute something to someone is an implicit part of any evaluation of how well a specific organisation or system is performing. Some believe that attribution is essential to meet the three requirements for evaluation of research outputs and outcomes:
- accountability – demonstrating that public or charity funds have been used well;
- advocacy – making a convincing case to government and others for continued or increased funding of research;
- action – helping researchers and research funders to establish what succeeded (and why) and using this to develop strategy and improve implementation.

However, different stakeholders have different needs:
- Researchers and research funders want to know how well they are doing and how they might do better. They also want to identify news and narratives to publicise their achievements. Attribution is not always essential to achieving this.
- The public will ask whether spending on medical research is improving their health, but are not interested in who funds it. They may be engaged by stories of research breakthroughs, but will not care about numbers of publications or citations. This group has the least interest in attribution.
- Policy makers' main concern will be whether a publicly-funded research agency's policies are helping to achieve national objectives. Often, there is a strong audit tradition which wants to trace the impacts of specific decisions. Policy makers have the highest expectations and a desire to attribute achievements to particular agents.

The drive for attribution

Since the 1950s, the environment in which governments take funding decisions has become tougher. In developed countries, science spending has come to account for a larger share of national expenditure as governments recognise scientific discovery as a generator of national wealth. Although prosperity has increased significantly in many countries, so too have public expectations about the services that governments should provide. Competition between different calls on public expenditure has therefore intensified. In addition, for some countries the level of taxation is a political issue. So, not only do governments want to know that public expenditure on science is being put to good use; they also want reassurance that the research base is doing as much as it can to translate discoveries into innovative new products or services.

This focus on results is evident in the US General Performance and Results Act (GPRA) of 1993. The purposes of the GPRA included "improv[ing] the confidence of the American people ... ... by systematically holding Federal agencies accountable for achieving program results" and "improv[ing] congressional decision-making by providing more objective information on ... ... the relative effectiveness and efficiency of Federal programs and spending".

Similarly, the UK government is strongly focused on delivery, and the UK Research Councils are expected to demonstrate at a detailed level how they are helping to achieve national objectives. Accountability for UK Research Councils is partly achieved through reporting within an Economic Impact Reporting Framework. This Framework considers investment inputs into the research base or into innovation, the generation of knowledge outputs, innovation outputs and outcomes, and overall socio-economic impacts. The framework also looks at three systems factors influencing economic impact: the framework of government policies, the efficiency with which knowledge is exchanged, and the demand for innovation in the public and private sector.

Consequently, governments are likely to ask searching questions about attributable achievements.

The challenges posed by attribution

However, there are three key questions about attribution:

1. Is it possible, in practical terms, to attribute performance to organisations in as precise a way as some stakeholders desire?
2. Assuming that this is practical, how credible is the resulting attribution?

3. Can evaluators meet stakeholders' timescales for showing that research funders' actions have had an impact on the innovation system? Timescales matter if a clear link between funding decision and health impact is to be demonstrable. Yet it may be 10 or 20 years before the impacts of research can be fully seen or evaluated.

The simplest model of the process of turning research investments into socio-economic benefits identifies four elements along a 'logic chain':

1. *Inputs:* the resources that funders put into research and training
2. *Activities or throughputs:* research and training through which investment is turned into outputs
3. O*utputs:* the products or services provided e.g. increased knowledge and human capital, resulting from research and training which might be measured as citations and trained staff, and
4. O*utcomes:* the intermediate and/or long term accomplishments and effects resulting from spending on research and training e.g. new diagnostic tools, new treatments, new understanding of disease (intermediate) or the impact on knowledge, human capital, prosperity and health (long term socioeconomic impacts).

Were the world as simple as this 'science-push' linear model implies, it would be easy to attribute improvements in human health right back to initial spending decisions by individual research funders. In practice, the real world is much more complex than this. For example:

- it is difficult to establish the extent to which a specific piece of research has contributed to a health gain, because the improved intervention will typically have arisen from a series of research insights building up over time. These will then have been developed further by industry or in the health service itself; there is no single chain of causation
- the chains of causation run in all directions; demand for innovation is as important as the generation of new ideas. In effect, translation of research is a roundabout with traffic coming and going in all directions
- even a single research breakthrough may have been achieved with grants from several research funders
- an innovation in one country will often draw on the research and technological outputs of other countries.

This final point matters less in the US which alone accounts for a large part of the world's science and innovation activity, and which mainly depends on its own discoveries. It is a bigger issue for European countries which are a smaller part of the international science and innovation effort, and therefore more likely to absorb ideas from outside.

The attribution problem becomes more challenging, the further one progresses along the logic chain towards outcomes and impacts. As Martin and Tang state in "The benefits from publicly funded research" published by the Science Policy Research Unit in 2006.

"…it is highly difficult to attribute overall economic impacts…to the effects of a particular policy or investment, due to the multitude of factors over a lengthy time period which also caused the impact."

and

"attempts to add up all the economic and social benefits and to relate them to the initial investments in research are doomed to failure."

Despite the difficulties, there is still a big appetite for attributing health outcomes to research investments. However, there are circumstances under which a less rigorous approach based on 'contributions' could meet stakeholder needs.

