

**Maximising the Impact of Health Technology
Assessment: The Australian Case**

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ABSTRACT

In recent years there has been growing recognition of the need to consider the economic evaluation of health care in Australia. Increasing resources are being devoted to assessment of the costs, risks and benefits of health technologies; and considerable progress has been made in methodological development. However, the relationship between evaluation studies and changes in policy and practice is less clear. The paper explores some of the factors influencing the effectiveness of the links between economic evaluation studies on the one hand and changes in health policy and practice on the other. It is emphasised that mechanisms for encouraging a rational diffusion and use of health technology (and by implication economic evaluation) need to make an impact on (at least) two parallel decision making processes. The first concerns **planning** decisions about which facilities to provide and which programs or therapies to reimburse or fund, while the second is concerned with **clinical** decisions about the care to be given to individual patients.

Maximising the Impact of Health Technology Assessment: The Australian Case

1 Introduction

In Australia, as in a number of other advanced countries, there has been growing recognition in recent years of the need to consider the economic evaluation of health care. Increasing resources are being devoted to assessment of the costs, risks and benefits of health technologies. This is hardly surprising given the powerful forces which can encourage the use of expensive health technologies.¹ Considerable progress has been made in methodological development of economic evaluations in health, and although several weaknesses recur in the published literature and a number of controversial areas remain (Drummond 1987), it can be argued that the appropriate methodology has broadly been established (Department of Clinical Epidemiology and Biostatistics, McMaster University, 1984).²

Much less clear is the relationship between evaluation studies and changes in policy and practice. The purpose of this paper is to explore some of the factors influencing the effectiveness of the links between economic evaluation studies on the one hand and changes in health policy and practice on the other. It is recognised that (at least) two parallel decision making processes exist in health care. Mechanisms for encouraging a

¹ They include: (i) financial rewards for doctors in a fee-for-service system; (ii) incentives for the over-provision of expensive technologies arising from the marketing efforts of equipment suppliers or pharmaceutical manufacturers; (iii) the 'technological imperative' to use if available; (iv) the medical ethos of doing everything possible for the patient; and (v) patient pressure on reimbursement agencies and practitioners.

² See Appendix 1. Of course, a range of questions could be raised about the checklist. For example, in relation to the third point, if an RCT was done was there adherence to the protocol including true randomisation, did the RCT itself provide good evidence of effectiveness and overall how relevant that was? More generally, having examined that useful set of criteria, a further question might relate to what chance would there be of conducting a study that fully met these requirements and how many studies approximating to these criteria could realistically be put in place, given such factors as the inevitable limitations on resources and the various questions on timing, impact and process raised later in this paper.

rational diffusion and use of health technology (and by implication economic evaluation) need to make an impact on both decision making processes i.e. *planning* decisions about which facilities to provide and which programs or therapies to reimburse or fund, and *clinical* decisions about the care to be given to individual patients (Drummond 1987; see also Ham and Hill 1984).

The paper is divided into four sections after this brief Introduction: aspects of the policy context which influence the relationships between health care evaluations on the one hand and changes in policy and practice on the other; specific Australian case studies; factors which tend to increase the impact of health technology evaluations; and finally, five ways of improving the relationship in Australia between evaluations and changes in policy or practice.

2. THE POLICY CONTEXT: BLACK BOX OR BLACK HOLE?

To those who have not had personal experience in the policy making processes of Government, their operation often seems confusing if not baffling (U.S. Office of Health Technology Assessment, 1978).³ In general, it appears that few health technology evaluation studies were decisive in their influence on changed policy or practice, that there were normally a range of other factors involved as well as the evaluation study, that the process could often be of significant length and that there was little evidence to suggest that, in general, studies which were better technically had a greater influence in changing health care policy or practice.

We initially consider the overall process in four parts dealing with relationships:⁴

- (i) between the perceived situation in the health care system and the health technology assessments;
- (ii) between health technology assessment and changes in policy;
- (iii) between health care policy and changes in practice; and
- (iv) between changes in practice, monitoring and the need for reassessment.

(i) The first relationship is between the perceived situation in the health care system and the health technology assessments to be made. It is well recognised in the literature

³ Health technology can be defined very broadly, to include "the drugs, devices, and medical and surgical procedures used in medical care, and the organisations and supportive systems within which such care is provided" (U.S. Office of Health Technology Assessment (1978)). If we take this broad definition at face value we can identify a number of major health care policies and programs in Australia where economic analysis and individual health care analysts with an economics training have had a significant involvement. For example, the national health insurance program introduced by the Whitlam Government in 1975 ("Medibank") owed much to Dr J. Deeble and Dr R. Scotton, both in conception and in implementation. This paper adopts a more restricted definition of health technology and is particularly concerned with health technology assessment relating to new medical or surgical equipment or procedures (such as magnetic resonance imaging, liver transplantation, extra corporeal shock wave lithotripsy and cervical screening for cancer).

⁴ See Selby Smith (1989) for background information about health technology assessment in Australia. In more recent overviews Hailey and Roseman (1990) consider health technology usage and assessment issues in Australia and New Zealand and Hailey and Crowe (in press) note the recent evolution of the Australian Health Technology Advisory Committee.

that a set of objective conditions is not, by itself, sufficient to explain why particular problems or issues are defined as problematic and worthy of study.⁵ Palmer and Short (1989) have argued that analysis of the concepts of power and interest indicate that issues may not reach the policy agenda, because the agenda is controlled by those who have an interest in retaining the status quo, and perhaps because in some cases those who stand to benefit from changes in policy or practice which might result from health care evaluation accept the status quo. Wiseman has advanced certain criteria influencing the choice of topics for detailed evaluation from a rationalist perspective: in particular, the size of the issue, its nature (e.g. whether tightly constrained or not, particularly complex or contentious), its future implications and the political setting. However, other British writers have argued that potential issues for study must pass three tests if they are to survive: to command attention, to claim legitimacy and to involve action. For example, Ham has stated that "it is not sufficient for the conditions alone to exist, because however serious the conditions are, they will not receive consideration unless an individual or group draws attention to them" (Ham 1985).

