Evidence-Based Health Care Processes: Some Issues of Evaluation and Application

Shared Country Experience

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Foreword by
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Foreword

During the time I was Chairman of the Australian Health Ministers' Advisory Council I led a group known as G9/10 which advised the government of Australia and the Prime Minister on the reform of health, community services and aged care[1]. It was quite clear that that task was not helped by the absence of a way of presenting the health and health services and the outcome of various policy interventions in a way which was understandable to Ministers of Finance and to heads of government. There is a familiarity within the family of health services about the nature of health and health care organisation but insufficient attention has been given to ways in which it is presented outside health portfolios.

Gro Harlem Brundtland, speaking at a conference in London (14th January 1999) asserted that 'health is a key factor for human development: for the development of nations and for economic growth. New research shows that health is a net contributor to long term economic growth and particularly to lifting the poor out of poverty. In a time of global trade and investment when nations are searching for ways to gain competitive edge we have been sitting on a great secret. We need to remind presidents, prime ministers and finance ministers that they are health ministers themselves'.

The OECD Working Party on Social Policy and its framework of health indicators for outcome-orientated policy making could secure the confidence of ministers of finance and heads of government and could prove to be of major benefit to those involved in health policy development, resource allocation and the provision of health services, as well as the community at large. Better understanding of health and health care in the economy might also be achieved.

The Nuffield Trust's programme of work includes looking at the issues associated with globalisation. We are interested in globalisation because of the efficiencies it represents in finding, sharing and making relevant the collective experiences of different countries in tackling convergent health care system challenges. One area under development is to explore expenditure on health as a positive contributor to good economics. This is certainly an area for international collaboration.

The Nuffield Trust's philosophy is to look outwards as well as to look inwards using robust evidence to test, analyse and influence the development of the health care system. It is clear that there is great interest internationally in performance benchmarking - a critical exercise for continuous quality improvement. And there are increasingly important questions about how to compare the quality and effectiveness of the health care systems in different countries.

The Australian Government has made an important investment to international developments in this field by sponsoring the conduct of a project based at the OECD on evidence-based medicine and health outcomes approaches. In support of this investment, the

[1] Making gains in health. *Medical Journal of Australia.* Vol 166, 2 June 1997

Nuffield Trust hosted a workshop to explore the scope and limitations of these approaches by bringing together leading academics, practitioners, and policy advisers from six different countries to discuss their different experiences. The aim of this report is to make the material presented at the workshop, and the main lines of discussion, available to others concerned with the issues discussed.

Health care is a complex business and increased use of a range of different types of evidence of effectiveness can improve the performance of the health care system. It can do this by marrying the sources of evidence traditionally used by clinicians with approaches that add much stronger predictive power. All efforts to support their development should be supported as long as both strengths and weaknesses are clearly understood. Using cost-effectiveness analysis throws up the issue of population versus individual care and resources allocation needs. Evidence of effectiveness relies on adequate data availability but data takes time to generate. Increasingly there is also a need to monitor outcomes more pro-actively to allow the accumulation of information about the effects of new practices. In fact given the time frames within which policy decisions need to be made and the longer time frames needed to understand the longer term impacts of new practices, this capacity to strategically target and implement follow up of new practices may become critical in the future.

Using more explicit sources of evidence will inevitably throw up the tensions between aspects of health interventions that are specific and measurable, what the patients want and the populations needs. These tensions need to be managed - not used as an excuse to throw out useful new tools.

Evidence Based Medicine/Health Outcomes approaches make these tensions explicit. But there is also a mismatch between expectations and the realities about the 'state of the art' of evidence based medicine and health outcomes approaches. This is graphically illustrated by the recent work commissioned through the Agency for Health Care Policy and Research. And there has been little effective focus on the implementation side. Sir Michael Peckham, in his recent Rock Carling address for the Nuffield Trust[2], proposed that a new parliamentary Committee be established to look at the impact of health services research. What is needed is an understanding of the change processes that might best contribute to the implementation of evidence of effectiveness.

There are examples of the successful implementation and outcomes of findings based on evidence of effectiveness but they are patchy at the macro level. There is evidence of effective implementation of findings at the micro level but the best evidence occurs in the context of rigorous evaluation and monitoring.

What Evidence Based Medicine/Health Outcomes approaches offer that is new, is the availability of information about effectiveness for a much greater range of people. It could lay a vital part in the management of social expectations of the health care system. But its complexity also can contribute to the public loss of confidence in the scientific approach if more effort is not put into managing communications. Patient experiences, values and uncertainties must feed into this process. A recent project conducted for the Nuffield Trust in conjunction with the RAND Corporation reviewed the issues associated with appropriate public disclosure. This issue had arisen partly through the introduction of physician and

[2] Peckham M. A model for Health, Innovation and the future of health Services, *The Nuffield Trust.* London: 2000

hospital public performance profiling and its impacts on outcomes and providers. It is clear from this report that managing communications of this nature, that are for the public good, requires dedicated resources and cannot be managed well as an adjunct to normal reporting activities.

To go further than this and use some of these newly emerging tools to best effect requires tackling some of the bigger questions. For example, most of the strategies for implementation have been at the micro -level, this is certainly where the best evidence of effectiveness is. But it may be the case that there is no genuine alignment between incentives and what is known about best practice. Disincentives at the meso- and macro- levels may wholly or partly offset any specific implementation strategies. In what ways do forms of financing lead to inappropriate practice?

What investment do we need to develop financing systems that target genuine long term patient outcomes rather than processes of care?

Evidence Based Medicine guidelines are expensive to generate and must be relevant to clinical service settings. What new approaches do we need to target work on the health gain at areas where 'institutional' boundaries exist that may present covert organisational imperatives that militate against best practice? How do we ensure that the effects of other members of health teams work to use evidence to improve performance?

These are big questions. Answering them will need some specific investment and development time. They will also require political support for long term evaluation of some of the central issues of health services organisation and financing as they will inevitably open up new territories that have been overlooked until now. It was to see to what extent they were being addressed in several countries at the forefront of the quest for effectiveness in health that The Nuffield Trust hosted the OECD workshop to share experience more widely by making the material presented at the workshop, and the main lines of discussion, publicly available. With that in view, the report comprises an overall summary of the workshop's deliberations, prepared by Dr Vivienne McLoughlin of the OECD, and summaries of the individual presentations.

John Wyn Owen, CB
London: March 2000

Overview Paper

Vivienne McLoughlin

Vivienne McLoughlin

** This paper was written while the author, an officer of the Australian government, was attached to the OECD Secretariat. The views expressed are those of the author, and do not necessarily reflect the opinions of the OECD Secretariat or its member governments.*

Introduction

In preparation for the OECD Social Policy Ministers' meeting in June 1998, a survey of all OECD countries was undertaken to elicit views on a wide range of social issues. The summary of that survey reported that most countries expressed concerns about the effectiveness of their health care systems. The number of countries that developed special quality commissions and quality assurance agencies is one demonstration of this increased level of interest. Examples include: the Australian Cochrane Collaboration; the Network of Health Promoting Hospitals in Austria; the Canadian Health Services Research Fund; the newly created ANAES - Agence Nationale d'Accreditation et d'Evaluation en Sante in France; the Health Results Measurements agency in Mexico; the National Health Academy in Turkey; the National Institute for Clinical Excellence in the UK and the Presidential Commission on Quality and Consumer Protection in the United States.

These agencies and commissions are exploring the use of evidence of effectiveness and cost effectiveness in clinical practice and focusing on the effects of services in terms of outcomes. In addition several countries have set up nation-wide performance standards and quality assurance programmes to encourage the development of high-quality health care delivery systems. Many of the quality commissions are occupied with improving planning mechanisms in order to improve co-ordination and quality of care. 'Quality of service delivery is being tied to reimbursement of services in many countries', the report concludes.[1]

In the communique released following the OECD Social Policy Ministers' meeting in June 1998, Ministers agreed that the focus of health policy reform should be on improving health outcomes, within the context of ongoing efforts to improve cost-effectiveness...[2]

In response to this interest, the Australian Government sponsored a project to describe the processes of identifying evidence based medicine and health outcomes approaches (EBM/HO); to describe the mechanisms that different countries are using to apply these approaches; and to evaluate successful and unsuccessful applications.

1 OECD (1998),'Social and health policies in OECD countries: A survey of current programmes and recent developments', Labour Market and Social Policy Occasional Paper No. 33.

2 OECD (1998), (SG/COM/NEWS(98)70), News Release, 24 June 1998. Meeting of the Employment, Labor and Social Affairs Committee at Ministerial Level on Social Policy. The New Social Policy Agenda for a Caring World. Paris.

In April 1999, a workshop was hosted by the Nuffield Trust to provide input to the OECD project. The meeting was intended to bring together a group of leading academics, policy advisers and practitioners to explore the potential scope and limitations for 'evidence based medicine (EBM) and health outcomes (HO) approaches' to improve clinical performance and value for money.

The summary that follows is a distillation of the major themes emerging from the workshop and is followed by summaries of the individual workshop presentations. Although some additional material on definitions has been added to assist the reader, most of the workshop material assumes some prior knowledge of the issues. There is a large literature on topics such as health technology assessment, evidence based medicine and performance measurement and review that has not been included here. While the terms, 'health' and 'health care' are used here in the broadest sense to refer to the products of all the professionals involved in the delivery of health services, most of the examples apply to medical interventions and the medical profession. This is partly because much of the literature derives from these fields and is not as well developed in other professional areas.

Essentially there were two main topics addressed by the workshop. The first was the process of identifying evidence, both of effectiveness and cost-effectiveness. The second was the translation of these findings into practice.

PART 1 - THE PROCESSES OF IDENTIFYING EVIDENCE

What is meant by 'evidence based medicine/ health outcomes approaches'?

For the purposes of the OECD project, this term has been taken to encompass the group of tools that are used to strengthen the use of evidence about effectiveness and cost-effectiveness in improving the clinical performance of health care system. These tools include approaches described variously as *Evidence Based Medicine* and *Evidence Based Health Care Practice, Health Outcomes Measurement, Health Technology Assessment, Clinical Practice Guidelines and Outcomes Effectiveness Research.* Each of these tools has a slightly different emphasis. They are used in various different ways across countries and within the scientific literature. So it is useful to outline some of the main definitions and issues surrounding these different approaches.

'Evidence Based Medicine' is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients'.[3] *'Evidence based practice'* has been defined as, 'the practice of making every decision based on a systematic appraisal of the best evidence available.'[4] The concept that applied specifically to evidence based medicine has, in this way, been extended to health care more broadly and to management and policy as well as service delivery.

[3] Sackett DL, Rosenberg WM, Muir-Gray JA, Haynes RB and Richardson WS. (1996) Evidence based medicine: what it is and what it isn't. *British Medical Journal,* 312 (7023): 71-2.

[4] JA Muir Gray, 1997 *Evidence-based HealthCare How to make health policy and management decisions,* Churchill Livingstone.

There is a good deal of confusion in the use of the term 'health outcomes' in the literature.[5] In part this confusion derives from differences in the levels of application. For example, different participants in health care have different reasons for interest in, and uses for, health outcomes information. This could include:

- Patient and individual clinician's interest in monitoring the progression of the condition
- Managerial and financing interests in performance, and
- Broad policy interests in improving population health.[6]

At a population level the OECD has adopted the following definition of health outcomes. Health outcomes are defined as the 'measure of the attributable effect of the presence or absence of an intervention on a health state'.[7]

For those involved in managing services, either clinicians or managers, this definition cannot easily be made operational. First, the attribution of the effect on a health state of any particular intervention cannot be made in a service setting. Establishing attribution of cause and effect requires a rigorous research method. Secondly, the time frames involved in the determination of the final outcome for the patient are usually longer than the patient's ongoing contact with the service. For example, it can take 3-4 years to determine the success or failure of a hip replacement.

While there are examples, such as in heart transplants, where health outcomes may be clear at the point of service, monitoring the effectiveness of the service for most conditions has led to the use of either proxies of final outcome or of process indicators. There are very few real proxies of final outcome. Attempts to develop process indicators that are in some way associated with what is known about best practice have led to the development of clinical practice guidelines.

Clinical Practice Guidelines have been defined as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances'.[8] The use of the term 'systematic development' implies the need for a clearly defined search for, and assessment of, relevant information with an emphasis on the strength of the relationship between the recommendations and the underlying scientific evidence and their usefulness in determining health and cost outcomes. Some related terms include protocols and clinical pathways.