The pros and cons of the 'contribution' approach

Focusing on what a research funder has 'contributed' to an achievement offers considerable advantages:

- it is a more realistic reflection of the real world, where ultimate outcomes depend on many different pieces of research and development funded by diverse research organisations
- related to that, an approach such as this which avoids spurious accuracy and heroic assumptions is likely to be more credible in the eyes of sceptical stakeholders
- the standards of evidence required to demonstrate a contribution are less exacting than those required to attribute a specific share of an outcome to a particular research funder
- a contribution to an achievement is news and, because it is often a simple argument, newsworthy. Therefore, contribution can be a suitable parameter where the objective is advocacy for retained or increased funding for the research organisation.

However, there are contra-arguments:

- a contribution is an estimate and may not even be quantitative, which makes the approach vulnerable to criticism by sceptics
- claims need to be handled sensitively, particularly where funders are competing for government funding or charitable donations. In these circumstances, the contribution claimed must be sizeable relative to the contribution of others.

'Horses for courses': deciding which approaches to use

Quite which approach to adopt will depend on the type of evaluation question being addressed.

Holding a funding agency accountable for the outputs and outcomes

Some sort of attribution cannot be avoided where stakeholders wish to hold *accountable* a research funding agency whose funds they are providing. As mentioned earlier, this will be easier the nearer the 'deliverable' is to the initial research or training investment. This is because the contributions of other agencies or factors will be less significant, and the time lag between a research funder's decision and something happening will be considerably shorter.

This is why it is reasonable to aggregate inputs, activities (where these are measured on a comparable basis) and immediate research outputs (trained people, publications) across sets of projects or programmes funded by a single body.

If the aim is to trace a research funder's contribution towards a 'downstream' economic or health outcome, it is possible to work forwards along the logic chain from the funder's original investment. Such a case study approach can generate a headline-grabbing *advocacy* story, making the case for funding medical research. The problem comes when attempts are made to combine funder-focused case studies to gather a systematic estimate of the attributable outcomes.

The UK Research Councils tried in 2007 to undertake a baseline analysis of the economic impact of the work that they fund, taking 18 case studies across the breadth of the research and training they support. While individual case studies yielded compelling information about the benefits arising from research council funding, it proved impossible to combine the results to get an overall meaningful 'value' of benefit across the councils.

It is even more difficult to work back from a health gain (e.g. improved survival in disease) and attribute a share of that gain to a specific funder of original research.

Judging national performance

The extent to which individual national agencies have contributed to national performance is likely to be far less significant for governments than how well the nation is doing overall. However, given the increasingly global nature of research and development, there will still be issues about attributing relative national performance. Clearly this will be a challenge if the focus is on an improved global health outcome. It can even be an issue with research outputs, so many of which now involve cross-national authorship.

In 2007, the UK Evaluation Forum launched a programme of work to estimate the rate of return of benefits attributable to investment in UK medical research (see footnote 5). This has been a co-operative project sponsored by the MRC, the Wellcome Trust and the UK Academy of Medical Sciences. The question of attributing the role of individual funders in economic benefits did not arise, as the Forum focused on the benefits to the UK of spending on UK medical research as a whole. However, there were still attribution challenges, as the study had to make reasoned assumptions about the degree to which UK health improvements had depended on non-UK research.

Benchmarking is not an absolute requirement for assessing national performance. The UK Evaluation Forum's hypothesis was that the returns to the UK of investment in UK medical research exceed the cost of that research. However, some evaluation questions will require international comparisons. One challenge in benchmarking is the need to be able to classify health research funding consistently across different countries.

How well is the science and innovation system performing?

Much useful information can be obtained by looking at science and innovation at a systems level, irrespective of who funds the work and in which country it is based, using case studies or other approaches. This does not preclude within-study attribution to funding mechanism or funder, but the aim is often to draw general conclusions about particular types of support (e.g. publicly-funded knowledge transfer programmes or co-funding by industry), rather than the actions of individual funding agencies or nations. Such systems-based evaluation studies allow a holistic approach and can offer a more sophisticated analysis than one which is simply focused on 'deliverables'.

These studies can therefore provide useful information for policy makers on whether the national innovation system is functioning, and suggest policy changes, without necessarily pointing the finger at particular agencies. However, the increasing emphasis on delivery has also led to calls for early evidence that spending on science funding and the policies of research funders are having a beneficial national impact. Using systems analysis, it is possible to address this need without attempting to attribute 'downstream' outcomes to individual decisions taken 'upstream' by research funders.

Systems analysis allows the identification of the critical success factors that determine how well the system works. Some of these factors will be influenced by the actions of research funders. For instance, support for academia/industry exchange fellowships, collaborative training, and networking meetings, all promote knowledge transfer (KT) between academia and industry. This, it is said, feeds through into future economic benefits. There are weaknesses in the argument, not least that it assumes there is a continuing upward relationship between increasing funder investment in KT and economic benefit. However, a case can be made that incremental changes in funding or activity are a reasonable indicator of future marginal socio-economic benefits. Metrics based on appropriate research funder spending and activities are therefore a reasonable 'leading indicator' of the future impact of current research funder actions.

Leading indicators can thus give government valuable early assurance that funders' decisions are likely to have a positive socioeconomic impact. Such approaches avoid the impasse of demonstrating immediately the economic effects of research spending decisions that may take many years to come into being, and of having to attribute specific benefits to specific funders.

While the focus of such studies is on how a national science and innovation system is working, they can also provide a basis for international comparisons being made between innovation systems of different countries.