In general, evaluation activity tends to be closer to incrementalism than rationalism (Lindblom 1964, 1979), with elements of mixed scanning, where there is a review process, either explicit or implicit, complemented by a selection process for those particular areas which are to be studied in detail (Etzioni 1967). From another point of view the choice of assessments to be undertaken, subject to the available resources, may be viewed as involving both a political and social process (involving, *inter alia*, the values and relative power of interested parties) and also a technical process of evaluating options in the light of agreed values and expected constraints (e.g. Lee and Mills 1979). The process of identifying problems and setting the agenda for health technology assessment (including influencing how the assessment process will be undertaken) involves a range of parties and may be influenced by their interaction: an example of the former might be the desire of radiologists to include in the Medicare Benefits Schedule an item providing reimbursement for MRI services. An example of the latter might be the effect on pharmaceutical suppliers of the introduction by the Federal Government of a requirement that new drugs to be listed on the Pharmaceutical Benefits Schedule in future must provide information on cost-effectiveness additional to the information previously required.

The Report of the Committee to review the role and function of NHTAP (Selby Smith 1989) noted that certain major aspects were considered when deciding whether an assessment should be carried out: i.e. the costs of a technology (both capital and recurrent); its effect on infrastructure and other services; the number of people to whom it might be applied; the availability of competing technologies; the probable significance of the technology in terms of effects such as mortality, morbidity or quality of life; the level of usage and potential for inappropriate use; training/accreditation/education issues; whether the technology had already been adequately assessed (in Australian terms) by another organisation including overseas bodies; and whether an assessment would be likely to influence future deployment and usage of the technology. Decisions on whether to undertake an assessment of a technology have also been influenced by the state of development of the

⁵ The Institute of Medicine (1985) has argued that in the U.S. "there are no consistent and reliable procedures for identifying emerging technologies that may have major consequences" (p.13). But in Australia it can be argued that this has been a role of the National Health Technology Advisory Panel, and now the Australian Health Technology Advisory Committee - and that it has, by and large, satisfactorily discharged this responsibility for some years. However, identification of technologies which will have a major impact remains an uncertain process and advisory bodies will have limitations in undertaking this process.

technology and the possibility of significant further advances, safety considerations, and implications if its introduction is delayed.

Economic evaluations of health technology need not be confined to new or emerging technology (although they have tended, in practice in Australia, to focus more strongly on these than in relation to older, more established technologies). However, they do require comparisons to be made. The comparative costs and benefits probably will not stay constant over time. For example, the wider introduction over time of a new technology may mean on the one hand that, *ceteris paribus*, greater experience leads to lower costs and better practice, but also that the procedure is utilised by providers of lower skill on average and on patients for whom it is of lower marginal benefit. There can be important questions about when to select particular health technologies for assessment, as well as which technologies (see for example Hailey, Cowley and Dankiw, 1990). Timing aspects can be influenced not only by technical aspects but also by social and political aspects, such as the strength of the interests pushing for (or opposing) a formal evaluation, whether the pressure is to delay introduction (e.g. to reduce growth in government outlays on health) or speed it up, or the current stage of the electoral cycle at the State or Federal level.

As a number of writers have argued (e.g. Glennerster, 1980, 1981) not all participants in planning or evaluation are equal. The processes need not be neutral and can be value-laden. From one point of view health care evaluation studies might be seen as a response to the scale and complexity of the health system, while from another perspective they may be seen as more concerned with power and control, an ideological cover for maintaining or even strengthening existing dominant interests. The studies chosen and the way in which the evaluations are undertaken can provide mechanisms for particular interest groups to affect the organisation, delivery and perception of health programs and services. The wider the range of interests involved the more important it can be to focus on negotiation and bargaining when seeking to understand why some evaluations were undertaken and not others, as well as when and how. Values in health care can lie at the heart of much discussion about objectives: power, perspectives and belief systems can all be important (see, e.g., Mooney, 1979) - and, of course, values in health care can also be strongly linked to the reasons why some analyses and recommendations are acted on, while others are not.

Once it is accepted that there is a multiplicity of decision making groups - even within individual health agencies - and that there are limits on the ability of any one individual or group to impose its will on others, then it is not obvious what meaning to attach to the so-called "objectives" of the agency, *a fortiori* for the health system as a whole. In order to achieve goals, health care organisations (and groups within them) may have to exchange resources: common goals cannot necessarily be assumed, although common action can be negotiated. Lee and Mills (1982) have argued that these goals are the product of an internal political process of negotiation and bargaining, out of which there emerges a dominant coalition with an agreed set of goals (which may be temporary rather than permanent). They stress the importance of clarifying the objectives of the various actors if attempts are to be made to reconcile their differences in the particular health care organisation, or the more general health care system.

In the analysis of Marmor and Christianson (1982) health care policies and programs are viewed as political goods, which are traded in a political marketplace for votes and financial support. Governments supply, at varying costs, health care policies that affect both individual consumers and those organised as interest groups; while the demand for the policies reflects the benefits that the participants in the markets expect to experience. Governments, bureaucrats and constituents, who demand policies and programs of various kinds, pursue their own objectives in the political marketplace, where the value placed on

any policy will reflect the interaction between the relevant interest groups. Clearly evaluation activities can play a significant role in these processes. The more diverse the interests and the wider the range of parties potentially concerned with the assessment of a particular health technology the more difficult it is likely to be to obtain agreement on how to conduct the evaluation process and when.