Health Technology Assessment (TA) is described as a process that 'examines systematically the consequences of the application of health technologies (broadly defined to include drugs, devices, medical and surgical procedures etc that comprise interventions)'.[9] It has tended also to derive from policy processes that control the diffusion of new technologies.

[5] Sansomi, I, 1998, Health outcomes-made to measure, workshop paper presented at the Health Outcomes Conference, Canberra, August 1998.

[6] A F Long, 1997, 'The role of health outcomes in health care evaluation,pp33-43,in A F Long and E Bitzer, *Health outcomes and evaluation: context, concepts and successful applications,* ECHHO.

[7] OECD (1998), 'Social and health policies in OECD countries: A survey of current programmes and recent developments', Labour Market and Social Policy Occasional Paper No. 33.

[8] Institute of Medicine. 1992, Guidelines for Clinical Practice: From Development to Use. In : *Field MJ,* Lohr KN, editors Washington, DC: National Academy Press.

[9] Henshall, C. *et. al.* Priority Setting for Health Technology Assessment. Theoretical Considerations and Practical Approaches. A paper produced by the Priority Setting Subgroup of the Eur-Assess Project, *International Journal of Technology Assessment in Health Care,* 13:2 (1997), 144-185.

Finally, *Outcomes Effectiveness Research* is defined as, 'evaluations of the impact of health care (including discrete interventions such as particular drugs, medical devices, and procedures, as well as broader programmatic or system interventions) on the health outcomes of patients and populations'.[10] This term is most widely used in the United States. It may include economic impacts and emphasizes real-world settings, multidisciplinary teams, and a range of outcomes including not just mortality and morbidity but also functional status, quality of life and well-being. It may entail primary data or synthesized reviews.

Another term emerging more recently is *'Disease Management'*. This refers to 'a systematic, population-based approach to identify persons at risk, intervene with specific programmes of care, and measure clinical and other outcomes'.[11] It is seen by some as the 'child of the cost controllers' and associated with the development of managed care forms of organization.[12]

It was clear from the workshop that there are differences between OECD countries in which of these terms are used more predominantly and how the terms are used. In fact in France, there are cultural issues associated with difficulties in translating these terms into French. The term evidence based medicine, for example, is seen as an Anglo-Saxon normative approach to science. The term 'technology assessment' appears to be in broader use across European countries other than the UK, and its scope is much more broadly comprehended within these countries, although there is also discomfort with the term.

The different origin of the various tools has also played a part in the confusion. For example, health outcomes work in the UK is often seen as part of cost-effectiveness analysis and therefore a tool of health economists, whereas in Australia, the health outcomes approach is advocated mainly by those interested in strengthening population as opposed to individual perspectives.

For the OECD project, the term 'evidence based medicine and health outcomes approaches' is used to refer to this group of tools - all of which describe efforts to improve the performance of the health care system in providing effective care. Collectively these efforts also rely on and articulate the evidence of effectiveness. This may be of various levels of rigor. For example, professional opinion is commonly regarded as less adequate evidence than observational or case management studies, with the preferred level of evidence being the use of randomized controlled trials. Sophisticated processes have been developed to systematically review the available evidence and assess the implications of multiple different findings. Where evidence is unavailable or insufficient, efforts are made to collect evidence by using appropriate methods to track the outcomes of service interventions.

There is a debate about whether clinical evidence of effectiveness is sufficient without the inclusion of analysis of cost-effectiveness. Cost-effectiveness analysis provides additional evidence about the cost of an intervention, often the cost falling on a fixed budget for health care. Hence it provides a reminder of the opportunity cost or health outcome foregone by undertaking the intervention concerned. This will illuminate the inevitable tension that arises from using scarce resources in alternative ways. However, the conduct of an analysis of cost-effectiveness requires additional effort to acquire cost data.

[10] Tunis, S and the Lewin Group, D Stryer, 1998. The outcomes of Outcomes Research at AHCPR. Interim report prepared for AHCPR.

[11] T Bodeheimer, 1999. Disease Management- Promises and Pitfalls, *New England Journal of Medicine*, v340, no.15 (Apr.15), pp. 1202 - 1205.

[12] T Bodeheimer, 1999. Disease Management- Promises and Pitfalls, *New England Journal of Medicine*, v340, no.15 (Apr.15), pp. 1202 - 1205.

The use of cost effectiveness analysis, sometimes referred to as the fourth hurdle, goes well beyond the parameters of safety and efficacy that have been used traditionally by regulatory bodies for the introduction of new products into domestic markets.

From an analysis of the use of the various terms associated with evidence based medicine and health outcomes approaches, it is clear that these processes all involve the systematic evaluation of evidence of effectiveness and cost effectiveness. There is a debate about the extent to which cost effectiveness is an integral part of the processes (see for example, Maynard, 1997[13]). However, there is also evidence that those making financing decisions only take into account cost effectiveness if there is evidence of effectiveness, (see, for example, Henry (1999) in the case of the Australian pharmaceutical evaluation, or Steiner *et. al.* (1996) for medical coverage decisions.[14] In the latter case, cost effectiveness appears to be taken into account only where effectiveness is of equivalent power between new and existing treatments. For this reason, the paper focuses predominantly on issues of effectiveness in the first instance.

What is the use of these tools intended to achieve?

The roots of evidence based medicine approaches have been attributed to clinical epidemiology.[15] Although others, for example, Knottnerus, J and Dinant G, 1997, describe the development of EBM as arising as an extension of the methodological development of RCTs.[16] Their development has been stimulated by research illustrating large unexplained variations in both the treatments for particular conditions and the outcomes of these treatments. Further impetus arose from the demonstration of disturbing lags between evidence of effectiveness and changes in clinical practice.[17] So their inception lies in improving information about clinical practice with the intention to improve such practice.

However, any changes in clinical practice that reduce ineffective or harmful treatments will have implications for expenditure and offer the promise of improving cost control as well as potentially generating savings. It is clear that there are strong expectations that these tools will contribute not only to improving information about performance but to actually changing practice and in doing so improve effectiveness for given resources or generate savings.[18] Although it is also the case that demonstrating that new products or services are cost effective may add to total expenditure.

While some would argue that evidence based medicine is only a strengthening of the scientific basis of the profession, it is also understood by many as an art, partly because health

[13] A Maynard, 1997, Evidence-based medicine: an incomplete method for informing treatment choices. *The Lancet,* v349, pp 126-128.

[14] Henry, D. 1999 ISPOR 99 'Beyond Drug Acquisition Costs Lessons from the PBS' in Australia Plenary paper presented at the International Society for Pharmaco-economics and Outcomes Research. Washington DC; C Steiner, N Powe, and G Anderson (1996). The review process used by U.S. health care plans to evaluate new medical technology for coverage. *Journal of General Internal Medicine,* 11, pp 293-302.

[15] A Stevens, R Milne 1998. 'A knowledge- based health service: how do the new initiatives work? *Journal of the Royal Society of Medicine,* n35, v 91, pp 26-31.

[16] Knotternus, J and Dinant G, 1997 Medicine based evidence, as a pre-requisite to evidence based medicine. *BMJ,* 315, pp 1099-1100.

[17] Antman, EM., Lau, J., Kupelnick, B. et. al.. ,1992. A comparison of results of a meta-analysis of randomized controlled trials and recommendations of clinical experts. *JAMA,* 268:240-8.

[18] AHCPR, 1995, *Better Quality Can Cost Less: The Evolving Role ofAHCPR.* Interim Report to the National Advisory Council. September.

status relies on the interplay of a large number of biological as well as emotional and psychosocial factors. The complexities of health and the nature of medicine create some special challenges for those who seek to promote practice in areas of scientifically proven interventions. These challenges are accompanied by a number of practical issues such as:

- The availability of data of sufficient quality, and
- Processes for analysis and assessment of the findings.

Available data of sufficient quality

Most publicly funded health research is funded through investigator driven processes where the research and clinical community determine the nature of the investigations. Some commentators have illustrated the mismatch that this often generates between the nature of illness in the community and the topics that receive most attention from the research community.[19] The view was expressed at the workshop that the problem is not lack of research funds but the lack of proper application of research funds. There is a strong need for research efforts to be better targeted on the needs of the population and those who are providing health services.

Even when the topics under investigation are highly relevant to the performance of the health care system however, the way the research problem is specified may or may not be useful. Further, one of the comments made at the workshop was that a large volume of the material generated is redundant because of its poor design or execution. The availability of data for the estimation of cost-effectiveness is, of course, even more scarce. One review found that only about 220 out of 1200 studies contained sufficient information to assess the cost-effectiveness of some existing interventions.[20] There is a widely held view that there is an inadequate supply of research staff who are skilled either in determining clinical effectiveness or the conduct of cost-effectiveness studies.

Another reason for the lack of quality data is that the nature of some health problems is still poorly understood. Diagnostic uncertainty is particularly prevalent in presentations to primary care physicians. It is also the case that the treatment of many conditions requires good patient-doctor communication to ensure compliance, so the evaluation of a specific intervention must recognize the context in which it is delivered.

The prevalence of co-morbidities will also limit the relevance of the evidence to clinical practice, as most of the available data will have been generated through trials that control for variables outside the condition being studied. In a similar way there are problems generated because trials are based on carefully selected populations whereas average practice must cover all patients.

Randomized Control Trials (RCTs), seen by many as the gold standard of evidence of effectiveness, also take time. Not only does this create difficulties for those charged with making decisions about the interventions being tested in this way, it raises issues about how to manage

[19] See for example, Frankel, S and West, R. 1993. *Rationing and rationality in the National Health Service,* MacMillan, Basingstoke,pll.

20 T O Tengs *et. al,* 1995, Five hundred Life-Saving Interventions and their Cost-effectiveness, *Risk Analysis,* v 13, n 3, pp 369-390.

the changes in technology which may occur midway through the trial. The development of treatments for AIDS is a good example of the ethical dilemmas around trial inclusions and exclusions. Observational studies represent a different type of evidence, with different methodological constraints.

There are of course also debates about the methods used in cost-effectiveness analysis, including some of the tools such as the SF36 and the EUROQual, as measures of quality of life. The development of some of these methodologies is still in its infancy, although there are a number of well-validated tools that are not used as widely as they could be. Participants at the workshop recognized the difficulties in directing researchers to the right tool to be used in the right way. The importance of these approaches however is in their focus of what patients think and value. The choices made by some patients about treatment are not always consistent with the views of their doctors about what constitutes the best form of care. It is also clear that there are differences in values between consumers that have an illness and the majority that do not.

So for a number of reasons, there are often reports that the evidence is insufficient, or there is no available data, from those trying to use evidence of effectiveness. Where there is no adequate data, service managers have started to adopt new methods for actively collecting information about the care provided and outcomes for patients, in order to be able to evaluate the effectiveness of their services. Experience in the Netherlands indicates that the process of tracking outcomes and using empirical data to complement the evidence from RCTs is particularly likely to be persuasive to clinicians.

Where large populations are involved, active data collection at the point of service can be particularly useful. For example, the quality registers in Sweden have been effective in the early identification of problems with implants. These registers usually collect data from 80-100% of the services provided by the specific specialties covered. However, where there are smaller population sizes, these ongoing data collections are likely to be less useful. In the United States where a lot of this activity occurs through managed care organizations, competition between providers may limit the possibilities of exchanging information. This means that relatively rare conditions are unlikely to be effectively evaluated through these sorts of processes.

Processes for analysis and assessment of findings

Despite the relative lack of data that is well targeted and robust, there is a growing mountain of information about research efforts across the vast field of medicine. The volume of this material presents a problem in assessing its quality and comparability.

In response to this, there has been an investment in efforts to synthesize and focus the available information. This has mainly occurred through the conduct of systematic reviews tailored to specific problems facing the health care system. One example of such work is that carried out by the NHS Centre for Reviews and Dissemination based at York University, in the UK. One specific study involved the review of evidence of the relationship between the volume of services provided by hospitals and health outcomes.

There was also some discussion of the fact that sometimes the findings are counter-intuitive, or that people do not want to believe them. Examples of this came from Sweden where recent work on the effectiveness of some large scale community preventive interventions had concluded that there was no evidence of their effectiveness and yet intuitively these results seem wrong.

In the context of the pressure on resources in the health care sector, the use of cost effectiveness analysis has become increasingly important. The additional information provided by cost-effectiveness analysis has the potential to radically change the ranking of interventions, in terms of their overall value to the community. For example, on the basis of evidence of effectiveness alone one intervention could appear to rank very highly against a second intervention. If the first treatment is very costly and effective only for a small proportion of the affected patients, the second may be preferred.