National Institute of Health Research: http://www.nihr.ac.uk

SYSTEMS OF INNOVATION IN BIOMEDICAL RESEARCH: AN INITIAL SKETCH

Susan Cozzens, Professor of Public Policy and Director of Technology Policy and Assessment Center, Georgia Institute of Technology, U.S

In understanding the full impacts of biomedical research, the concept of systems of innovation (SI) may prove to be helpful. Drawing on recent work in my team, this brief discussion paper reviews the current dominant SI concepts and outlines some of the ways they might be generalized to understand several dimensions of impact of biomedical research. The common SI variants are all oriented towards economic growth outcomes. Under these concepts, biomedical research in Sweden would be part of the national system of innovation, the sectoral systems of innovation in pharmaceuticals and biomedical devices, and several regional systems of innovation. In addition, however, we can also picture biomedical research as part of a system of innovation directed to health outcomes and perhaps social cohesion as well. The latter part of the paper attempts to identify the concepts that would be used in an analysis of this latter type.

The discussion takes innovation to be a process of problem solving. In its broadest sense, innovation means doing things in new ways. When conditions change and routines no longer work, humans experiment and learn. In a narrower sense, innovation means developing new ideas into new products or processes. Whether the process happens in the public domain or in the market, the sign of successful innovation is something new being used widely to solve a problem.

Systems of Innovation: National, Regional, Sectoral

The concept of national innovation systems is attributed to Freeman (1987), Nelson (1993), and Lundvall (1992). All three scholars work in the tradition of evolutionary economics (Nelson and Winter 1982), where technological change is seen as a process in which entrepreneurs and inventors generate a variety of new technologies but only some of those variants survive the selective pressures of market and non-market conditions. The process is strongly path-dependent – success of a technological variant at one point in

time sets the conditions for the survival of later variants. The idea of national innovation systems helps to systematize this perspective by providing tools to describe the complex organizational ecology in which technological change happens.

The three basic elements of a national system of innovation (NSI) are firms, research organizations, and rules of the game. Innovating *firms* are at the center of the picture. They have a stake in introducing new technologies to gain competitive advantage in the market and are therefore the driving force in the system. Firms maintain competitive advantage through *learning and capacity building*, processes that are much broader than the traditional notions of invention or R&D (research and development). Research organizations (primarily universities or government laboratories) can help in this process of learning and capacity building, so they play a support role in an NSI. "Absorptive capacity" (Cohen and Levinthal 1990) – the ability of the system to use new information generated elsewhere – can benefit significantly from the efforts of research institutions. Finally, "institutions" or rules of the game, in North's sense of the term (North 1990), are also important in the environment. They can make it easy or hard for entrepreneurs to start new firms and for new technological variants to be introduced, tested, and adopted. Interaction among three sets of actors – firms, research organizations, and government – is the fundamental process that helps firms generate new ideas and new technological variants and thus enables the system as a whole to build capacity and learn.

These concepts have provided a framework for a wide range of compara-tive studies of national systems of innovation (for example see chapters in Freeman and Lundvall 1988; Nelson 1993; Muchie 2003; Cassiolato 2003; Lundvall, Intarakumnerd, and Vang 2006). In addition, they are being taken up broadly in the practical world of science and technology policy, where the phrase system of innovation is developing its own set of diverse variants. For example, in developing countries, where firms are often less active in driving innovation, policymakers may use the term to refer primarily to interaction among government agencies, universities, and public laboratories. Some of the innovation systems literature has been specifically directed to the problem of so-called "catching up" – using new technological opportunities to create economic growth in less affluent countries (Fagerberg and Verspagen 2007), including spreading the benefits of growth widely (Sutz 2003).

Two other levels of the innovation system concept, both sub-national, have taken their place beside national systems in the literature. Philip Cooke, has applied the concept to regional (sub-national) development (Cooke et al. 1997). A regional system of innovation (RSI), like the national variant, has firms at the center and includes research organizations and government.

The defining characteristic of a regional system is its geographic concentration, allowing more face-to-face interaction than in the frequently more disperse national system. Since much technological knowledge is believed to be communicated tacitly, face-to-face interaction can be an advantage, and the agglomeration of firms that need each other's skills in a particular place is posited to improve the chances of innovation happening there. Regional authorities can create both incentives for interaction and rules of the game that are favorable to firm success, and thus attract industry into the region, providing jobs and creating demand for services. Much research has examined this process (for example, Fritsch 2004, Asheim 2005, Holbrook 2006).

The second major offshoot is the sectoral system of innovation (SSI). Pavitt (1984) laid the groundwork for the concept, and Malerba and his coauthors have more recently developed it using a later generation of system of innovation concepts (Malerba 2002, 2004). A sectoral system of innovation brings together the three organizational elements in relation to a product or product group. The concept differs from the traditional one of an industry sector in the theoretical development of the concepts of interaction and learning. Although the concept is relatively recent, scholars have used it to examine a number of sectors from high-tech to traditional (for example, Lau 2002, Wengel and Shapira 2004, Mu 2005, Sumberg 2005, Sundbo 2007). Malerba is currently leading an effort at cross-national comparative studies in five sectors: agricultural supply and processing, automobile production, pharmaceuticals, telecommunications, software, microelectronics.[3]

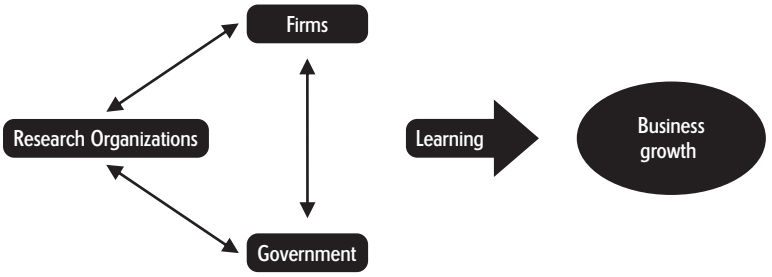
Generalizing Systems of Innovation

In order to apply SI concepts to the several dimensions of impact of biomedical research, let us pause to articulate an extension of the SI concept involved, to something we might call a human development SI. As we have seen, the core sets of actors in a system of innovation are firms, research organizations, and government agencies. Interaction among them creates a network, and the SI tradition posits that interaction in that network leads to learning in the form of generating, testing, and adopting new products or processes. A simple diagram might depict these relationships as follows.