(ii) Secondly, once the decision has been made to undertake a particular health technology assessment (and on how it will be undertaken), what is the relationship between the assessment and the changes in policy (if any) which result? Of course, inertia on the part of policy areas may be an outcome - it may even be a valued one on occasion. The issue attention cycle identified by Downs (1972) can involve substantial fluctuations in the intensity of public attention to particular issues and rapid shifts from one issue to another. This can place considerable obstacles in the path of careful, well-designed, long term evaluation studies linked to changes in policy and practice. Health care, because of its media potential and substantial emotional content, may be more than usually susceptible to this phenomenon. Jennett (1984), in commenting on a report in the U.K., argued that while the media are important in promoting and informing debate about health care issues, including evaluative aspects, they are liable to create unrealistic expectations. And, of course, manufacturers and distributors of medical technologies vigorously promote their own products.

Any attempt to assess the relationship between evaluation and policy change is complicated by the variety of participants who may be involved, and the various levels of the health care system which may be relevant to the assessment in Australia (e.g. Federal, State or local government;⁶ governments, providers, suppliers and consumers; policy or planning compared to clinical decisions for individual patients). The policy process has its own logic; and it may be that in some cases the policy makers are more open to the evidence and conclusions generated by the health technology assessment than in others. At least they should be able to understand the implications of the assessment and have the information available at a time which is relevant for the decision to be made. Good information which arrives after the decision has been made is a very imperfect substitute for the same information when the process of decision-making is continuing. The trade-off between more complete and more timely evaluation information is important to both those who conduct health technology assessments and those who use them.

Evaluation may be seen by the policy maker as something of a wild card. Potentially, evaluation can provide data for better-informed decision making, but the evaluation data may not be easily assimilated into policy decisions, and in some cases may be regarded as embarrassing if they point to a need for significant change. Furthermore, evaluation is only

⁶ For example, there may be limited incentive for State Governments to incur the potential criticism of powerful health interest groups by additional regulation of medical practice or tighter registration requirements if the financial costs of not doing so are primarily borne by the Commonwealth through the Medicare Benefits Schedule. Even the Commonwealth may find it hard to "resist the pressures that clinicians and equipment manufacturers can bring to bear when allegedly beneficial technology is being denied to the community" (Palmer and Short, 1989, p.181). More generally, it may be more difficult to carry a case for increased regulation in health care, even if based on careful evaluation, in a climate of opinion where Australian governments of all political persuasions are tending to be more sympathetic to deregulation, the greater use of markets, corporatisation and privatisation of government activities throughout the economy (for example, see Caplin et al, 1991,; and the individual papers by Harris, Sturgess and Keith).

one input to the policy making process. There are dangers for those who assess health care if it is not appreciated that the most elegant and detailed analysis may have no impact on the policy process and any subsequent action by government if the timing is wrong, the results are not presented in a way that is intelligible to policy makers or the recommendations are fundamentally flawed in political terms.

The policy process can vary widely, but often tends to be quite complex. For example, at the Federal level the consideration of a health technology matter (e.g. possible introduction of a new item to the Medicare Benefits Schedule), when a relevant assessment has been undertaken, could involve a range of groups. The health technology assessment, if undertaken by the former NHTAP⁷, might be published.⁸ The draft might be modified in the light of public comment. Policy aspects of the review (e.g. introduction of a new Medicare Benefits Schedule item) would be the responsibility of the Department not the NHTAP/AHTAC or its AIH-based Secretariat. The Department might take account of a range of other matters in addition to the health technology assessment e.g. government policy on expenditure restraint, views of the organised medical profession, representations from other parties (such as State Governments, the Consumers' Health Forum, or manufacturers/importers/distributors of appropriate equipment). The result might be modification of the original NHTAP proposal or development of alternative options; if the changes were substantial further consultation might be deemed desirable.⁹

The Department would, especially in relation to matters with potentially significant implications, be expected to consult at an early stage with the central co-ordinating departments (especially the Departments of Finance and Prime Minister and Cabinet): these consultations can lead to changes in departmental priorities or emphasis. The Department, at this stage if not before, would seek the Minister's views; and depending on the complexity and sensitivity of the issue the Minister might wish to consult his or her colleagues: for example, if the technology had substantial expenditure implications consultation would occur with the Minister for Finance. If there were substantial implications for Federal-State relations consultation might even occur with the Prime Minister. Discussions between Ministers would generally be complemented by discussions between their Departments; and at each stage the discussions could raise new issues,

⁷ Support for NHTAP was located within the Australian Institute of Health, an independent statutory body within the portfolio of the Federal Minister for Community Services and Health but outside his Department.

⁸ All NHTAP assessments were published, and a similar policy is anticipated for AHTAC (although some advice to AHMAC may be sought on a more confidential basis and is unlikely to result in published reports). The activities of NHTAP have been directed towards appraisal of devices and procedures where 'device' means any instrument, apparatus, implement or machine. Health technologies have been defined as those activities and procedures which involve the use of devices or equipment to prevent, diagnose, treat or cure disease and which contribute substantially to the total cost of health care (or potentially could do so). In general, NHTAP did not assess chemotherapeutic agents except as necessary in the course of evaluation of other types of health technology. AHTAC, as the successor to NHTAP, has retained this general direction, but has slightly wider terms of reference which permit it to accept requests for assessment of pharmaceuticals from the Commonwealth Department in consultation with the Pharmaceutical Benefits Advisory Committee.