Interpreting the findings also needs to take into account issues such as service readiness and affordability. While an individual procedure may prove to be both effective and cost-effective, many cost-effectiveness analyses would not include consideration of the extent of changes to the organization of services that may be required or the lead times necessary to introduce the service, including the recruitment and training of staff etc.

Examples were provided at the workshop of a number of areas in which findings had been ignored in policy decision processes, but there were also many examples, such as the increased implementation and uptake of immunization and screening programs, that could be more closely attributed to evidence of effectiveness. Overwhelmingly, it was felt that providing the facts was a necessary pre-requisite for enabling informed judgements to be made about desirable changes in practice.

In summary then, there are still significant methodological problems and a paucity of appropriate data for the identification of effective health care interventions. Nevertheless, there was considerable discussion about the fact that there has been far less investment and focus on dissemination and implementation than on the identification of effectiveness and cost-effectiveness.

PART 2 - TRANSLATING RESEARCH INTO PRACTICE

Even where the evidence is robust and clear, the translation of the findings from these processes into changes in practice encounters a further series of issues. What are the most effective strategies for ensuring the uptake of good practices? To what extent does the context within which health professionals practice influence their performance? How do we know whether changes have taken place? These issues were explored in some depth at the workshop. The main points have been summarized as follows:

- Appropriate processes of dissemination
- Suitable incentives and organizational form
- Methods to evaluate changes in practice

Dissemination processes

A recent report prepared for the AHCPR in the USA highlighted that the fact that making information available did not of itself impact on clinical practice. To address the problem of poor dissemination of findings, the approach now being taken by the AHCPR is to require a capacity and process for implementation of the results before commissioning work to identify the evidence of effectiveness. This process can be seen in the selection process for the funding of their Evidence-based Practice Centers.

Other vehicles for getting into the dissemination processes early on are through using multi-disciplinary groups of practitioners and consumers as part of processes to oversee the research.

Findings from consumer based research made available at the workshop outlined what consumers think about the information on achieving good health outcomes. Criticisms included that; access to the material is poor; it is not based on research about topics that most people want to know about; it is over optimistic; it is not honest; not comprehensive in terms of treatment options; poor on self-care; vague about sources of the evidence; often out of date; and with few suggestions for action.

There are many parallels between these criticisms and those made by the professionals who are intended to use the material. There needs to be more work directed to developing access to information that is user friendly for the end-users. In addition, the culture of medicine and the circumstances of clinical practice seriously constrain attempts, even by practitioners with a serious interest, in evaluating their outcomes. There is strong pressure to conform to peer group pressures. This can create either a barrier or a motivator for changing clinical practice. There is also evidence about the importance of initial medical education and the apprenticeship system in guiding styles of practice.

As part of the consideration of dissemination issues, one participant commented about the need to pay more attention to understanding, 'who wants what from whom?' It is clear that different interest groups will have various agendas in advocating either the restriction or the promotion of different findings. Where there is a commercial motive, there is a clear wish to access materials about the assessments prior to the actual implementation decision and this raises issues about freedom of information. Examples were provided from both the AHCPR and the Australian Medical Services Advisory Committee's processes.

Where the tracking of outcomes contributes to performance review there are different schools of thought about whether information about performance should be made available publicly. In America, as one of the participants noted, 'the genie is out of the bottle' on public disclosure which allows the comparison of the performance of both groups and individual practitioners. In general however, those from other countries represented at the workshop felt that the issue was less clear cut. There are those who believe that unless the information is used as part of self-regulation, it will be distorted. There are others who believe that external regulation is needed because professional self-regulation is ineffective. If information is to be made public, there is also the question about whether it should identify only the performance of the group, or institution, rather than disclose the performance of individual clinicians.

The Nuffield Trust is working with the RAND Corporation to explore the circumstances in which appropriate disclosure can be more effective in improving performance and not lead to 'gaming' or covering up mistakes.

Effective Incentives and organizational factors.

Various reviews have been undertaken of the range of variables known to influence changes in clinical practice[21], each of these have indicated that financial incentives have a significant role to play in changing physician behavior. Despite this finding, however, there is still very little known

[21] Lomas, J. 1994. 'Teaching old (and not so old) Docs new tricks'. In E Dunn, P Norton *et. al.* (eds), *Disseminating Research Changing Practice, Research Methods for Primary Care,* vol 5, Sage, USA.

about the successful operation of either non-financial or financial incentives. Some of the non-financial incentives derive from the professional culture of medicine, aspects of which were covered in the preceding text.[22]

Over the past two decades there has been a major focus across most countries with developed market economies on exploring organizational arrangements that might improve the efficiency and effectiveness of health care system delivery. Many changes are still occurring in the organizational forms through which services are provided. At the workshop the phases through which health care reform had evolved were described as a context for discussion on organizational form.

From the late 1970s to early 1980s, cost-containment had been a major pre-occupation that had later given rise to concern about efficiency at the local level and responsiveness to providers. The late 90s had been characterized more by concern with priority setting processes and rationing, with an increased emphasis on the contribution of public health issues. The management trends are now much more oriented towards standard setting, performance management, target setting and output controls. These trends have fostered the development of a series of tools for performance measurement such as the HEDIS and the Consumer Assessment of Health Plans Survey (CAHPS). They have also contributed to the increased pressures experienced by both clinicians and managers in the workplace. Pressures that, in turn, make it difficult to either focus on or implement the findings about the effectiveness of specific interventions.

A number of speakers described the complexity of the health care funding and delivery systems within their countries. The complexity of these systems and the diversity of funding sources often unintentionally create barriers to effective practice as each funding source seeks to minimize its own share of health spending and in doing so throws costs onto other sources. It is also the case that where funding levers appear to exist, there are often strong political and practical reasons why they cannot be used effectively.

There was some discussion of the specific examples of the evolution of forms of managed care in the US and the recent establishment of the Primary Care Groups in the UK.[23] Organization forms of managed care have been developing with such rapidity in the US that it has become difficult to describe and analyze their effects. Some of the most important discriminating features between the traditional fee for service arrangements in the US and the emergence of the many forms of managed care were outlined. The moves towards managed care have included; less freedom of choice of provider with the introduction of preferred provider contracts; post hoc reimbursement as opposed to prior agreement of negotiated prices; clinical autonomy versus doctors prepared to work within the framework of utilization review, guidelines or prior authorization of follow up treatments.

The two main types of managed care were described as the preferred provider arrangements that are closer to the fee for service model, and the health maintenance organizations (HMO) model. One of the major differences implicit in the Health Maintenance Organization models over the preferred provider model is the clear location of responsibility for comprehensive

[22] Davis, D A, Thomson, MA, Oxman AD et. al., 1995. 'Changing physician performance: a systematic review of the effect of continuing medical education strategies', *JAMA*, 274: 700-706.

[23] Wensing M and Grol R 1994. Single and combined strategies for implementing changes in primary care: a literature review, *International Journal of Quality in Health Care*, 6: 115-132.

benefits and for the organization and access to care. Most HMOs are at risk for the total costs of the health services they provide and usually share these risks with their providers in some way. Examples were provided of the increased adherence to acceptable guidelines where the savings that result from changed clinical practice can be redirected into physician income.

In those organizational forms that are in competition for patients, there are stronger incentives for agencies to seek information about their quality of the care and about the effectiveness of the various aspects of their services. For example, the reconfiguration of appointment schedules where longer waiting times emerged on Mondays. Some examples were provided of the closed systems being used by some HMOs to track all aspects of patient information. These have been demonstrated to lead to the identification of areas of improvement as varied as parent education for the support of asthmatic children and decreased surgical complications. However, the power of these processes to monitor and detect adverse health outcomes is dissipated in a competitive environment when the information is useful for commercial purposes and therefore cannot be shared across organizations. The problem becomes one of achieving sufficient sample sizes for particular conditions. There may be a role here for government intervention.

The new Primary Care Groups in the UK also have fixed budgets and face excess demands from their patients. From this perspective it would be expected that there would be some incentive to pay attention to the findings from EBM/HO approaches. However, because there is little competitive pressure, as patients seldom change their GP in the UK, the incentives in this case are likely to be less effective.

These approaches using capitated group practices or unified budgets were contrasted to arrangements for pursuing quality that were hampered by line budgets provided by different funding sources. For example, the coverage of medical services and exclusion of coverage for pharmaceuticals that may lead to pressures to substitute some forms of treatment for others.

Understanding some of these effects requires better definition and thinking at the systems level. There was clear agreement at the workshop that there are few effective frameworks and methodologies at the systems level to be able to analyze and evaluate the impacts of a range of changes in policy and practice across the health care sector. Consequently there is little knowledge about what works and does not work at the systems level.

Methods to evaluate changes in practice

There are basically two main ways of looking at performance monitoring for quality. These are to monitor the outcomes of care or the processes of care. In the latter case, the monitoring of progress occurs by checking whether the care complies with evidence based guidelines. Grimshaw *et. al.* (1993, 1996), for example, have conducted a number of systematic reviews of the implementation of clinical guidelines.[24] Where performance monitoring is intended more broadly to improve quality, there are two main approaches. One is to focus on trying to eliminate adverse outcomes or events and generating benchmarks about minimum

[24] Grimshaw JM, Russell IT, 1993. Effect of clinical guidelines on medical practice. A systematic review of rigorous evaluations. Lancet, 342, pp 1317-1322; *Effective Health Care Bulletin.* 1994, 'Implementing Clinical Guidelines. Can guidelines be used to improve clinical practice?' Bulletin, n8. Leeds, University of Leeds; JM Grimshaw and MA Thomson, 1998 'What new efforts to change professional practice achieved?', *journal of the Royal Society of Medicine,* suppl no 35, v 91, pp 20 - 25.

performance levels. The other is to focus on progress towards an optimum goal. Different monitoring activities are implied by these different approaches.

To ensure the safety of the public in accessing health care services, it is necessary to monitor a range of events that are potentially avoidable or may be the direct result of the care process. Looking at outcomes and the evidence from trials enables adverse events to be minimized. The usual process has involved Confidential Inquiries to enable an objective review of outcomes in circumstances that might have been avoidable. These processes have been demonstrated to lead to changes in professional behaviour. Punitive measures in response to adverse event findings have also been observed to lead to a culture of covering up mistakes.

The second approach is to focus on making progress towards an optimum standard. Here a range of activities are designed to develop a culture of continuous improvement by bringing evidence of outcomes into an open and accountable process where providers are encouraged to compare their outcomes with others working with comparable groups of patients. This has led to the development of more meaningful performance measurements. For example, the indicators collected for the National Quality Registers in Sweden have provided measures of performance in specific areas that have led to changes in practice.

What progress has been made to date?

At various stages during the workshop there was reflection about the progress that has been made to date in the use of the EBM/HO tools. While there is evidence that changes in practice have occurred as a result of systematic assessment of the literature, it is confined to specific examples of a very limited range of health care practices. In contrast other examples were provided where there was evidence of effectiveness or ineffectiveness that had not led to changes in practice. This led to a debate about the stage of development of the methodology underpinning the identification of effectiveness and cost-effectiveness and the differences in expectations between stakeholders and practitioners about what is achievable. One participant commented that changes were occurring but that the pace was frustratingly slow.

Good evidence from the US has documented the differences between researchers and policy makers in defining what constitutes good progress in this field. The researchers report good progress on describing effective health outcomes. Policy makers are looking for examples of successful implementation that can demonstrate improved health outcomes as well as cost savings. It was suggested that there is a serious possibility that what can be achieved through the use of these tools may have been over-sold.

In a policy environment there is pressure to make decisions on the best information available, however variable the quality of the information is. There is a continuous need to offset the timeliness of the decision making process with the need for accuracy of outcomes. To achieve changes in clinical practice requires very robust evidence. Where the evidence is also of a very specific nature and can be easily quantified, it can be used as the basis of policy decisions. In contrast, many findings can be complex. For example, an analysis in the Netherlands of the effectiveness of a particular costly drug indicated an increase in survival of a couple of months. This finding did not make the decision-making process about the use of the drug any easier. The findings can also have significant effects on different stakeholders. For example, the finding that investing in the training of staff to conduct higher level care does not improve the

outcomes for patients. In these cases, decision-makers must take into account the strength of the evidence in balancing the tensions between broader social and economic objectives.