[3] http://www.merit.unu.edu/research/projects_view.php?id=182

Diagram One.

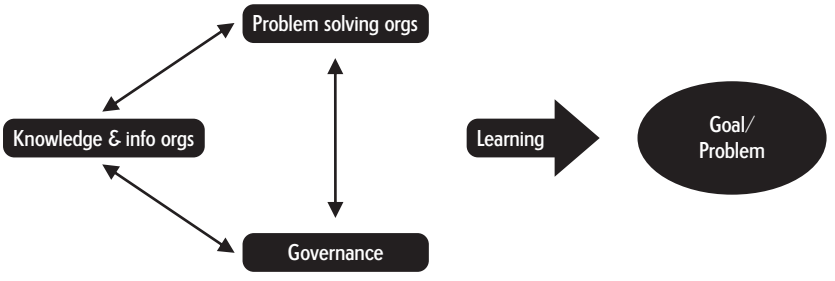
A standard system of innovation.



Although the goal of a standard innovation system is implicitly economic growth or business success, in creating a more general SI version we want to include the possibility of non-commercial goals. We also, then, want to allow for other organizations to be in the lead in creating movement towards that goal. We will use the phrase problem-solving organizations (PSOs) to indicate this more general category, which will point to firms in some systems, but in other instances might point to utilities, health services, etc. Following this generalizing logic, the GSI concept refers more generically to knowledge and information organizations (KIOs), rather than research organizations, to include different kinds of knowledge accumulation, for example in networks of practitioners. It also incorporates governance rather than government to include a broader range of deliberative processes such as voluntary consensus formation among non-governmental groups. As in the standard model, the various organizations interact to achieve the goal, and their interaction produces learning, that is, the process of generating variants, testing them for effectiveness, and diffusing effective ones.

Diagram Two.

A more generalized innovation system.



Biomedical research in standard systems of innovation

When examining the role of biomedical research in the national system of innovation, its biomedical character is not the dominant feature. Taking Sweden as our example, we find instead that actors drawn from across sectors are prominent in interactions, such as Swedish industry, of which pharmaceuticals and medical devices are only one segment; the Research Council itself; the universities as KIOs; a variety of regulatory bodies, including such cross-sectoral ones as the patent system, anti-trust laws and enforcers, and labor unions. The national rules of the game and the nature of interaction of these actors are thought to affect innovation rates across industries and fields within a country. Indicators of the contribution of biomedical research to the national system of innovation might include international standing, training of professionals who go into other research fields, use of biomedical research findings in other fields of Swedish research, and participation of biomedical researchers in organizations that build the overall strength of the research enterprise in Sweden.

Biomedical research plays a specialized role, however, with regard to certain sectoral systems of innovation, in particular in pharmaceuticals and biomedical devices. Both sectors are active in Sweden, and systems of innovation theorists would expect that the strength and global connections of Swedish biomedical research contributes to their strength. Again, interaction between research and industrial institutions would be seen as an important element of continued competitiveness, including creating breakthrough knowledge that could be incorporated into competitive advantage for Swedish firms. An appropriate governance environment for these particular industries would then be a part of the picture as well. Pharmaceutical, for example, is an industry group that relies heavily on patents to protect intellectual property for a period of time long enough to recoup high R&D costs. The drug and device approval process would also be an important element of the governance environment for these industries. Indicators of the impact of biomedical research in the sectoral system of innovation could include the competitive status of the sectors themselves (as an outcome variable), the international standing of the research field, and collaboration and contact between research and business.

Finally, the health industry sectors play particularly strong roles in certain regional innovation systems and not others. The Øresund region, for example, which includes Lund University, is working hard to capitalize on its biomedical research strengths, turning them into a rising regional standard of living by generating local employment, particularly in high-

wage jobs. The regional approach would focus in particular on complementary industries that might thrive in the neighborhood of the region's biomedical strengths. Indicators of contribution to the regional economy might be related firms located there, along with the number of people they employ at what level; new firms started in health-related sectors; and spin-offs from biomedical research or health-related firms in other sectors.

We might note that all this business activity has implications for income inequality in a country. High technology development usually adds a few high wage jobs at the top of the income distribution, which in turn generate low-paying service jobs towards the bottom. Whether this kind of development increases or decreases inequalities in the country where it happens depends in part on the redistributive mechanisms in place there, i.e., whether the profits generated are taxed to provide other kinds of benefits in other places. Production of high technology goods, on the other hand, usually generates mid-wage jobs that reduce inequality, regardless of redistributive policies.