⁹ A view canvassed at a recent health technology assessment seminar was that bringing the results of an assessment to the attention of policy areas should be considered an impact, even if the influence exerted was small or difficult to determine precisely (Behney, 1990).

different emphases and the need for reconsideration.

Formal consultation within the Government would be necessary before the change in policy became more than a proposal; in general, agreement by Cabinet to the Minister's recommendations and incorporation of any financial implications within the Budget framework. Any substantial modifications at this stage would raise the possible need for reconsideration and further consultation with important affected groups, both within and outside government. Assuming either that this was not required or that it resulted in relatively little substantive change the focus would now shift from policy formation to implementation. Nevertheless, in practice the process of implementation can raise opportunities for obstruction by aggrieved parties as well as genuine difficulties of practical implementation which can feed changes back into the original policy as well as forward into practice and program administration. The distinction between policy and administration and between bureaucratic and political aspects can be blurred during the process, there are many opportunities for reconsideration and modification, policy determinations can be influenced by implementation aspects, developments elsewhere in the portfolio (and outside it) can be important, and there is scope for a range of personal aspects since credit, trust and position can all be involved.

(iii) Thirdly, there is the issue of the relationship between changes in health care policy and changes (if any) in practice, at either the level of the health care system as a whole or at the level of the clinical treatment of the individual patient. It does not automatically follow that a change in policy will result in a change in practice, still less that policy change will necessarily improve the health status of the Australian population. An earlier study in the UK concluded that "what emerges with force is that a seemingly "well-designed" central policy - even when matched by resources - is not sufficient to ensure implementation if it challenges the motivations and inclinations of those who must carry it out locally" (Lee and Mills, 1982, Chapter 1).

If relevant groups and individuals do not know of the change in policy they will not be able to change their practice in response to it. This suggests the importance of active dissemination of policy changes, together with explanations of why they have been made, the basis on which the policy changes were derived (including health technology assessments to the extent that they were influential) and the results which are anticipated. These steps are likely to be more effective, and hence implementation of policy changes is likely to be more extensive, if key groups and individuals have previously been aware of the developing evidence for change and the costs and benefits of alternative courses of action,¹⁰ and also as the assessment process becomes more congruent with the reimbursement system.

The AIH has noted that, in Australia, the introduction and diffusion of health technology is determined by a complex interaction of market forces, public funding and regulation. Governments exercise financial and regulatory influence, but other major interested parties also have a significant influence. As a result, the introduction of technologies may not always be consistent with health care priorities (AIH, 1990, Chapter 6). Also, the avenues of control open to government, such as financial incentives through either hospital budgets or setting the rate of Medicare benefits for reimbursement of procedures, are widely recognised as crude and imperfect ways of influencing the diffusion of technology. Hailey

¹⁰ For information about the diffusion of certain medical technologies in Australia see Richardson (1988). For some evidence on the possibly tighter capital constraints in the public than the private hospital sector see Selby Smith (1990).

and Roseman (1990) note that Australia has found it difficult to focus on a single, coherent national policy to fund innovations and control investment in medical technology; and that diffusion and use of technologies may to an extent be independent of government policies and controls.

The Institute of Medicine report gave considerable attention to the effects of evaluation on the diffusion of technology in the United States (and in particular whether the method used to evaluate a technology has an effect on its diffusion). In their view, "built into the notion of diffusion is the expectation that social change is not instantaneous and that some difference in practice among physicians at a moment of time is therefore reasonable and likely" (Institute of Medicine, 1985, p.8). The Institute identified ten factors that bear on the adoption and abandonment of medical technology, four of which they argued were relatively insensitive to change by policy-makers i.e. prevailing theory, attributes of the innovation, features of the clinical situation, and the presence of an advocate. However, in their view, of the other six factors three - practice setting, decision-making process, characteristics of the potential adopters - may be subject over time to some policy influence, while the other three - environmental constraints and incentives, conduct and methods of evaluation, and channels of communication - were seen as relatively susceptible to influence by policy makers.

They concluded that evaluations are likely to exert a greater impact on diffusion if they are buttressed by attention to other controllable factors (such as channels of communication, environmental constraints and incentives) that affect the adoption and abandonment of medical technology. "The connection between favourable assessment of a technology and its subsequent diffusion into practice is a wandering path among clinicians, educators, researchers, professional bodies, journal editors, hospitals, drug and device manufacturers, third-party payers, regulatory agencies and others. Their various perspectives obscure responsibility for the diffusion of technologies" (Institute of Medicine, 1985, p.8). They recommended that clearer lines of responsibility be established to make better medical practice a consequence of the evaluation of medical technologies. If health care professionals in general, and medical practitioners in particular, tend to be conservative in clinical practice (often for good reason) this orientation can have a marked influence on the use of new health technologies, including an understandable reluctance to abandon pre-existing methods and a tendency to retain previous referral patterns.

Furthermore, when policy change is intended to encourage changes in practice, the latter follows the former. But precise relationships are difficult to develop in this area, many other influences can be at work, and the outcomes may not always conform at all closely with expectations. Also, the evidence on which the initial health technology assessment was based may not continue unchanged over time, there can be significant changes in relative costs and benefits (and in the segment of the population at which the technology is targeted). The conclusion we draw is that the precise effects on changes in practice resulting from alterations in policy can be subject to considerable uncertainty and need to be kept under continuing review to ensure that the initial suggestions continue to be appropriate and modifications are made where necessary.