Despite these potential conflicts it was generally felt that the explicit nature of evidence provided by these tools had proved useful and had led to a greater degree of rationality in health services planning than would otherwise have been the case. There was general interest in exploring how to extend the scope of application of these tools.

What factors are likely to limit progress?

This mismatch between policy expectations and the state of the research development may be a barrier to faster progress. If policy makers fail to see the methodological difficulties involved and become impatient to see results in terms of cost savings, there may be less funding made available at a critical stage in the development of methods and collection of data. Similarly, if researchers fail to understand the questions facing policy makers, their work may be less relevant. The same outcome is likely to occur.

Other more practical considerations mentioned earlier include the lack of evidence that is of sufficient quality and rigor and well enough tailored to appropriate policy questions.

In terms of the capacity to influence clinical practice and translate findings into practice, a range of other barriers was also identified. These included at the macro, or national programme level, the paucity of reliable information on effectiveness, safety and cost-effectiveness of new technology at the time it is needed, patient expectations, political imperatives and competing demands for resources. At the organizational level, poor dissemination, lack of skills to manage scientific information, competing demands for decision, lack of material resources, 'covert organizational imperatives' and financial risks have been identified as barriers to effective practice. For clinical providers, barriers include paucity of data, tradition and training, patient expectations, 'perceived need for system changes beyond the immediate control of the practitioner', financial disincentives, lack of confidence in the sources of evidence and competing demands for action

Suggestions were made about some solutions to this, such as the need to better focus research investments and the need to build the capacity for skilled researchers both in terms of effectiveness and cost-effectiveness research. The lack of recognition of this field as a legitimate area of scientific research was also raised.

However, in addressing the mismatch between expectations and the stage of development of these tools, the major emphasis needs to be on the translation of research into practice. This would involve the development of a much better understanding of the service and organizational arrangements and how they impact on effective health care practices as well as a much better understanding of how incentive structures operate.

What factors may enhance progress?

Achieving the potential for the use of these tools may rest on three main considerations. The first is thoroughly embedding their development and use into a functioning performance management process within the health care system. The second is a strong policy framework that clarifies 'who wants what from whom?' and 'who is accountable for quality?' The third is

the extent of involvement of the public in the processes of priority setting, the development of the performance indicators and the use of the information to help drive the quality agenda.

While there are debates about whether self-regulation or external regulation is more effective, objective evidence is more likely to be used if those responsible for service provision ask for it, and want to use it, to improve services. Managed care organizations need to improve their services to compete. They seek information about outcomes to improve their services. Clinicians who want to ensure they are providing the best services collaborate to collect information. In the United States, the AHCPR program for evidence based practice centers now requires that the centers demonstrate a commitment to implementing the findings of their research, prior to making the funding available. The Ambassador program run by the SBU in Sweden, was also provided as an example of a process to engage stakeholders with information about effectiveness.

Aligning incentives so that they support what is known to be best practice is clearly important. One example from a managed care organization showed that both savings and improved practice and improved adherence to clinical protocols could be achieved. This occurred when doctors endorsed the protocols as being appropriate medical practice and were told they would share in the savings that would be generated by their adherence to the protocols. There are also examples of remuneration systems that provide higher payments for more intense procedures that may not always be warranted.

There was clear acknowledgement of the increased involvement of consumers in health care system developments. One example of important work in this area is the Consumer Assessment of Health Plans Survey (CAHPS), a tool developed by the AHCPR. The results of the use of surveys of these types are now being used to market care to consumers in the US and to drive co-operative quality improvement programs.

What is the appropriate role for government?

The countries represented at the meeting included those with governments providing a high proportion of total health expenditure, and those providing a low proportion. Despite this, most of the funding for the development of national agencies and processes to evaluate the available evidence of effective health care practices is from the public sector. In several countries most of these agencies review not only newly emerging conditions and treatments, but also existing practices. In the US, a review of public and private sector activity indicated that most of the outcomes effectiveness research activity in the private sector covered the most prevalent conditions, such as cardiology, asthma, diabetes etc. The private sector was less active in exploring the needs of specific population groups. There was also a role for government in the development of methodologies and performance standards.

Clearly there are various possible roles for government. Which of these roles are appropriate will be determined by the nature of the health system in each country. Governments that both fund and provide services are likely to need to take on roles that are not appropriate for governments that provide services through private providers.

Countries such as Australia illustrate the complexities in allocating accountability for quality in health systems with complex financing arrangements. In Australia, the Federal Government is responsible for private medical services, both in and out of hospitals. The states and

territories are responsible for hospitals and community services. The same providers may work in both public and private settings. In the Netherlands, legislation has designated the responsibility for quality to providers and managers. The government's role is constrained to monitoring the existence and adequacy of the quality assurance systems.

The occurrence and widespread publication of adverse events in public hospital systems raises issues for governments. The political and legal implications of both government action and inaction in response to these events will continue to demand some level of government involvement from the point of view of public safety, even where the sources of funding are not under direct government control.

Is it worth pursuing further?

One participant made the comment that most other industries want to know what happens to their products so that they can improve their quality and respond to their markets. How can quality be improved without measuring outcomes? Another example can be drawn from a recent editorial in the British Medical Journal which makes a comparison between health care and other sectors in highlighting the adverse event rates in some of the 'world's best hospitals'[25].

Increased public expectations of health services, new interventions and the pressures of cost containment will ensure a continued focus on improving quality and value for money.

Despite the complexities of what constitutes improved outcomes, there are examples of changes in practice based on evidence of effectiveness and cost-effectiveness, e.g. breast cancer screening, some immunizations, the use of some drugs and diagnostic technologies. There is also evidence of large variations in practice in response to particular conditions that suggest that there is room for improvement in the use of some interventions for which there is robust evidence of their effectiveness.

However, the subject of the workshop's deliberations was complex. It was being discussed by a group of participants for the first time. Its conclusions could not be clear cut. While the participants at the workshop did not focus specifically on the most effective avenues for action, the table on page 22 summarizes some of the main points made and some of the ideas about possible actions.

What can be gained from further cross-country collaboration?

Given the common problems being experienced across a range of countries, there would appear to be much to gain from future collaborative work. It is often the case that a study undertaken in one country could be of great interest to other countries. If even a small amount of standardization of technique were negotiated, the findings could be more directly relevant and useful to other countries.

While researchers in the field have been active in collaborating internationally, this has not been the case so much for policy makers. There are few opportunities for health policy advisers to exchange views about effective policies to apply the findings of evidence of effectiveness. Given the need for a greater focus on the translation of this work into practice, there would seem to be much to gain from international collaboration. This exchange could usefully include discussion about processes of performance review and aligning incentives to support best

[25] Berwick, D and LL Leape, 1999, Reducing errors in medicine. It's time to take this more seriously. *BMJ*, 319:,ppl36-137.

Workshop outcomes		
Steps in the process of identifying and using evidence in practice	**Issues**	**Possible actions**
Primary data collection	Paucity of data in social and psychosocial areas, and for more vulnerable population groups Need for development of methods to describe organizational and systemic factors	Commissioning of data and methodological development Stronger incorporation of patients' perspectives Need for good priority setting processes
Synthesis and review of evidence of effectiveness and cost effectiveness	Need to incorporate cost effectiveness data to ensure the consideration of the broader impacts of any new interventions.	Need to increase the workforce with a capacity to undertake analysis of effectiveness and cost effectiveness data
Professional standards, training and dissemination processes	Paucity of appropriately provided, relevant materials	Need to support the development of appropriate tools to support clinicians' access to information Need for a better understanding of issues of translating evidence into practice at a clinical and organizational level.
Performance review and monitoring	Punitive monitoring systems lead to 'gaming' of performance information	Need for ongoing and specific feedback systems to be developed with the support of clinicians
Financing decisions	Financing systems that involve sharing the financial risks with providers may ensure that providers have an interest in more cost effective services but the evidence needs to be robust and convincing	Need for good integration between assessments and planning Need for better understanding of how financial incentives operate in practice

practice. The literature on incentives for providers suggests that the context in which the incentives are provided is critical to their effectiveness. This suggests the need for a greater understanding of the broader financing environment. Further international collaboration could maximize the benefits of investment in the evaluation of effective health practices for all countries with similar interests.

It is to be hoped that the experiences that were shared at the workshop will prove useful to practitioners and policy makers in all OECD countries.

IDENTIFYING SUCCESSFUL APPLICATIONS OF EVIDENCE-BASED MEDICINE/HEALTH OUTCOME APPROACHES

Dr Vivienne McLoughlin,
Directorate for Education, Employment, Labour and Social Affairs, OECD, Paris, France

Introduction: the OECD project which provided the context for the Workshop

Dr McLoughlin explained that, in the context of its wish to improve the performance of the Australian health care system, the Commonwealth Government was supporting a one year OECD project with three principal objectives: to describe the mechanisms selected countries were using to identify effective health care interventions; to document the application of these mechanisms in terms of the use of policy and financing levers; and to evaluate successful and unsuccessful applications.

Part of the project involved seeking information from a range of countries on the basis of a questionnaire or personal interviews. It had already become clear that there was a range of issues for consideration including: first, the various terms used; second, the extent and nature of the evidence about the impact of particular health initiatives; and, third, what was required to turn research findings into successful applications of evidence-based medicine. Dr McLoughlin briefly outlined these issues, and some of the questions they raised. She hoped that the Workshop would in particular contribute to the exploration of the second and third issues.

Terms

Project work so far had shown that a range of terms was in use in relation to improving the effectiveness of clinical performance, each having different origins and different meanings in different countries and among different stakeholder groups. Terms in use included 'evidence-based medicine', 'health outcomes', 'outcome and effectiveness research' and 'technology assessment'. For the purpose of the project, the term being used most often was evidence-based medicine, defined as:

> *The practice of making every decision based on a systematic appraisal of the best evidence available.*

Research and evidence

The systematic application of the evidence-based medicine approach as defined above could only start from a base of appropriate research into the impact of a procedure or product. Given that evidence-based medicine had been advocated for a range of purposes - eg to improve

information about performance, to improve performance itself and to control or reduce costs - research would need to evaluate an intervention against one or more of a number of considerations. These included safety, efficacy, effectiveness and cost-effectiveness, and might also need to include appraisal of its implications for the organisation of services and their affordability.

Project work to date suggested that relevant research had been mainly in relation to the impact of new products, such as drugs and equipment, though there had been some research in relation to new procedures such as heart transplants, vaccinations, and screening.

This finding raised two immediate questions:

- to what extent could research be used to evaluate procedures and products already in common use, as well as new developments?
- to what extent could research be used to evaluate professional and institutional performance, as well as procedures and products?

Turning research into a successful application of evidence-based medicine

It was also clear that the availability of appropriate research findings, although an essential basis, did not itself constitute the successful application of evidence-based medicine. The transformation of research into application required its translation into policy, and then implementation in terms of service delivery. What examples were there of this being achieved in practice, and what conditions had it been necessary to meet? On this latter point, specifically:

- was it essential for the relevant research findings to be agreed by all relevant parties before they could be translated into policy?
- what infrastructure was needed in order first to translate research evidence into policy and then to secure its implementation?
- what policy and review and financing levers were necessary to secure implementation (eg differential funding of either service purchasers or providers based on performance)?
- what were the criteria for judging whether policy implementation led to improvement in the key aspects of health outcome and cost (as implementation could only be deemed a successful application of evidence-based medicine if under ordinary, as distinct from research, there was clear evidence of improvement)?
- was it possible at this stage to estimate - albeit in very broad terms - the return that might be achieved in countries where evidence-based medicine was practised throughout the health care system?

INTERNATIONAL HEALTH CARE DEVELOPMENT AND REFORM: THE CONTEXT FOR EVIDENCE-BASED MEDICINE AND HEALTH OUTCOMES APPROACHES

Professor David Hunter,
Nuffield Institute of Health, Leeds, England

Three phases of health care systems development observable over the last twenty years
Professor Hunter said that analysis of health care policies in Britain and a range of other countries over the last twenty years enabled three distinct phases to be identified:

a) in the later 1970s and early 1980s, the focus of concern was cost containment at the macro level, and the main policy instruments included prospective global budgets for hospitals, controls on hospital building, controls on the purchase of medical equipment, efforts to limit doctors' fees and incomes and restrictions on numbers of doctors in training;
b) from the late 1980s to the early 1990s, the emphasis switched to concern about efficiency at the micro level and responsiveness to users. In this phase the principal policy instruments were the introduction of market-like mechanisms, management reforms and budgetary incentives;
c) in the late 1990s the focus had switched again, to concern with priority-setting and rationing, with increased emphasis on the contribution of public health measures and general practice to addressing key health issues, and the introduction of approaches such as evidence-based medicine, health technology assessment and what is referred to as 'managed care'. In this current phase, attention was increasingly being paid to the widely-observed fact that there were large variations in medical practice, with major implications for cost and outcomes.