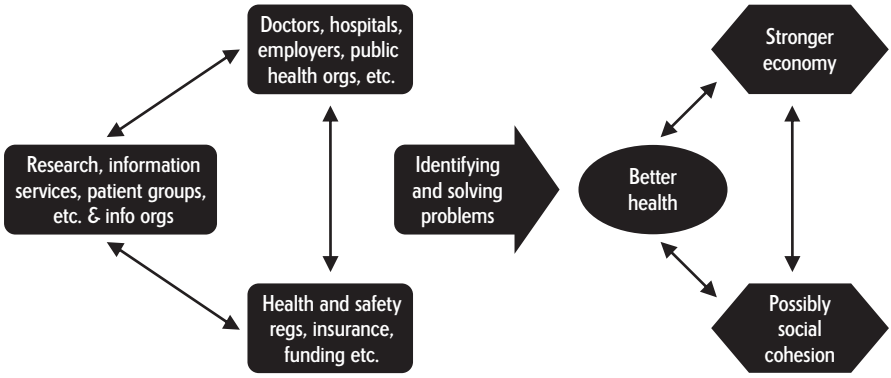
The Health Innovation System

All this economic activity, however, might not pay off in better health for Swedes, except through the indirect route of employment and general prosperity. Likewise, the health of the pharmaceutical and biomedical device industries does not necessarily indicate that Swedish research is contributing to addressing human health challenges. Innovation systems aimed at these goals could be envisioned using the more generic model introduced above (see Diagram 2).

In the health version of this model shown in Diagram 3 below, the problem-solving organizations (PSOs) include doctors, nurses, and hospitals; public health institutions; and perhaps others such as employers. Knowledge and information organizations (KIOs) would include not only research institutions but perhaps patient self-help groups, public information centers, and communication channels such as the media. The governance environment would include health and safety regulation along with investment in insurance and health care. The learning process would consist of identifying and addressing health problems and the outcome measure would be health, with ancillary benefits for economy and society.

Diagram Three.

A health innovation system.



Turning again to the implications for income inequalities, we know that health outcomes are affected by income inequalities (Wilkinson 1996). But if the health outcomes of the innovation system are unequally distributed, health inequality can also contribute to income inequality by affecting education and employment. Conversely, if the health innovation system takes social cohesion as one of its long-term goals, then programs can be targeted to low-income and vulnerable groups, contributing to overall employment and productivity.

Technology Policy and Assessment Center: http://www.tpac.gatech.edu/

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SOCIAL AND CULTURAL IMPACTS OF HEALTH RESEARCH

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Before analysing the social and cultural impacts of research, it is first necessary to define what we mean by 'impact'. The impact(s) of research occur when others besides the research group itself notice the results, refer to these results, use the results or even commission further research. Outcomes of research can eventually lead to societal changes, generally called societal impact. Societal impact can be further differentiated into social (public sector), economic (private sector) and cultural impacts; however these impacts often overlap.

Choosing the right analytical frameworks

When selecting the most appropriate framework for analysing research impact, four factors need to be taken into account: the perspective, the level of aggregation, the time horizon and the focus of the analysis.

- The *perspective* adopted may be that of the research institutions themselves, funders and commissioners of research (research councils, charities, industry), governmental bodies (national, international), health insurers, patient groups or the lay public.
- The *level of aggregation* may be low (individual researcher, research group or research project), intermediate (faculty or research programme) or high (research discipline, research council, charity, industry or university).
- The *time horizon* may be retrospective (evaluation) or prospective (assessment of research plans, foresight or policy decisions). The horizon may be short (years) or long term (decades).
- In terms of *focus*, the analyst can choose between two approaches. A longitudinal focus looks at impacts and outcomes belonging to one piece of research (for example a project, programme or discipline). A transverse focus looks at outcomes and impacts established within a certain time frame (for example by a group or institution) but not necessarily belonging to the same piece of research. This allows interaction between research entities and target groups to be considered.

In general, lower aggregate level analyses tend to adopt shorter time horizons combined with a transverse focus. Higher aggregate level analyses typically use longer time horizons and a longitudinal focus.

Mixing up analysis frameworks designed for different perspectives, aggregate levels, time horizons and focuses can confuse rather than clarify discussions.

Social and cultural impacts

Research can have four kinds of impact: scientific, social, economic and cultural. As mentioned earlier, these impacts often overlap. For example, a substantial increase in the level of public health will generally lead to other social, economic, cultural and even scientific impacts. Research outcomes and impacts affect different sectors of society – the target groups – and can eventually contribute to changes in the science community, the public sector (health care), the private sector (products and services) and the general public (public health, culture).

This paper focuses on analysing the social and cultural impacts of health research. Societal changes are not considered here because of interpretation problems. It often takes many years or even decades before the outcomes of basic science research lead to societal changes – the 'time lag'. In addition, societal changes are frequently the result of many different factors, making it hard to determine the impact of a particular piece of research – the 'attribution problem'.

Analysis of social and cultural impacts of health research

Impact is defined above as the reaction of others (target groups) to research results. To analyse social and cultural impacts one must therefore analyse how the health sector and general public engage with the results of health research. It is important to differentiate between activity – the various outputs of the research – and true social and/or cultural impact.

For example, publications or media appearances by the researcher do not constitute impact in and of themselves – they are simply additional outputs of the research. Of course a publication in the media can often be an important (sine qua non) proxy of impact, but it is essentially a knowledge product rather than an impact. The public reaction to a publication or media appearance is the first step towards impact. The true final impact will be the referral to, citation of and use that is made of the publication over time. To use a typical example, the publication of a Nature article (often celebrated with a bottle of champagne) is an important proxy of impact

while citations are not available to be analysed. But as soon as citations can be counted, a Nature article that is never cited (more than 10% of them) will be as devoid of impact as any other publication that is never cited and as tasteful as tap water compared to the earlier champagne.