This conclusion appears to be strengthened by the complexities arising from the involvement of differing levels of government in the Australian health care system and the recognition that their separate interests are not always well aligned with each other, or those of producers and consumers in relation to particular policy changes. Examples include out-patient services provided in public hospitals funded by State Governments compared to general practitioner services funded by the Federal Government through Medicare; or pharmaceuticals paid for by the Commonwealth when received through the

Pharmaceutical Benefits Scheme rather than by the States when provided through public hospitals. Also some assessments, especially those dependent on generation of local primary data, are reliant on the goodwill and cooperation of specialists and other experts in health care institutions (Hailey, Crowe and McDonald, 1991).

The Australian experience has been that control of health care technologies, and therefore the influence of assessment, has been strongest in the early stages of usage and diffusion. In the early stages, governments and other funding areas will typically have greater leverage and can expect higher levels of cooperation from the institutions and professional staff using the technology. In practice, decisions on health care technologies in Australia, once taken, are difficult to reverse. Policy areas may react slowly to put in place measures to support increased scope for a technology or to control diffusion and restrict usage. Some of the difficulty has arisen through lack of information, including down stream assessment data. Other problems are that some funding mechanisms rather lend themselves to ready extension of services, and that there has commonly been some level of expectation of a flow on in numbers and distribution of services after initial introduction of a new technology.

There may also be administrative and logistic barriers to change - for example hospitals and specialists working in them may be reluctant to abandon methods that are in place and whose replacement might have significant consequences in terms of capital equipment, training and changes to infrastructure. Introduction of a clear policy on reviewing health technologies after their introduction may be helpful (possibly through a 'contract' involving some form of sunset provision).

A range of possible mechanisms for encouraging rational diffusion and use of health technology, by implication economic evaluation, have been outlined by Haan and Rutten (1987): they classified the mechanisms into regulation by directive and regulation by incentive, although the balance of mechanisms used may be expected to differ systematically between types of health care system.

Under "regulation by directive" they identified three mechanisms, each of which can be seen as having some applicability in the Australian situation (but generally with a rather limited number of cases of economic evaluation having been used):

- planning of facilities, specialist departments or specific technologies e.g. trials established following NHTAP evaluations of magnetic resonance imaging or lithotripsy, role delineation for individual hospitals, development of specialised facilities at a limited number of centres or geographical relocation;
- exclusion of technologies from public funding. M.B.S. reimbursement is almost completely confined to legally qualified medical practitioners, while certain medical treatments, even if provided by legally qualified medical practitioners, are not eligible for general reimbursement under the Schedule (e.g. MRI examinations which were eligible to attract Schedule fees and were only available at certain approved locations);¹¹

¹¹ This policy is to be changed (to grant funding only, no MBS fee at all). In principle it would be possible to confine certain treatments to certain categories of patients, certain conditions or locations, although the Schedule has not been much used in this way. The Pharmaceutical Benefits Scheme also provides scope for excluding certain drugs from public funding at the Federal level (altogether, in part or subject to certain conditions).

- strengthening of pre-market controls for drugs and devices e.g. under the P.B.S. companies wishing to list new drugs in future have to demonstrate evidence of cost-effectiveness (in addition to information on safety and efficacy which have long been required). On the other hand, in recent years there has been pressure (including from industry) to weaken rather than strengthen pre-market controls.

Under "regulation by incentive" Haan and Rutten (1987) identified five mechanisms.

- reforming budgetary and reimbursement schemes for health care institutions. For example, DRG's are under consideration (Scotton and Owens, 1990) and there is growing recognition that, as has been pointed out by overseas studies, the long run viability of any DRG-type payment system depends on its ability to adapt to appropriate changes in clinical practice and also to encourage it (e.g. Romeo, Wagner and Lee, 1984; US Office of Technology Assessment, 1983). Also changes are occurring in the funding arrangements for nursing homes (Rees, 1986) with significant effects on incentives which are currently working their way through the system and in related areas, such as home and community care for aged and disabled people. In such cases it is important that the calculated reimbursement or prospective payment rates take account of evidence on the relative cost-effectiveness of alternative treatment methods for clinical conditions, that careful attention is paid to prompt and effective dissemination of system changes to key target groups, and that the effects of the changes are carefully monitored. The consequences of earlier discharge policies by hospitals are being felt downstream by some nursing homes and other non-acute services, including community and domiciliary care (and the burden on carers and their families).
- encouragement of budgetary reform within individual health care institutions e.g. through the Victorian hospital agreements process or the high priority accorded by certain hospitals to improving their management performance.¹²
- changes in payment systems for health providers. The organisation and financing arrangements for health care in Australia provide a possible institutional structure to do so (e.g. through the MBS), there have been some investigations (e.g. of health maintenance organisations - which do not fit easily into the current health insurance arrangements) and changes could be made to the balance between salaried practitioners and those remunerated through fee-for-service. However, in general, we conclude that there have been relatively few studies of how incentives could be incorporated into changes in the fee schedule.¹³ We suggest

¹² For example, of the two largest teaching hospitals associated with the Monash University Medical School the Monash Medical Centre has given high priority to development of clinical costing, improved information systems and internal management change (and its CEO teaches the hospital administration unit in the University's MBA program), while the Alfred Hospital appointed an executive from private business as CEO and has, *inter alia*, emphasised improved information and costing systems, improved management at various levels in the organisation, performance indicators linked to objectives and enhanced training and development.