At the root of these successive shifts in the focus of health care policy were widely shared but elusive goals, namely how best to: provide health care which enhanced health gain; ensure that the services were of high quality; regulate service providers; and achieve equity of access to services. The three phases of health care policy were different approaches to seeking to address these four persistent policy puzzles.

A consensus on both diagnosis and prescription

Among those responsible for developing health care policies, there seemed to be a consensus emerging both on the problems that needed to be addressed and how they might best be resolved.

There were perhaps six principal aspects of the emerging consensus on the diagnosis of the problems of health care systems:

i) the persistent rising costs of providing health care, a matter compounded by:
ii) growing demands on health care systems attributable to rising public expectations and, in some countries, ageing populations;
iii) the failure of the supply of services to match growing demands;
iv) traditional, bureaucratic health service systems were insufficiently sensitive to changing needs and expectations, partly because:
v) such systems were led by service providers, rather than driven by the needs and wishes of service users, and
vi) in such systems, arrangements for holding clinicians to account were weak.

In the light of this shared diagnosis of problems, a shared prescription for the development of health care systems was emerging. In part it was based on what has been termed 'new public management', an inter-connected series of initiatives that governments were introducing across the public services as a whole. This approach was characterised by greater emphasis on professional management in the public sector, drawing on the style of management found in the private sector with its concern for standard setting, performance management, target setting and output controls; its widespread use of specialisation between provider and producer functions and contracting; and its discipline and parsimony in resource use.

In the specific context of health care systems, the emerging consensus was based around the creation of a degree of competition through the separation of purchasing and providing functions and the devolution of management responsibilities; the involvement of users in priority setting, and moves towards explicit rationing; and an increasing focus on cost containment, clinical effectiveness and health outcomes.

Evidence-based medicine in the context of newly emerging forms of health system

The fundamental aim of evidence-based medicine was clear, and well described by Haines and Jones:[1]

> *To promote the uptake of innovations that have been shown to be effective, to delay the spread of those that have not yet been shown to be effective, and to prevent the uptake of ineffective innovations.*

The focus of attention tended to be on new therapies and treatments rather than existing ones, although the latter were not wholly neglected.

The evidence-based medicine approach was plainly of interest to those concerned with the development of health care systems. At the meta level, the development of evidence-based medicine was facilitated by the increasing ease of communicating scientific knowledge and transferring technologies between countries and sectors of the health care system. At the macro level, the development of evidence-based medicine was being assisted by national governments' Research and Development strategies and initiatives such as the National Institute for Clinical

[1] Haines A and Jones R, 'Implementing Findings of Research', British Medical Journal, 308, 1994, pp. 1488-92.

Effectiveness (England and Wales) and (Australia), and international co-operation through the network of Cochrane collaborating centres.

While the aim of evidence-based medicine could not be faulted, Professor Hunter drew attention to some of the practical limitations to its implementation that needed to be understood and addressed.

First, there was the question of the nature of the available evidence. There was a hierarchy of forms of evidence ranging, in ascending order of value, from the opinions of respected authorities, expert committees, etc., through non-experimental studies, non-randomised matched case-controlled trials and single randomised controlled trials to (the 'gold standard') multiple randomised controlled trials. It was important to judge what forms of evidence could appropriately be drawn upon for the purposes of seeking the wider implementation of evidence-based health policy as distinct from medicine or health care. Indeed, a concentration on evidence-based medicine and randomised controlled trials threatened to marginalise broader health policy objectives aimed at tackling inequalities and improving health.

The nature of the evidence was not the only limitation. It was also important not to overlook that there were limits to what could be measured and quantified. Research was dominated by quantitative methods; qualitative research was also important to enable those responsible for health care systems to have a full picture of how the systems were working in practice. Such methodologies were especially important in assessing user views of outcomes and in establishing lifestyle changes.

A third important limitation was the abilities of both managers and clinicians. Clinical effectiveness was one issue on a crowded agenda for both doctors and managers. It was a complex matter taking time to implement. Because of the pressures on them, there was a risk that clinicians simply would not have the ability to read, absorb and where appropriate reflect in changing practices all the information that was becoming available. Managers, too, were under many pressures, and many, notably non-clinicians, lacked confidence in discussing clinical matters, and even doubted whether they had a legitimate role in this area.

A fourth limitation was the absence of attention to development. The NHS Research and Development strategy, for instance, had hitherto concentrated on research and the development agenda had been neglected. Often, the problem was not one of collecting evidence but of acting on what already existed. There had to be a balance between acquiring appropriate evidence and then applying it to change practice.

Finally, there was the attitude of clinicians. Their traditional focus was the individual patient, not the health of the population, and they had historically been concerned with clinical priorities rather than management priorities, and with advocacy of their services rather than with assisting in prioritisation and resource allocation. There was a danger that, especially if it was over-sold on the basis of a weak evidence base, clinicians would experience the drive to promote evidence-based medicine as a top-down process driven by the wish to cut costs, and thus as an unwelcome attempt to modify their clinical practice and even undermine their status as specialists.

Conclusion

In conclusion, while it was hard to fault the principle underlying the drive to implement evidence-based medicine, in practice there were clear dangers in proceeding with insufficient

care. There was a gap between research conditions and those in clinical practice, and it was important not to 'over-sell' research findings. It was important to recognise the significance of qualitative issues as well as quantitative ones, especially in the area of improving the public's health, and a clear need for action-orientated research in the whole field of health care practice and users' experiences of it.

APPLICATIONS OF OUTCOME AND EVIDENCE BASED APPROACHES IN HEALTH CARE

Professor Alan Maynard,
York Health Policy Group, University of York, England

The context for evidence-based medicine: a history of reluctance to address issues of evidence or focus upon outcomes

Professor Maynard observed that those responsible for health care systems, in Britain and elsewhere, often failed to take well-established evidence into account when framing policy. Examples of largely ignored evidence included the findings that:

- above 200 beds, there ceased to be cost savings through the development of larger hospitals, and indeed there was evidence of diseconomies in hospitals over 600 beds;
- there was no general relationship between the volume of particular types of work clinicians undertook and the quality of the outcomes, measured in terms of adjusted mortality rates. Thus the widely-repeated view that, to stay competent, a clinician had to undertake a given procedure a minimum number of times a year was not always supported by evidence on the quality of results;
- the centralisation of health care services in an area on to a single site reduced the extent to which people used services, partly by shifting costs from the health care system to patients and carers through, eg increased travelling costs and time.

It was not only in relation to health care that policy makers ignored evidence. In the social work field, for example, a randomised control trial had been conducted in the 1950s into the effectiveness of social workers' interventions with juvenile delinquents, and had shown that such interventions made no difference to the delinquents' subsequent behaviour. Yet the findings seemed largely to have been ignored.

This seeming reluctance to take account of evidence was part of a wider problem, reluctance to focus upon, still less to act upon, issues of outcome at all. Although there were limited exceptions (such as the Confidential Enquiry into Perioperative Deaths in the UK), it was questionable how much had been achieved in terms of improving outcomes by, for example, the widespread development of clinical audit and successive Chief Scientists research and development programmes in the UK or HEDIS (Health Employers' Data Information System) in the USA.

The reasons for this reluctance

In Professor Maynard's view, there were two major reasons why progress in addressing issues of health outcome had been so slow.

First, there was a reluctance to depart from the traditional means of addressing (perhaps more often failing to address) possible shortcomings in clinical performance - informal, private discussion between doctors largely uninformed by systematic evidence.

Second, even for those ostensibly concerned with outcomes there was a confusion of objectives. There were clear distinctions between clinical effectiveness, cost effectiveness and clinical cost effectiveness. By way of illustration:

- procedure A might be shown to achieve a better clinical outcome for a given condition than procedure B, and would clearly be the treatment of choice from a solely clinical perspective;
- however, procedure B might be shown to cost more than procedure A, and thus be clearly the treatment of choice from a solely cost perspective;
- where resources are finite, however, the most beneficial result for the health of the population served required purchasing to be determined by cost effectiveness evidence.

Research and purchasing had to be informed by cost effectiveness data. Clinical effectiveness data were inadequate alone.

Making progress with EBM

Over the last twenty years progress in addressing issues of clinical outcomes had been glacially slow. If more rapid progress was to be made over the next twenty years, those wishing to see the wider development of the practice of evidence-based medicine should be concerned with three principal issues:

a) achieving a focus on clinical cost effectiveness. The objective in health systems concerned with maximising the health gain to the population concerned from the available resources should be clinical cost effectiveness rather than just clinical effectiveness. From this perspective, it was perhaps more appropriate that EBM should be used as an acronym for economics-based medicine rather than for evidence-based medicine;
b) recognising the clinical cost effective objective in the form and strategies of bodies such as the Cochrane centres created to focus upon issues of outcome. A proper economics input was necessary. In its absence, research findings would be incomplete and relate only to the more limited notion of clinical effectiveness. (The lack of capable researchers able to make the necessary economic input was currently a practical constraint, but if the focus truly was on clinical cost effectiveness, this shortfall in supply could be addressed);
c) changing attitudes about concern with outcomes. Instead of leaving discussion about outcomes to the traditional means referred to above, perhaps in the belief that no one but doctors could understand the issues, the need in the context of clinical cost effectiveness was for much greater openness. Giving decision makers (purchasers, providers and consumers) 'the facts' about cost effectiveness was a necessary requirement if issues of outcomes were to be properly addressed, enabling informed judgements to be made about necessary changes in practice. However, facts alone were inadequate: appropriate (evidence-based) incentives to ensure dissemination and the translation of evidence into practice were essential. These structures were poorly researched: an issue only now being addressed by research funders.

AUSTRALIA - PERSPECTIVE FROM THE NATIONAL HEALTH DEPARTMENT

Mr Robert Wells,
Department of Health and Aged Care, Canberra, Australia

The Australian health care system

Mr Wells said that currently 8.5% of Australia's gross domestic product was spent on health care, approximately 70% of which came from public sector funding sources (Federal, state and local governments, sometimes using non-governmental organisations as the immediate funder) and 30% from private sector sources (insurance and commercial companies and individuals' private means). As well as having a wide range of sources of funding of health care, the Australian system was characterised by a large range of service providers - public and private hospitals, private specialists, general practitioners, home care services, nursing homes, disability services and providers of alternative therapies.

Apart from its role as a major source of funding, the Federal government's responsibility for the health care system was that of administrator of the whole system. It had little direct control over providers, and was able to exert influence primarily through third parties, such as the states and non-governmental organisations, through which Federal money was made available.

Viewed from the Federal Health Department, the Australian health care system was complex, it was unclear who was accountable for what, and it was difficult to know how to bring about change in such a complex situation.

Challenges facing the system

Currently the Australian health care system faced a number of challenges. First, there was the question of how such a complex system could be managed to deliver affordable, good quality care. Affordability was of particular concern as there were fears of a costs 'explosion', or at best continued growth well in excess of economic growth rates, fuelled by demographic changes and new technology. Second, there was a need to make improvements in the quality of aspects of the health care system, for example the services available to sub-groups within the population, eg the Aboriginal people, as well as to improve population level health outcomes. Finally, there was a need to meet these challenges in ways which met both public and political expectations. These were essentially the continued availability of top quality and accessible health care for all based on need, not capacity to pay. For the Australian public, 'top quality' included the successful outcome to medical interventions and minimal waiting times, as well as up to date hospitals and equipment.

The notion of evidence-based medicine was not currently one that entered the Australian public's consciousness, and it would be negatively received if it was perceived as being about saving money, reducing services, cutting quality or allowing 'scientific evidence' to over-ride the

health professional's and patient's judgement of the individual's needs. To those charged with policy responsibility for the health care system, however, evidence-based medicine, *provided* it led to changes in practice rather than simply adding to the volume of largely unacted upon research publications, was obviously relevant when considering how to respond to the challenges summarised above.