Referrals to scientific results in the professional health sector literature and lay media – which show that other groups are engaging with the research – may thus be regarded as a stronger proxy of social and cultural impact.

The practical use of research results is a still stronger proxy of impact, while still not qualifying as impact in itself. Professional and lay public use of health research (knowledge use) may include the introduction and use of new guidelines, new health care procedures, new preventive measures/advices and new health care policy measures. The problem of attribution might already start to emerge at this stage.

Other forms of professional and public responses include attendance of professional and lay meetings and/or courses where the new research results are shared – i.e., the process of knowledge transfer.

Esteem indicators (knowledge esteem) such as professional and lay public honours, prizes and invitations to meetings, boards and committees may also be regarded as proxies of impact.

Finally, the research results may have such a big impact that professional and/or lay public institutions with a societal goal, such as charities and explicit societal governmental research programs, choose to commission further research. The earning capacity of a research group might even be considered as an ultimate indicator of impact which combines both scientific and societal merits.

Counting and comparing social and cultural impacts of health research

At present, we must be very modest about our ability to count or even compare social and cultural impacts of health research. The analysis of societal impacts of health research is at a similar point to that where counting scientific impact was decades ago, before ISI[1] was established and even more importantly accepted in the medical science community.

As with analysis of scientific impact, we can improve our understanding by adopting a process approach involving many trials (and errors). This should be encouraged. Most important is that the medical science community becomes aware of the importance of societal impact evaluation of health research as a crucial addition to scientific impact evaluation:

[1] Institute for Science Information

- to improve public accountability, demonstrating how scientific and societal impact can be achieved synergistically, not at the expense of each other (a false contradiction)
- to enhance public, private and political advocacy.

This process is now underway in the Netherlands. The eight University Medical Centres (UMC's) have agreed to follow the proposal of the Advisory Council for Health Research to start measuring indicators of social and economic impact. At this stage, there is no need to quantify or even weigh the results, as the main purpose is to create awareness, not comparative scoring. The methods for quantifying and weighting societal impact still need to be developed and established; there are no universally-accepted proxies in the way that, for example, citation scores are accepted as a measure of scientific impact. However, many Dutch UMC's, with the Leiden UMC as frontrunner, are conducting pilots to quantify and weigh their results.

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IMPLEMENTING IMPACT ASSESSMENT AT THE CANADIAN INSTITUTES OF HEALTH RESEARCH

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The Canadian Institutes of Health Research (CIHR) is Canada's national and largest government funder of health research in the country. The mandate of CIHR is to excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system (Bill C-13, April 13, 2000).

Established in 2000, CIHR promotes a problem-based, multidisciplinary and collaborative approach to health research. Its unique structure brings together researchers from across disciplinary and geographic boundaries through its 13 virtual Institutes. CIHR provides grant funding across a multitude of programs covering both open, investigator-initiated research and strategic or targeted research areas.

Developing a CIHR impact assessment framework

In 2005, CIHR began work to develop a framework and indicators to measure the impacts of health research. The development process included national and international consultations involving academics, government, research agencies, health organizations and associations. Participants identified different stakeholder groups with an interest in impact information and their individual interests or information needs.

The framework was originally published in the 2006 conference proceedings of the OECD Blue Sky II conference , and has since been presented at various venues to a variety of stakeholders. Feedback and comments have been sought and the framework revised accordingly.

In January 2009 the Canadian Academy of Health Sciences (CAHS) completed their independent assessment of frameworks to measure the return on investment of health research and recommended the payback framework as adapted by CIHR with some slight further modifications. CAHS also proposed new indicators within the impact categories.

Impact categories

The CIHR framework is based heavily on the 'Payback model' created by Martin Buxton and colleagues (1994). Both the CIHR framework and the Payback model consider impact across five broad categories that encompass a range of indicators. The payback categories are knowledge production, research targeting and capacity building, informing policy and product development, health and health sector benefits, and economic benefits. CIHR adapted these categories slightly such that the CIHR impact framework now includes the following five categories:

- Advancing Knowledge: this category includes discoveries/breakthroughs, contributions to the scientific literature
- Building Capacity: this category includes the development and enhancement of research skills in individuals and teams
- Informing Decision-Making: this category includes the impacts of research in the areas of science, public, clinical and managerial decision-making, practice and policy
- Health & Health System Impacts: this category encompasses advances in prevention, diagnosis, treatment and palliation as well as advances in the way the health system functions
- Broad Economic Impacts: this category is divided into the following subcategories: commercialization of discoveries; direct cost savings; and human capital gains.

The main difference between the Payback model and the CIHR impact framework is the way two of the categories are conceptualized. The CIHR framework splits the second payback category and retains only the capacity building aspect with the research targeting aspect being shifted into the third category. The third CIHR category, informing decision-making is also slightly broader than the category as described in the payback model.

Within each category, CIHR has attempted to identify indicators at different levels or orders of effect. Lower order impact indicators (e.g health benefits to participants in CIHR funded clinical studies) are more directly related to CIHR funding than are higher order impact indicators. However, the higher order impact indicators (e.g overall improvements in patient outcomes in a given area) are important for CIHR to attain its mandate.