¹³ Note, however, that in August 1986 selected pathology rebates were reduced by 25% and an advisory committee was established to adjust rebates further as appropriate. In May 1987 the Commonwealth announced that rebates for ultrasound and CT scanning were to be revised downwards by 25% and 22% respectively, and the number of categories of CT services increased in an attempt to achieve fees which reflected operating and professional costs. However, pathology tests and services have continued to grow in terms both of numbers of tests and expenditure. Deeble (1991) has noted that over the first six years of Medicare the increase in pathology services per person was 46% - the largest increase in medical services. Further, the majority of pathology services are undertaken within the public hospital system

that it would be useful to study, for example, whether consistent incentives are implicit in the Medicare Benefits Schedule or PBS to encourage physicians to treat patients in particular ways (e.g. using drugs compared to practitioner time, or using expensive technology), whether doctors are aware of these incentives and the extent to which they respond to them. In the longer-term it would be desirable to learn more about how the reimbursement arrangements could be used more aggressively and pro-actively e.g. by withdrawing payment for procedures known to be inefficacious and by offering attractive fees for procedures where benefits are known to exceed costs.¹⁴

- encouragement of competitive arrangements. There are a number of ways in which this occurs in the current Australian health care system, and the encouragement could be increased (e.g. introduction of the resident classification instrument in nursing homes, the possible introduction of diagnosis related group funding for hospitals and the consideration of health maintenance organisations noted above).¹⁵ There is scope for linking such changes in incentives to the results of economic evaluations of the costs and benefits of alternative approaches. The results could be monitored in terms of process, output and health status outcome.
- development of medical audit and utilisation review schemes. They can operate at a general level, but tend to operate particularly at the micro level of the department, individual practitioner or health care group. Although they have been used quite widely in Australia, there is considerable scope for increased use of economic criteria and for more concerted, systematic and consistent efforts to disseminate the results of economic evaluations. Lomas (1990) suggests that research recommendations are particularly likely to affect behaviour when the target audience is already receptive to change, the message is timely and it is delivered by a credible source in a relevant way. In his view, such a favourable conjunction of conditions is probably the exception rather than the rule. However, experience suggests that it will not be easy to establish close links between those undertaking economic evaluations and those who take clinical decisions for individual patients.

(Hynes, Lea and Hailey, 1989) and have not been subject to this control by the Commonwealth. After a brief levelling off in numbers of services, CT examinations funded under Medicare have continued to grow rapidly, increasing from 254,000 services in 1987/88 to 360,000 in 1989/90 with benefits rising from \$M50.2 to \$M78.7.

¹⁴ It seems doubtful that the scientific literature, assessment reports, professional guidelines and government regulations will necessarily have the desired impact on the users of devices. Both Hoffenberg (1989) and Greer (1989) have considered some of the problems of getting appropriate information to the medical profession, so that doctors can make properly informed decisions. Difficulties arise from a number of factors, including the distrust of published data in the journals, which often refer to marginal improvements and have little appeal for the practising physician, some of whom may regard publications as vehicles for promoting the views of medical scientists. From medical teaching, G.P.'s and others are influenced by views of consultants who may have a vested interest in received or traditional knowledge, giving rise to some bias. Greer's work suggests an undue influence on decision making both from promotional material from manufacturers and anecdotal information, often gleaned at the local level from colleagues. There may also be motivation to try and outwit the system, be it government regulations or guidelines imposed by professional organisations. Financial incentives, obviously, can also be an important influence on practice.

¹⁵ A version of the Enthoven managed competition approach in which a greater role for private hospitals and private insurance is envisaged within an overall Medicare-type environment has recently been advocated by Scotton (1990).

Clearly the relationship between changes in health care policy and the changes (if any) which occur in practice at either the level of the health care system as a whole or at the level of the clinical treatment of the individual patient is subject to a range of influences. In many cases the economic evaluation, even if it has been undertaken, is unlikely to be decisive. However, it appears to be important that the mechanism chosen for encouraging the rational diffusion and use of health technology be consistent with the overall culture of the health care system; that implementation strategies take account of the relative costs and benefits of alternative overall approaches and specific treatments; that careful attention is paid to prompt, systematic and effective dissemination of system changes to key target groups; that the changes be considered from a variety of different viewpoints (e.g. Federal Government, State Government, Local Governments, individual health care institutions, practitioners, consumers, their families and informal carers); and that the effect of the changes, since they cannot always be accurately predicted, be carefully monitored over a period of time (with consideration given to both process and outcome). However sophisticated the evaluation, the results and the processes by which they are translated into practice have to be acceptable to those upon whom implementation depends (and be able to accommodate conflict of interests, values and power).

(iv) The fourth relationship is between changes in practice, monitoring and the need for re-assessment (if any). This includes consideration of changes in the health care status of the population influenced by the technology. We consider two aspects: first in relation to individual health technology assessments; and secondly in relation to the overall process by which health technology assessments are undertaken. In relation to the first aspect it is already clear that changes in policy may not lead to precisely the changes in practice which were expected, with more or less confidence, at either the level of the overall health care system or at the level of the individual provider of clinical services. Even if they do the relative costs and benefits of the technologies being compared may not remain constant. Indeed some evaluations involve trials of given length, so that the initial decision to establish a trial (e.g. of magnetic resonance imaging or lithotripsy) may incorporate a reassessment at some future date. In other cases the commitment to reassess the alternatives is less explicit. In general, the value of a once-only assessment may be doubted (Banta and Thacker, 1990). Nevertheless, the once only assessment has the potential to set useful initial conditions for introduction and application of the technology.