Overall options open to the Federal government

In considering how the challenges summarised above might best be met, the Federal government could take one of a number of options. It might judge that the challenges were more likely to be met if it withdrew from the task of trying to 'manage' the system, and instead left matters to the market. On this option, the Federal government's role would be limited to funding (through vouchers which left individuals free to choose their health care provider) and ensuring that members of the public had enough information to enable them to make informed choices. The ultimate test of the quality of services provided would be litigation. Other options were to build on the Federal government's present role as administrator of the system, either by 'trying harder' to improve health outcomes through more extensive efforts to change clinical practices, possibly through the use of evidence-based medicine facilitators; or through the more extensive use of regulation, which would require the extensive use of 'watchdogs'.

In practice, none of the above options seemed likely to be successful in meeting the challenges, and therefore a different, systems, approach was being tried. This involved viewing the complex arrangements for funding and providing health care as a true system, with the goal of achieving better health outcomes at population and individual levels. Four inter-connected strategies were then necessary to achieve this goal, namely strategies for funding arrangements, service provision, the supply and education of the health care workforce, and quality.

On this view, it was not possible to expect system change without seeking change in all parts, or without considering the implications of change in one part for the others. The underlying aim was to achieve a change in culture, and this in turn required sustained leadership and proper attention to the conditions necessary to change human behaviour.

The possible place of evidence-based medicine within a systems approach to the challenges facing Australian health care

As indicated above, potentially evidence-based medicine could contribute to meeting the challenges, *provided* it was possible to go beyond the publication of research findings and change practices. Within a systems approach, this called for carefully tailored interventions to overcome possible barriers to the take up and implementation of research findings. Thus structural and organisational barriers needed to be overcome by specifically structural and organisational interventions; shortfalls in professionals' knowledge and skills required educational interventions; and evidence of the lack of awareness of poor practice required interventions through audit and feedback.

A number of specific initiatives had been taken, or were planned, as part of tailored responses to potential barriers. These included establishing:

- **the National Health and Medical Research Council,** which not only funded research into evidence-based medicine through Australia's Cochrane Centre, but was working in partnership with professional bodies on developing guidelines and 'tool kits' to help change attitudes and keep professionals up to date;
- **the Pharmaceutical Benefits Advisory Committee,** whose remit was to ensure that ineffective drugs were not on the market;
- **the Medicare Services Advisory Committee,** on which the Chairman, Dr Weedon, would be making a presentation;
- **the National Institute of Clinical Studies,** expected to be operational before the end of 1999, with the remit to identify, develop and promote best clinical practice throughout the public and private health sectors; encourage behavioural change by the medical profession; and contribute to the Government's overall safety and quality agenda.

Taken together, within the context of the Federal government's systems approach, it was hoped that the four bodies referred to above would facilitate the wide implementation of evidence-based medicine within Australia, which in turn would substantially contribute to successfully addressing the current challenges facing health care in Australia.

AUSTRALIA - THE WORK OF THE MEDICARE SERVICES ADVISORY COMMITTEE

Dr David Weedon,
Chairman, MSAC, Brisbane, Queensland, Australia

Constitution and terms of reference

Dr Weedon explained that the MSAC was a 14 member multi-disciplinary advisory body, with all members appointed by the Federal Minister for Health and Aged Care and not there in a representative capacity, to advise the Minister:

a) 'on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness and under what circumstances public funding should be supported', and
b) 'on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness'.

In addition, the MSAC had the authority to examine established medical technologies and procedures against the same criteria.

The Committee's work was, as its title suggested, advisory, but it was in a potentially very influential position for its recommendations, if approved by the Minister, could result in acceptance or rejection of new technologies and procedures for the Medicare Benefits Schedule, which provided a significant government moiety towards the cost of the particular service.

The MSAC's working mode and programme to date

The Committee had been established in 1998 and was expected to meet four times a year. Most of its work was thus undertaken by its executive staff and supporting committees, each chaired by a MSAC member.

In the first year the Committee had completed a range of tasks including: determining its meeting procedures; drawing up a conflict of interest policy for members and the form of confidentiality declarations; drafting applications and guidelines for its assessments; settling the style of its publications; establishing its website; and holding feedback sessions with a range of stakeholders. Tasks currently under way included drawing up a discussion paper on criteria for recommending that a technology or procedure be funded on an interim basis (paragraph 1(b) above refers) and appointing consultants to assist the Committee's assessment work.

The assessment process and the studies to date

Those wishing to have new medical technologies or procedures included on the schedule approved for Medicare funding were invited to apply to have the technologies or procedures concerned assessed.

Evidence of studies of the effectiveness of the technologies and procedures was then analysed against a six level hierarchy of types of evidence. In ascending order of value, the six levels were: evidence obtained from case series, either post-test or pre and post test; evidence from comparative studies with historical controls; evidence from comparative studies with concurrent controls; evidence from well-designed pseudo-randomised controlled trials; evidence from at least one properly designed randomised controlled trial; and evidence from systematic reviews of all relevant randomised controlled trials.

Once the evidence had been assessed by the Committee, the findings were sent to the applicant for comment, before a final judgement was made and advice put to the Minister.

In the first year the MSAC had completed four studies: on photodynamic therapy, saline infusion sonohysterography, endoluminal grafting, and automated breast biopsy. It was hoped that in time there would be many more such assessments and that through them the MSAC would be a significant promoter of evidence-based practice. Its recommendations would lead to new technologies and procedures shown by evidence to be effective being added to the schedule approved for Medicare funding. Over time, it was intended to review many technologies and procedures already in widespread use, with a view to having those not shown to be effective by research evidence removed from the schedule.

FRANCE - THE APPLICATION OF HEALTH OUTCOMES APPROACHES AND EVIDENCE-BASED MEDICINE

Dr Hervé Maisonneuve,
Directeur de révaluation, Agence Nationale d'Accréditation et d'Evaluation en Sante, Paris, France

Introduction

Dr Maisonneuve explained that in France there was confusion in doctors' minds when it came to clinical epidemiology, evidence-based medicine (EBM), consensus among experts, and other methods for proposing clinical guidelines. These concepts were not well understood; in general, the force of opinions prevailed over facts. Medicine was seen as a delicate balance between art, science and professional experience.

To the French, EBM sounded as if it were a logo, an Anglo-Saxon acronym for a normative approach to science, and tended to generate resistance from doctors. There was even no consensus on how the expression should be translated: *medecine factuelle, medecine fondee sur la/les preuves, medecine basee sur la/les preuves, medecine fondee sur les donnees acquises de la science, medecine basee sur les faits prouves,* or just *EBM.* Nor did the term systematic research have a standard translation. Revue methodique was used by some journals since revue systematique was not very explicit.

In France, health outcomes approaches were mainly the province of the research community and were little known outside this world. Grants to fund research on health outcomes in 1999/2000 were expected to collect more information.

Development of EBM in France

The key stages in the development of EBM in France had been:

1987 - Academic clinical epidemiology teams (Lyon) joined the International Clinical Epidemiology Network (INCLEN); Reseau d'Epidemiologie Clinique International Francophone (RECIF) became a training centre for clinical epidemiology (University Claude Bernard and Fondation Merieux in Lyon).

1990 - A national agency (ANDEM: Agence Nationale pour le Developpement de l'Evaluation Medicale) was created to develop methods for the critical appraisal of the literature, the organization of consensus conferences among experts, the drafting of clinical guidelines, and technology assessment.

1991 - The MacMaster critical appraisal articles were translated into French and adapted for publication in a journal for general practitioners. Publication was refused by the *Presse Medicale.* They appeared in *La Revue du Praticien* instead.

- ANDEM initiated the consensus conference programme and began drafting clinical practice guidelines.

1993 - *References Medicates Opposables (RMOs)* were introduced for GPs and specialists. RMOs were strict rules forbidding certain unwarranted or dangerous practices, derived from clinical practice guidelines. Non-compliance with RMOs led to fines.

1995 - The first meetings on *'Medecine factuelle'* were held.

1996 - The beginning of the Cochrane Collaboration (Lyon).

1997 - The first issue of a French translation of the *EBM Journal* was published. The number of individual subscribers to the journal was about 500. However, the journal was read by about 5000 hospital staff to whom it was circulated.

- The ANAES (National Agency for Accreditation and Evaluation in Health Care) took over from ANDEM. The ANAES was a government agency with a two-fold mandate: first, to set up a system for accrediting the 3,700 public and private hospitals in France, and second to promote professional evaluation of health care. The ANAES had a mandate for all professionals (physicians, nurses, physiotherapists, dentists, hospital managers, midwives, etc.) in both the public and private sectors, including hospitals and ambulatory care.

Examples of the application of EBM in France

Dr Maisonneuve gave four examples of the application of EBM: consensus conferences, clinical practice guidelines, *references medicales opposables (RMOs)* and technology assessment studies.

Consensus conferences were attended by between 500 and 1,000 doctors and were therefore a means of informing the medical profession about EBM. The ANAES conducted between four and six such conferences each year and helped professional and academic societies organize a further five to eight.

The impact of the conferences was measured. For example, in January 1994, the French Federation of Psychiatry (FFP) and the National Union of Friends and Families of Mentally-ill Patients (UNAFAM) held a consensus conference on 'Long-term Medical Therapy of Schizophrenia'. Its conclusions were widely disseminated through several channels (publication, press conferences, mailing, etc). Recently, the ANAES had measured the impact of six of the conference's recommendations by a variety of methods. In particular, it assessed changes in the prescribing habits of psychiatrists in a cohort of over 2,000 schizophrenic patients under follow up by the Institute National de la Sante et de la Recherche Medicale (INSERM). A small statistically significant improvement was noted for the most important recommendation ('prescribe just one neuroleptic') in the wake of the consensus conference, but the change could not, of course, be directly ascribed as an impact of the conference. Similar improvements were not, however, observed for all the recommendations, suggesting that dissemination campaigns have to be reinforced and better targeted.

Clinical practice guidelines. The ANAES had published 150 clinical practice guidelines during the last seven years. For example, a guideline on the diagnosis and management of essential hypertension in adults aged between 20 and 80 was written after a detailed review of all the main guidelines on this subject worldwide. It was released in September 1997 and widely publicized.

References Medicales Opposables (RMOs). Clinical guidelines made recommendations which were rooted in a state-of-the-art overview of the available evidence. They might concern practices which were appropriate, inappropriate, or in the 'grey zone' of uncertain appropriateness. Some guidelines gave rise to RMOs, which were different in character, being clear proscriptions written in a style reminiscent of the Ten Commandments. All RMOs began with the phrase *'II riy a pas lieu de ...'* (it is inappropriate to …). They applied to GPs and specialists working in the ambulatory care sector but not to hospital doctors. There were no RMOs for dentists and physiotherapists partly because the scientific literature was too scant to draft guidelines based on evidence that could be used as a basis of RMOs.

Technology assessment studies. The assessment of the efficacy and utility of new devices was a rapidly expanding area with enormous public health and economic implications. Dr Maisonneuve gave two examples that demonstrated the problems of diffusion and cost.

- The evidence for the clinical efficacy of implantable defibrillators was strong enough to be able to advocate their use. The 1997 ANAES recommendations stipulated that defibrillators should be implanted by experienced teams only, whether in the public or private sector. However, defibrillators were rarely implanted, even today, because restricting their diffusion to centres of excellence remained an unsolved problem as there is no official recognition of what constituted an 'experienced team'.

- ANDEM had critically appraised the literature on bone densitometry and, like other agencies, concluded against the use of this technique for the mass screening of menopausal women. The *Securite sociale* decided against reimbursement. However, the number of osteodensitometers in France had greatly increased. On reimbursement forms an osteodensitometer test was often entered simply as a scan, and then the *Securite sociale* did reimburse.

Limitations of EBM

Despite the progress reported above, Dr Maisonneuve identified a number of shortcomings in respect of EBM:

- Currently less than five French universities provided training in the critical appraisal of literature.
- As in other countries, there was room for improvement as regards dissemination and implementation of EBM.
- There was little evidence for a direct causal link between EBM and changes in clinical practice.
- Guidelines and RMOs had a limited life-span.
- The distinction between an agency responsible for evaluating the scientific evidence of a strategy or technology, and public bodies responsible for taking decisions, was not well

understood. The agency worked with experts, academic societies and provided guidelines based on evidence. Health policy decisions were taken by the government after consulting medical union representatives.

As a consequence of these shortcomings, health professionals tended to counterbalance what they knew of EBM with their own clinical experience.