CIHR Impact Assessment Projects

In 2007-2008 CIHR staffed a small dedicated unit of two staff to the area of Impact Assessment, within its Evaluation and Analysis Branch. It was

through the creation of this small unit that the implementation of the framework began. A great deal of the work described below is conducted by internal staff, often in partnership with staff in CIHR Institutes or in other agencies. Some limited contractor assistance has also been used, e.g. for bibliometric data and a bibliometric study (SARS and Obesity). Over the first few years of implementing the framework and collecting information against the impact indicators, CIHR has undertaken projects as partnerships or opportunities arose for doing so. Projects underway in 2009 are listed in sections a-h below.

Some of these projects look at impacts of a specific kind of research, e.g. Obesity, Sudden Acute Respiratory Syndrome (SARS) or cardiovascular research. Another project focuses more on specific categories of impact regardless of research area, such as commercialization resulting from health research.

a) Impact Assessment of Canadian Obesity research

This project is a collaboration between the CIHR Impact Assessment Unit and the CIHR Institute of Nutrition Metabolism and Diabetes (INMD). The impact assessment centers on INMD's strategic Obesity Initiative. The report will include three sections. The first will set the context and provide some background on Obesity and why the INMD identified Obesity as a strategic priority. The second section will include a description of research activities and inputs from 2000 to the present. The final section will be framed around the five impact categories. This impact assessment will include both qualitative and quantitative data covering multiple perspectives. The data collected includes interviews with Institute staff, a focus group with the Institutes' current advisory board (IAB) members plus a survey of current and past IAB members, two surveys of CIHR-funded researchers, analysis of CIHR media reports, an external bibliometrics contract, a review of existing administrative data and relevant literature, and possibly some stakeholder interviews.

The first survey was sent to a sample of researchers who were funded by INMD in line with the strategic priority on Obesity and Healthy Body weight. The survey focused on the individual research projects and their research outputs and outcomes.

The second researcher survey and the survey to IAB members focused specifically on the impact categories and sought the respondents' knowledge or perception of advances in these categories arising from the research.

The external bibliometrics contract was with the 'Observatoire des sciences et des technologies' (OST). The OST has provided an analysis of

CIHR-funded researcher publications in the area of obesity. It includes a comparative analysis of obesity-related publications in Canada and other G8 countries from 1998 to 2007. The bibliometrics study considered only articles, research notes and review papers published in indexed journals. CIHR jointly developed a search methodology with the OST to identify 'Obesity' research. The methodology includes number of publications, average relative citations, average relative impact factor, specialization index, and international collaboration rates.

The preliminary findings were presented to the INMD's IAB in June 2009. A final report was received in the fall of 2009.

b) Impact Assessment of SARS research

The CIHR Impact Assessment unit is participating in an impact assessment of SARS research conducted between 2003 and 2008, led by the CIHR Institute of Infection and Immunity (III). The report will follow roughly the same structure as the Obesity Impact assessment. It also includes data from multiple sources, such as a researcher survey, end of grant reports, researcher CV's, publication data from the OST, and information from CIHR's administrative database. The report was completed the end of June 2009 and can be found at: http://www.cihr-irsc.gc.ca/e/39904.html.

c) Impact Assessment of commercialization of research

A preliminary report on one aspect of commercialization of health research (patents of Canadian researchers and specifically of CIHR-funded researchers) was prepared as background information for CIHR's Commercialization Advisory Committee meeting in February 2009. A full project plan for obtaining and using a range of commercialization and economic indicators will be developed in conjunction with the overall impact assessment plan considering feedback on the initial report.

d) Research Reporting System

CIHR has created and is working on implementing an on-line research reporting system to collect information directly from researchers 18 months after the end of their grant. It will capture information along the five categories of impact, together with information about the research and knowledge translation practices employed by researchers during their research. As researchers themselves may not always be aware of broader impacts of their research, many of these wider questions include the option to report

"not applicable" or "do not know". The questionnaire combines both closed and open ended questions that will enable us to collect, analyze and report both quantitative and qualitative information on the results of CIHR-funded research.

We have recently used the on-line questionnaire with a sample of past recipients of CIHR Operating grant (grants with an authority to use funds ending by July 2008) to capture some of the historical outputs and outcomes of this funding program as part of the program's evaluation.

e) Impact Assessment of cardiovascular research: Project Retrosight

CIHR and the Heart and Stroke Foundation of Canada (HSFC) are participating in a three year, international study of the impacts of cardiovascular research undertaken 15 to 20 years ago in three countries: Canada, the UK, and Australia.

The project is being led by RAND Europe and uses the Payback impact assessment framework mentioned earlier, developed by Martin Buxton of the Health Economics Research Group (HERG-Brunel University). This project builds on the past experience of the RAND and HERG teams and utilizes their case-study methodology.

Each country has completed between 9 and 12 case studies and is preparing a country-specific context paper. The RAND/HERG team will compile the various sources of information gathered and will ultimately produce a RAND monograph based on findings across the three countries.

CIHR's Impact Assessment unit staff are leading the Canadian case study work directly. This is definitely one of the most ambitious and costly projects with which we are involved, given its international nature. However, it is also a unique opportunity as it is the first attempt to explore impact in an international context. CIHR staff have completed the 12 Canadian case studies, which involved 39 interviews with Principle Investigator (PI) and other researchers or research users. The cases were identified through a stratified random selection methodology handled by RAND and applied across the three countries. The project also includes bibliometric data specific to the three countries and to each of the case studies.

For this project Canada also has the benefit of a senior level advisory committee co-chaired by Ian Graham (CIHR) and Sally Brown (the CEO of HSFC). Members include Cy Frank (University of Calgary), Peter Liu (CIHR-Institute of Circulatory and Respiratory Health), Grant Pierce (HSFC) and Margaret Rand (Hospital for Sick Children in Toronto).