While evaluation may have the potential to delay the introduction of a new health technology or to modify its use, it may be more difficult to revise the decision once a treatment is introduced. This is not to say, however, that new data, new analyses and new insights, either from the continuing evaluation of the new technology or elsewhere in the health care system may not raise the possibility of reconsidering previous decisions. In practice, the objective may prove to be the elimination (or at least reduction) of the worst aspects of an unevaluated system e.g. to moderate the political influence of powerful interest groups, sensational media highlights or resource allocation through the "Buggins turn" system. One objective is to establish a virtuous cycle, whereby high priority evaluations are undertaken, decision makers pay attention to the findings, the policy instruments chosen provide incentives for change in the desired direction (at both the overall system level and at the level of the individual patient), these changes improve health status and either the relative costs and benefits of alternatives remain largely unchanged or re-evaluations are undertaken where they diverge substantially. It seems to us that, *ceteris paribus*, this will tend to occur more frequently if the evaluations are competently conducted, there is a broad interchange of information about costs, benefits and alternatives, and a range of viewpoints are considered. Monitoring and evaluation may be assisted if those who finance new technologies require those who use them to state what they hope to achieve and how they propose to measure what they actually do achieve.¹⁶

¹⁶ Also there is a need to make more explicit the requirements of different areas (e.g. of the hospital) and to undertake appraisal of both the effectiveness of individual technologies and allocative efficiency issues. Appraisal of effectiveness implies the availability of adequate

It may be argued (Manor and Sheffer, 1977 - see also Behney (1990)) that evaluation activity should not be judged solely by its results, but also in terms of the extent to which it increases the probability of improving decisions and solving problems by facilitating the process. This is not to suggest an emphasis on the evaluation process to the exclusion of outcomes, but rather that the *process* should be evaluated as well as the more conventional outcomes. Weight may be added to this conclusion to the extent that the process is seen as linking a range of complex relationships which are not fully independent of each other. We agree with Palmer and Short (1989) that both the implementation process and the policy outcomes should be evaluated.

Another aspect relates to the organisational structures and hierarchies which exist in the bureaucratic organisations where the ongoing relationship between changes in practice, monitoring and re-evaluation tend to be centralised and need to be managed. Health policy making tends to be fragmented in these large organisations, and - typically - it is only at the apex, at very senior levels, that a capability exists for formulating priorities across the board. There may often not be, in one place, except at the most senior level, an overall responsibility for evaluation, policy implementation and monitoring. But at these levels officials generally have a range of other demanding responsibilities and may not be able to devote sufficient time and thought to particular evaluation problems and their possible solutions. As Ham has stated, "political systems can only cope with a limited number of issues at once and these are always subject to displacement by new emerging issues of greater appeal and force". It is possible, however, that the practicability of reconciling conflicting goals, values and interests may be easier at higher levels in the organisation hierarchy, where sectional interests, in terms of who gains and who loses, may not be so readily exhibited. At the higher levels the concerns of interest groups may be broader; if so, the possibilities for bargaining or compromise among the groups may be greater.

A further point is that the process by which health technology assessments at the Federal level are made in Australia has gone through a period of change, which commenced with a review of the National Health Technology Advisory Panel (Selby Smith, 1989). In general, the review supported the process for evaluating health technology in Australia, while making a number of recommendations designed to improve the process, including linking more closely the evaluations which are undertaken with their policy use and implementation. For example, closer liaison with the Federal Department and State health authorities was seen as important, greater priority suggested for dissemination of results to key target groups, some change in membership, greater priority to economic aspects of the evaluations conducted and also to other aspects such as labour force implications. Many of the review's recommendations were accepted by the Federal Minister, though a number were not implemented with the subsequent restructuring of the Panel. The Panel has subsequently been subsumed by the Australian Health Technology Advisory Committee which reports to the Health Care Committee of the National Health and Medical Research Council.

These changes have resulted in more immediate contact between the assessment body and health authorities on some matters. For example, AHTAC and the previous NHTAP have now conducted a number of urgent evaluations for the Australian Health Ministers Advisory Council on technologies and services being considered for funding under current policy on nationally funded centres. Recommendations from these assessments have been brought directly to the attention of AHMAC and have influenced decisions. There has been some increase in priority given to economic assessment by NHTAP and now AHTAC. More generally it can be questioned whether a system of health care evaluation can be both a system of control (which can imply a degree of rigidity and the availability of sanctions) and also a management tool to encourage innovative thinking, initiative and local self-reliance. We suggest that evaluation should be an input to control, an input to management and an input to policy, but - in general - will not determine any of these. Reviews and changes to

administrative arrangements can be costly, disruptive to proposed work programs and damaging to staff morale, with effective reduction - especially in the short-term - in the impact of assessment activity on changes in policy or practice, although refocussing of effort can enhance effectiveness in the longer-term.

Finally, there is the importance of people to the effective overall operation of these complex interrelated processes, which require co-operation, shared perceptions and information and a considerable measure of continuing trust. The rapid turnover of staff in relevant areas militates strongly against this being achieved; and rapid staff turnover has been a notable feature in recent years.¹⁷ The process can call for tolerance on the part of public officials in the interest of the long run improvement of the health care system; particular evaluations have the potential to reveal errors, undermine operating assumptions and open Ministers and bureaucrats to criticism. Other co-operating groups, such as industry and the professions, may also have their sensitivities exposed. There are workforce aspects, too, not only concerning the recruitment, training and retention of those who will undertake the various parts of the overall process linking evaluations to policy change, implementation and use, but also the arrangements to foster collaborative and co-operative work, including movement across - and consequent blurring of -the arbitrary boundaries between evaluation and policy, administrative change and practice.¹⁸

¹⁷ Hailey (1989) has noted that after a period of five years those involved in assessing MRI at the Health Technology Unit at AIH were dealing with perhaps the fourth generation of persons in the relevant policy area of the Department since the program started. Such turnover does not help in establishing understanding of the methods, strengths and constraints of evaluation.

¹⁸ Note that the range of viewpoints should include those of patients and carers, whose perspectives and experiences may provide important information on the outcomes from use of health technology, and on matters related to equity and access.