THE NETHERLANDS - EXPERIENCE OF THE APPLICATION OF HEALTH OUTCOMES AND EVIDENCE-BASED APPROACHES

Professor Niek Klazinga,
Institute for Health Policy and Management, Erasmus University, Rotterdam, Netherlands

The Dutch health care system

Professor Klazinga said that currently 9% of the Netherlands gross national product was spent on health care, mainly on services provided through private, not-for-profit organisations, funded on a Bismarckian insurance based approach. Equity and access to services were key values in relation to health care in the Netherlands. The government had a limited role in seeking to ensure that these values were achieved. Between 1979 and 1987 planning had been used as the key instrument in their achievement, and was generally regarded as having failed. Since 1987 government had relied on regulated market policies.

The policy context within which evidence-based approaches had been tried

The recent policy context had five main elements:

i) as a direct result of ideas about regulated markets, **quality policies** in respect of health care services and clinical practice, based on consensus and implemented in law;

ii) **patients' rights,** also implemented in law;

iii) the widespread use of **medical technology assessment;**

iv) the organisation of the insurance basis of the health care system on a **regional basis;**

v) a **remodelling of the insurance system** including reimbursement mechanisms.

Data-based policy making and evidence-based approaches to clinical practice

Since the early 1980s there had been several attempts to rationalise health policy making, including the introduction of national policies to meet the World Health Organisation's Health for All targets (an initiative that had been marginally successful); the development of future public health scenarios (attempts to bring together experts in epidemiology, economics and sociology to make predictions about the future); work on developing costs of illness data; instituting efficacy based drugs policies and the use of medical technology assessment.

Taken together, these initiatives had certainly helped rationalise the health policy decision-making process, but political pressures meant that in practice all forms of treatment ended up being covered by insurance arrangements.

Parallel to the initiatives referred to above, since 1990 considerable efforts had been made to use evidence-based approaches. The first phase, from 1990 to 1995, was profession based, and involved the establishment of a Cochrane centre, considerable research into health outcomes and the development of data bases and practice guidelines.

Since 1995, the approach to evidence-based practice had been widened to include inputs from other parties as well as the professions. As a result, efficiency based guidelines (eg in respect of hypercholesterolaemia) had been developed from cost/benefit analyses as well as traditional clinical research; work was under way to find means of ensuring that patients' values were taken into account in decision-taking; studies were under way into the appropriateness of different forms of health care (eg how psychotherapists and general practitioners treat depression); attention had moved from the development of guidelines to the drawing up of indicators; and different ways of seeking to implement research findings were being evaluated.

Limitations and side-effects of evidence-based approaches

There was thus currently considerable activity in the Netherlands in seeking to develop evidence-based practice. It was too early to judge what impact these efforts would make on the quality and cost of health services, and it was important to be aware of their limitations and side-effects.

At the most basic level, it was necessary to treat research findings with caution. Evidence-based medicine was population-based and that tended to obscure non-quantifiable matters such as the values of minorities and individual patient preferences.

Even when an appropriately cautious approach was adopted by policy makers and managers, implementing research findings in practice was problematic. There were inevitably different perspectives. In some cases, there would be resistance from individual clinicians whose practice was based on a particular, now questioned, technique. More generally, all clinicians were likely to find it difficult to combine evidence-based medicine and individual patients' wishes (and indeed rights) in the consulting room, and in treating particular patients would want to take account of the sort of non-quantifiable matters referred to above, as their experience suggested was appropriate.

Finally, even where evidence-based medicine was practised, it could not be assumed that the costs (and possible savings) would be as suggested by research. There was a substantial difference between the macro costs used in cost/benefit research and the actual mechanisms for payment used in practice.

Conclusion

While in principle evidence-based approaches were well worth exploring, and could make a substantial contribution to improving health outcomes and perhaps to reducing costs, they needed careful promotion and the proper infrastructure (and resources) if they were to be implemented effectively. Even then the results were uncertain: it was important for policy makers not to over-estimate the predictive powers of clinical researchers or economists and assume that their predictions were statements of certainty.

SWEDEN - THE WORK OF SBU (THE SWEDISH COUNCIL ON TECHNOLOGY ASSESSMENT IN HEALTH CARE)

Dr Egon Jonnson,
SBU, Stockholm, Sweden

The SBU's remit

Dr Jonnson explained that the SBU had been established ten years ago on the joint initiative of the Ministers of Finance and Health, to provide evidence-based information on matters of health for the general public, clinicians, and health policy makers.

The SBU's mandate was to synthesise research findings in the field of health, and focus on not only the health aspects but also on the economic, ethical, and social implications of different policies, procedures, and programmes for maintenance of health, prevention of disease, treatment of illness, and rehabilitation of disability and disorders.

The SBU was required to work strictly on the basis of scientific findings from published studies, and not to offer opinions. Thus the making recommendations or regulations, and issuing clinical guidelines, were outside the SBU's remit. It was regarded as a body for producing scientific facts, which different groups could make use of as they deemed appropriate.

The SBU's working mode

The SBU was governed by a Board, and had a Scientific Advisory Committee (SAC), composed of 25 people who to a large extent represented the Swedish scientific community concerned with health. The Board and SAC were responsible for the selection of topics for assessment, as well as the final review of the findings.

The topics chosen usually represented major public health problems, such as cancer, back pain, hypertension, depression, alcohol and drug abuse. All potential options of prevention, treatment and rehabilitation were identified, after which the assessments might be limited to certain, or stay with all, aspects of the problem chosen.

Work on each topic was led by a Director and monitored by eight senior researchers. For each topic a project group of about 10 -15 people from different parts of the country, representing knowledge and skill in the subject, and who were scientifically and critically oriented, was brought together and established under a chair appointed by the Director. The group was continually assisted by at least one of the senior researchers, and by secretarial support from the SBU.

Initially, each project group was given a two day intensive course, developed and taught by the SBU staff, in the art of critical and systematic review of scientific studies. The project group then developed its own criteria for selecting the literature to review. For some topics there might be enough studies to select only randomised controlled trials, but in general epidemiological, case control, and cohort studies needed to be included as well.

The reviews usually took two to three years to complete, but sometimes longer - reviews of radiotherapy for cancer and on whether antioxidants prevented disease had both taken five years. This timescale was understandable, given the extent of the research studies to be collated and considered, and the rigour of the review to which they were subjected. For example, in the case of a study into the risks of mild hypertension (diastolic pressure between 90 and 94), 16,000 research papers were identified for consideration. All but 31 were discarded on scientific criteria (for example, they covered too small a population, or were retrospective rather than prospective). The 31 were then subjected to a critical review of their methods and statistics, which resulted in 22 being regarded as sufficiently rigorous for their findings to contribute to the SBU's report.

Current reviews included intervention programmes for life-style changes; methods of treating back pain, depression, stomach ulcers, asthma, epilepsy and obesity; and home care.

When a project group had finished the report was always very extensive, sometimes more than 1,000 pages. The SBU staff then put in a great deal of effort to ensure the report was in easily understood language and reduced to a readable length (and translated into English). They also produced a summary with conclusions based on the facts, a one page executive summary, and press releases. In addition, special versions might be produced for particular target groups such as patients and pregnant women.

The dissemination of the SBU's reports

Dissemination was a major activity at the SBU, accounting for about 30% of its budget. In addition to the senior researchers, three full time employees were engaged on dissemination, undertaking local, regional and national conferences on the findings, arranging courses and seminars, and developing a network of 'SBU ambassadors'. Currently this network of ambassadors consisted of 25 physicians throughout the country who voluntarily spent 30% - 50% of their time (paid by their employers) to travel around and inform colleagues, and other interested people, of the results of the SBU groups' assessments.

The impact of the SBU's work

The impact of the SBU's work was quite substantial, as judged from eleven independent evaluations. Examples included:

- a review of all available evidence of the costs, risks and benefits of treatment of back pain showed that most treatment strategies could not be supported by scientific evidence as to their effectiveness. Worse, the evidence showed that several frequently used strategies, such as sick leave, certain surgical procedures and many inactivating methodologies, did more harm than good. These findings have changed clinical practice, away from medical and surgical interventions and from recommending rest and inactivity towards getting people to stay active and cope with the psycho-social aspects of their condition. The impact of the findings was also seen in a dramatic reduction in the rate of sick leave due to back pain;
- an assessment of the value of preoperative routine testing in elective surgery demonstrated that these procedures were (as was expected by the medical professions) low or of no benefit neither to the patient nor to the doctor in most cases. Since this evidence had been published

routine testing has decreased steadily to the point where it had now almost disappeared from clinical practice. The savings in terms of improved quality of care and safety for the patient were substantial, as were the financial savings which had amounted to five times the SBU's budget;

- in an assessment of optional drug treatment of mild hypertension the evidence was (contrary to the medical profession's expectations) that the old, and much cheaper drugs were not only equally effective in lowering the pressure, but (unlike more recent drugs) were also associated with evidence of prevention of disease and premature death. These findings had caused a halt in the prescription and sales of the new drugs in favour of the old ones, representing yearly cost savings of four times the SBU's budget;
- an assessment of bone density treatment showed that the treatment did indeed increase bone density, but did not lessen the risk of fractures. As a result of publishing the study the sale of bone density machines fell to zero.

More generally, an independent evaluation has shown that 75% of clinicians and hospital administrators were making use of the results of the SBU assessments in their daily work.

Wider networks

The SBU was linked to a number of similar agencies throughout the world through the International Network of Agencies for Health Technology Assessment (INAHTA). In total, the INAHTA members produced about 200 reports a year.

THE USA - THE POTENTIAL CONTRIBUTION OF EVIDENCED-BASED MEDICINE TO REFORM OF THE USA HEALTH CARE SYSTEM

Professor Alain Enthoven,
Graduate School of Business,
Stanford University, Stanford, California, USA

The goal of a truly reformed health care system

In Professor Enthoven's view, the proper aim of reform was to get incentives right for doctors and patients, and a truly reformed system would consist of prepaid (capitated) multi-specialty group practices where the doctors as a group accepted responsibility for quality and total costs. Evidence-based medicine had a major contribution to play in facilitating reform, for without it neither those financing health care nor doctors knew what medical interventions really worked, a necessary basis for cost-effective practice.

Changes over the last decade

Traditionally, the USA health care system was characterised by insurance arrangements to indemnify individuals for the costs of treatment, mainly provided by the doctor of their choice in solo practice, who charged on a fee-for-service basis.

Over the last ten years, however, there had been a switch to one of two forms of 'managed care' arrangement - preferred provider insurers (PPIs) or health maintenance organisations (HMOs). These differed in important respects, but they shared key characteristics. In both cases the individual covered by such an arrangement lost the free choice of his or her doctor, and instead was treated was by a clinician contracted by the PPI or HMO, on the basis of negotiated fees or prices, with the clinicians concerned working within the PPI's or HMO's quality and utilisation guidelines. (Patients covered by PPI could go out of network at the cost of a higher share of the bill. Hybrid arrangements had evolved such as point-of-service HMOs in which the patient could also go out of network for a higher share of the cost.) Managed care organisations sought to base their guidelines on evidence-based medicine.

The shift to managed care arrangements had been very imperfect. Outside California, the great majority of doctors did not want to accept responsibility to manage costs, so the PPIs or HMOs had to attempt to manage them. This had led to great frustration among doctors over the loss of their autonomy. Many employers had unilaterally changed from funding traditional cover to a managed care arrangement, and this had caused concern among employees (those whose arrangements had been unilaterally changed were twice as likely to be dissatisfied with their PPI or HMO than those who had had the choice of whether to change). Nevertheless, there had been rapid growth in the number of insured employees covered by PPIs and HMOs. In 1988, 71% received their health care under traditional fee-for-service arrangements, by 1997 only 18%.

The need for further change

Although the two forms of managed care arrangement represented movement in the direction of the ideal reformed arrangement referred to above, they still fell short. The PPI arrangements in particular (and PPI members exceeded HMO members) were simply a modified form of the traditional indemnity insurance arrangement, and in Professor Enthoven's view had largely failed to get the incentives right. What further changes were desirable, and what was the potential contribution of evidence-based medicine?

Essentially, incentives needed to be put in place to create the circumstances where doctor-manager teams would strive to change care processes in order to increase quality (measured by outcomes and satisfaction) while lowering expenditure. Some organisations were already seeking to do this, by reducing variations in practice. Specifically, groups of doctors had worked together to review the literature and their own practices in order to seek consensus on appropriate care; collected data on the outcomes of treatment for their patients; identified what practices or processes produced the best outcomes; prepared guidelines and set up arrangements to secure compliance. One organisation which had worked in this way was Kaiser Permanente where, for example, guidelines had been developed for the treatment of paediatric asthma and prescribing. Regrettably, these situations remained the exception rather than the rule, and many doctors seemed not to be much interested in outcomes data.