The final published RAND report is expected to be completed in the Fall of 2010.

f) Interagency Science & Technology impact report

CIHR, the Natural Sciences and Engineering Research Council (NSERC), the Social Sciences and Humanities Research Council (SSHRC), the Canadian Foundation for Innovation (CFI) and The Network Centers of Excellence (NCE) are working collaboratively to develop a common reporting framework based on the CIHR impact assessment framework and set of indicators described earlier. This collaborative effort grew out of a recommendation in the federal Science & Technology strategy. The common framework builds on the CIHR framework, with changes to ensure coverage of the full scope of the agencies involved (natural sciences, engineering, social sciences and humanities in addition to health). For purposes of this first, experimental common report, the common reporting framework was accepted by senior management at the three councils and CFI. Both agency-specific and more general international indicator data is being collected for this exercise, and the indicators include both quantitative and qualitative data. Data collection for the common report is complete and a preliminary draft has been prepared. A small working group will soon meet to discuss the draft and finalize the content of the report

g) Ongoing updates to and implementation of the CIHR Impact Assessment Framework

The CIHR framework first implemented in 2007 has been presented to various internal and external audiences, and their feedback and comments incorporated. In January 2009, the Canadian Academy of Health Sciences (CAHS) released a report: "Making an Impact: A preferred framework and indicators to measure returns on investment in Health Research", based on their independent work to prepare a framework and indicators that could be used to measure the impact of health research. We have compared this proposed framework and suite of indicators to the existing CIHR framework and currently-used indicators. Since the CAHS ROI framework builds on existing frameworks including the CIHR's impact framework, it is not surprising that the CIHR framework and indicators align well with those proposed by CAHS. Given the close alignment of our categories we have not made any further refinements to our framework.

CIHR has also been invited to participate in the National Alliance of Provincial Health Research Organizations (NAPHRO) evaluation subgroup. At a meeting in April 2009 the group discussed sharing best practices and data to help improve impact assessment. This provides an opportunity for us to collaborate on data collection and enables us to make comparisons where appropriate.

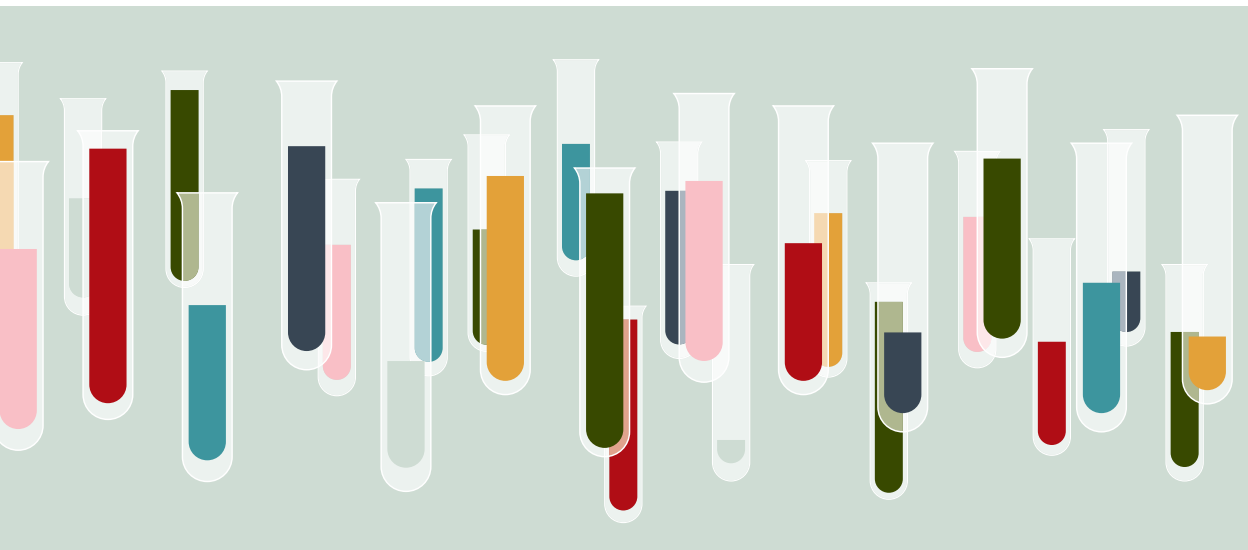
h) Impact Assessment Plan

Finally, after three years of work, it is time for the Impact Assessment Unit to set a longer-term plan of activities. In 2010–2011 therefore, we will be consulting within CIHR and with partners to set a plan of impact assessment projects over the next three to five years. There will likely be a mix of (i) projects that look at the impacts of certain types of research that we have not yet studied, e.g. mental health research, and (ii) projects to collect and use data relating to categories of impact, such as capacity development or commercialization impacts.

Canadian Institutes of Health Research (CIHR): http://www.cihr-irsc.gc.ca

This report reviews aspects of measuring impacts and outcomes of medical research. A core working group appointed at an international workshop in 2007, organised by the Scientific Council for Medicine within the Swedish Research Council, was tasked with creating a roadmap that defines key questions to explore and possible approaches to take. Their work was performed between 2007 and 2009.

Evaluators need more accurate ways to estimate economic returns and greater international collaboration is required to advance knowledge on crucial issues. These issues include understanding how innovation takes place, how to best analyse the social and cultural impacts of research and how research outcomes can be attributed to individual funders.



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