The contribution and limitations of evidence-based medicine

Where through the proper use of incentives groups of doctors could be persuaded to work in the way outlined above, guidelines should be evidence-based where practicable. Randomised controlled trials were in principle the gold standard form of evidence, but much improvement could be achieved on the basis of less robust evidence, for example by gathering and evaluating simple outcome data. Indeed, there were practical problems in the randomised controlled trial approach, for example handling situations where the technology changed while trials were in progress.

While the development of evidence-based medicine was potentially a major contributor to the further improvement of the health care system, it was important not to proscribe the use of treatments for which evidence in respect of effectiveness was not yet available. This was recognised by HMOs, which had agreed to fund the 'ordinary care' costs of new, unproven therapies when performed under the protocols of an approved clinical trial. (It was underlined by the fact that, for example, although treatments for prostate cancer were not yet based on scientific evidence, several prominent and rational doctors of Professor Enthoven's acquaintance with the condition had opted for radical prostatectomies.)

THE USA - EVIDENCE-BASED MEDICINE AND HEALTH OUTCOMES

Professor Heather Palmer,
Center for Quality of Care Research and Education, Harvard School of Public Health, Boston, USA

Health and the relevance of evidence-based medicine

Professor Palmer drew attention to the US Institute of Medicine definition of the quality of health care as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. This definition carried several important implications. First, through the phrase 'increase likelihood' it reflected the fact that successful health outcomes could not be guaranteed. Second, the word 'desired' implied that the patient should be able to input his or her preferences into clinical decisions. Third, the phrase 'consistent with professional knowledge' pointed up that the quality of care related to outcomes which could be improved by use of given processes of care.

These three implications were all relevant in thinking both about evidence-based medicine and its implementation. Only through scientific evidence could it be known what processes increased the probability - not the certainty - that given health outcomes would be achieved. Only by taking patients' preferences into account as well as clinical evidence was it possible to achieve *desired* health outcomes.

The potential and limitations of forms of evidence

In order for scientific findings to benefit patients, it was necessary for them to be transmitted to many busy health care professionals in diverse health care settings and then used in practice. A first step was the production and dissemination of guidelines - recommendations to guide decisions in the actual practice of medicine. These guidelines needed to be based on the best available evidence, but that was problematic. Evidence was only as good as the trial design.

In principle, randomised controlled trials produced the strongest evidence from the scientific perspective, but if a trial missed important outcomes and trade offs, or excluded relevant patients, the results might not apply in average conditions of use. For example, typical patients had characteristics that tended to exclude them from trials, such as co-morbidities, overwhelming socio-educational problems, or special vulnerabilities such as physical fragility or cognitive or sensory impairment. Further, patients had personal preferences, which were not usually consulted in trials. Practical guidelines, therefore, used expert opinion to adapt information from scientific trials to actual practice circumstances.

The clinical recommendations found in practice guidelines provided a basis for measuring and comparing quality among providers of health. Samples of patients eligible for a specific treatment according to guideline recommendations could be drawn from different providers and rates of treatment compared. This method using process data was preferred to using health

outcomes data to compare providers. The rationale for this preference was that none of the methodological features of randomised controlled trials was possible in outcome data comparisons, so that the evidence that outcomes truly differed from provider to provider was very weak.

An example of process-based measures to compare providers was a study funded by the Agency for Health Care Policy and Research. This study tested a quality measure constructed by identifying patients discharged after acute myocardial infarction and comparing rates of treatment with beta blockers among the enrollees of six different health plans. Many opportunities to improve health care quality could be found by this method of identifying low rates of use of treatment previously proven to produce better health outcomes.

The implications of evidence-based medicine and measurement of clinical quality for the beneficiaries of health plans

Beneficiaries were, of course, concerned about matters other than clinical quality, especially the experience of receiving care. In the US the Consumer Assessment of Health Plans Survey (CAHPS) was becoming the predominant tool for capturing 'patient experience', through such questions as:

over the last twelve months:

- how much of a problem, if any, was it to get the care you or your doctor believed was necessary?
- how often were staff at a doctor's office or clinic as helpful as they should be?
- how often did doctors or other health care providers listen carefully to you?
- how often did doctors or other health care providers explain things in a way you could understand?
- how often did doctors or other health care providers show respect for what you had to say?

The results of this type of survey were being used to market care to consumers, drive accreditation of health plans and drive co-operative quality improvement programmes.

As the first of the questions listed above suggested, however, beneficiaries were becoming more sophisticated in understanding what constituted 'necessary' care for their condition, and there were expectations that they would begin to use evidence-related clinical performance measures to choose health plans.

To date, there was only limited evidence that this was happening, and there were some barriers. For example, few employers passed on performance comparisons of plans to their employees. Further, there was real concern that plans that became known as good providers of care for chronic illnesses would attract the sickest patients, which could bankrupt the best plans. Thus while evidence about the performance of plans was of great potential to the individual, its availability posed potential problems for health plans.

THE USA - THE WORK OF THE AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Dr Carolyn Clancy,
US Department of Health and Human Services, Rockville, USA

The origin and nature of the Agency for Health Care Policy and Research

Dr Clancy said that in the USA there were three levels of health policy: the public policy level (Federal, state and local government), systems level policy (the large health care providers), and clinical level policy (large groups of professionals). The establishment of the Agency for Health Care Policy and Research (AHCPR) in 1989 was a Federal government public policy decision, reached under a Republican administration largely because of concerns about the rising costs of health care.

The remit of the AHCPR was to promote studies in areas of clinical work where there seemed to be no evidence, and to concert evidence in those areas of clinical practice where there had been a slow take-up of evidence-based medicine.

Since its inception the AHCPR had funded a range of research projects and issued a large number of guidelines for clinical practice. An interim report on its work had recently been completed.

Progress achieved

Many useful research studies had been completed and guidelines issued, and there were some clear success stories, for example in respect of beta blockers. Here, as a result of the evaluation of this treatment, actions by those at the public, systems and clinical policy levels and the impact on clinicians had led to increased take-up. Overall, however, progress had been somewhat disappointing, and the report evaluating the AHCPR's work had concluded that 'few studies demonstrate clear superiority of one clinical strategy over another, successful incorporation of results into practice or policy, or interventions that had improved quality or lowered cost'.

Perhaps the most important finding had been that, contrary to initial expectations, making information available did not in itself impact on clinical practice. Essentially there were four ways in which research findings could potentially impact: on the research community, on policy makers, on clinical practice, and on health care outcomes. So far, there was only limited success in impacting on clinical practice and, through that, health outcomes. It was now recognised that, while the availability of knowledge was a necessary condition to achieving impact in these, it was certainly not a sufficient one.

The next phase of the AHCPR's work

In the light of experience to date, there had been a significant shift in the AHCPR's work, with more emphasis on finding means of ensuring that evidence-based medicine made more impact

on clinical practice. For example, partly prompted by Congress but also because the AHCPR had become concerned about the large volume of guidelines being issued and their relatively limited impact on practice and health outcomes, the Agency had largely ceased to produce guidelines, and instead focused its efforts at potentially more effective, more locally based means of informing policy makers and clinicians about research findings, the funding of twelve evidence-based practice centres.

Future priorities for those wishing to see the development of evidence-based practice

In Dr Clancy's view, there were three particular priorities for the AHCPR and others concerned to see the wider take-up of evidence-based practice in the USA. First, while continuing to sponsor research into clinical effectiveness, within programmes attention should be paid to the particular problems of sub-groups within the population, for example children. Second, in parallel with research into effective techniques and procedures, there was a need to evaluate the impacts of the different environments in which patients received care. Finally, and perhaps most important given the AHCPR's experience to date, there was the need to evaluate what forms of lever were successful in causing the kind of change in clinical practice and health outcomes achieved in examples such as beta blockers.

EVIDENCE-BASED MEDICINE - THE PUBLIC PERSPECTIVE

Ms Jane Steele,
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Findings from Workshop on health, learning and community safety

Ms Steele reported that in 1998 65 people from a London borough had come together under the Foundation's auspices for a day and a half discussion of health, learning and community safety. The group explored the connections between what public services do to achieve outcomes in these areas, and the actual and potential contributions of individuals and communities.

On health, five inter-connected themes had emerged from the Workshop, namely concerns about: the quality of the services provided by the health care system generally; the implementation of the care in the community policy specifically; accountability and funding; the environment; and the contribution individuals could make in looking after themselves.

The main findings

In relation to the **quality of services,** there were concerns both about the organisational arrangements within which services were provided, and the quality of the services themselves. On the organisational arrangements, members of the Workshop had identified as defects the volume of paperwork that seemed to permeate the system, and waiting times for appointments. On the quality of services, there were concerns about lack of information (to service users and professionals); variations in the quality of services provided; continuity of care (a wish to see the same health care professionals throughout a course of treatment); and the narrow view taken by some health professionals (who seemed concerned with symptoms rather than causes, did not seem to take a person's lifestyle and environment into account, and did not provide information about possible alternatives to the treatment offered).

On the implementation of the **care in the community policy,** there was concern that services were failing to meet needs. Better targeting would be possible if providers consulted with users about what was needed.

On **accountability and funding,** there was concern that the NHS and other relevant public services were insufficiently committed to consulting service users and the public generally. This was the case both in respect of the organisation of particular services and in priority setting. Given the evident under-funding of services, it was accepted that prioritisation of services was necessary, but there was concern about the lack of openness and public consultation in priority setting.

Members of the Workshop were quite clear that people's health was dependent on much more than the health care system. **The environment,** in particular, was widely felt to impact greatly on health care. Environmental policies (such as reducing pollution), good housing and

a sense of community were direct contributors to people's health, while a proper public transport system was important for those needing to receive treatment in clinics or hospitals.

Finally, whilst the potential contribution of the individual in **looking after his or her own health** was recognised, and information on, for example, healthy lifestyles, was widely available, practical pressures such as lack of adequate child care facilities, poverty and poor housing made it difficult for many to implement what they knew to contribute to prevention of ill health.

Overall, the Workshop had shown that members of the public were both very interested in health matters and, when given the opportunity to explore issues in depth, demonstrated an understanding of the complexities facing those who had to make policy decisions about priorities, quality and publication of information.

The implications of the findings for evidence-based medicine

Ms Steele suggested that the Foundation's Workshop showed that the public - at an individual and collective level - had a substantial contribution to make to the wider practice of evidence-based medicine.

At the level of the individual service user, there were three aspects to the potential contribution of the public. First, from their experiences as users or carers, individuals could provide evidence about the effectiveness and outcomes of health care interventions that added to the scientific view of effectiveness and enhanced and elaborated research findings. For example, individuals could contribute their experiences of different aspects of service delivery and their impact on outcomes eg consultations, settings, types of providers. Similarly, individuals could offer experienced-based views on quality of life issues such as the significance of side-effects, which would be a valuable complement to research findings on clinical effectiveness.

Second, by being properly involved in decisions about their own treatment, and in particular by being offered the chance fully to discuss alternatives, individuals could make a significant impact on outcomes. For example, a given procedure might be shown to be clinically effective in a research context, but in ordinary circumstances its effectiveness would in part depend on patients adhering to the treatment regime. Such adherence was more likely when treatment possibilities had been properly discussed with the individual patient, who had then made a positive choice as to the preferred form.

Finally, there was the issue of the longer term impact of new practices or standards. Individuals had a contribution to make by being involved in the ongoing process of gathering and analysing evidence.

Underlying all three possible contributions were issues of communication and information. Lack of communication was a major source of dissatisfaction and complaint throughout the public services, and the NHS was no exception. To secure the potential contribution of individual service users, the health care system, and health care professionals, needed to take time to communicate properly. And the information that was communicated needed to be as full as practicable (especially in relation to alternative forms of treatment), up to date, and realistic (in particular, it should be honest as to likely outcomes, not over-optimistic).

At **the collective level,** there were clear reasons of principle as to why the public should be involved in matters such as resource allocation, priority setting, technology assessment,

defining quality and monitoring standards. The NHS and other relevant public services were, after all, publicly funded, for public use. However, in the context of evidence-based medicine there were practical reasons as well. Better decisions with wider ownership were likely where all relevant parties - policy-makers, professionals, managers and the public - were involved, each learning from the others' values and experience.