3. SOME SPECIFIC AUSTRALIAN CASE STUDIES

In this section, we consider nine examples of health technology assessments undertaken in Australia. Some characteristics of the technologies and their evaluation are summarised in Table 1. The examples have been chosen to illustrate different types of technologies-therapeutic, diagnostic and screening - and assessment at different stages in their life cycles. They reflect the evolving 'hands-on' experience of health technology assessment in Australia.

Most of the evaluations involved the work of national assessment bodies created by governments. Evaluations are also undertaken by professional organisations and the private sector, but these examples were chosen in view of their links to government policy processes. However, the assessments have been aimed at professional groups, administrators and industry as well as at government agencies.

The use in Australia of a rational advisory committee mechanism has had some successes. It has provided a mechanism for detailed debate, consultation and dissemination, with a wider perspective than some other evaluation approaches. The committee approach can also have high visibility for policy areas. However, there can also be disadvantages: for example, the mechanism may be slow, committee time is limited and some tasks are less readily undertaken.

While these technologies differ considerably there are some significant common themes. First, all the assessments considered here were either sponsored by government agencies or were initiated by assessment bodies or professional organisations with clear consideration for the requirements of policy areas. In each case, there was wide consultation with a range of players, usually including government, professional and industry sources. Secondly, in all but one of these examples, resource allocation was considered in some detail, although this did not always include economic analysis. The more common type of approach undertaken by the former National Health Technology Advisory Panel was to include cost analyses without proceeding to full economic evaluation. However, in the NHTAP and other reports, many of the concepts embedded in models of economic assessment of health care technologies were taken into account.

The description here is associated with the nature of the technologies and the assessment process in terms of major questions which follow from the material discussed earlier in this paper:

- the source of the assessment;
- the possible impact of the technology in terms of the number of patients or clients it might involve;
- whether the assessment was undertaken prior to diffusion of the technology;
- whether evaluation questions were clearly specified;
- whether alternatives were addressed;
- whether there was follow up after the initial assessment;
- whether the assessment influenced policy;
- whether it influenced practice and usage of the technology; and
- whether assessment influenced health status (although this will often be difficult to determine).

The summary in Table 1 indicates that these assessments met a number of the criteria canvassed in this paper and were influential. However, such a summary is inevitably subject to qualification. In each case, few of the questions can be accurately addressed by

a yes/no answer. Further, the influence of some of these assessments has yet to be fully established, given the inevitable interval between receipt of advice and policy formulation. We also note that the influence of an assessment on the policy process may be difficult to define.

Table 1 Characteristics of some Australian Health Technology Assessments

	Source of assessment	Impact of Technology	Evaluation before diffusion?	Evaluation questions specified	Alternatives addressed?	Follow-up assessment?	Influenced policy?	Influenced practice?	Influenced health status?
ESWL	(a) Govt (b) Assessors	(a) 6000 patients/y (renal) (b) 8000/y	Yes	Yes	Yes	Yes	Yes	Yes	Probably
Office Pathology	GOvt	Open ended 300,000/y	Yes	Yes	Yes	Partial	Yes	Yes	Not known
MRI	Assessors	Open ended 200,000/y	Yes	Yes	Yes	Yes	Yes	Probably	Probably
CT	Assessors	Open ended 500,00/y	No, established	Implicit	Yes	Minimal	Partial	Doubtful	Doubtful
Cervical Cancer Screening	Govt	1.2m/y ²	No – extension to service	Yes	Yes	Yes	Yes	Too early	Too early
Bone Mineral assessment	Govt	40,000/y?	No – some services in place	Yes	Yes	Yes	Yes	Partly	Not known
AICD	Assessors	250-1000/y	Yes-minimal use	Yes	Yes	Yes	Not Known	Too early	Too early
Liver transplant	(Govt)	100/y	Minimal prior to intro-p/a follow up	Yes, though limited	Yes	Partial	Partial	Doubtful	Possibly
ECMO	(a) Prof. (b) Govt	44 – 100/y	No, introduced	Yes	Yes	Partial	Yes	Probably	Unclear

The questions addressed by the evaluations were clear, and in each case, alternatives to the technology in question were addressed.

The sizes of the patient groups listed under the 'impact of technology' heading are of some interest when considering the commitment of scarce evaluation resources. At one extreme are the very large groups covered by diagnostic technologies, and those that are the targets of national screening programs. At the other are much smaller groups of high risk/poor prognosis patients for whom advanced but expensive technologies have become available in recent times. While the individual impact on population health status may be relatively small, there is a trend towards an increasing number of such specialist interventions which may often be seen as additive to existing health care services.

The first three examples included collection of Australian primary data through trials in hospitals and other settings. Primary data are very valuable for the assessment process, but their collection may be demanding, and limited by the co-operation achievable from those for whom assessment may be of limited interest.

(i) Extracorporeal Shockwave Lithotripsy (ESWL)

The Australian assessments of ESWL, a non invasive method for removing renal and biliary stones, have met many of the criteria for successful evaluation. The original version of this technology for treatment of renal stones was assessed at the request of the Federal Department prior to its introduction in Australia. The request was prompted by proposals from groups of urologists to install such machines, and concern that the numbers and distribution of lithotripters might prove to be inappropriate. NHTAP produced a detailed synthesis report in 1985 comparing ESWL with the alternative technologies of open surgery and percutaneous nephrolithotomy (NHTAP, 1985). The assessment included a detailed cost analysis, (though no formal economic analysis was attempted), considered the potential impact on patients and families (in terms of loss of income and other disruptions to normal lifestyles), and noted the possibility of future developments (such as cheaper forms of the technology and eventual application to treatment of biliary stones).

This evaluation directly influenced development of policy by Federal and State Governments on support for the technology leading to installation of two public sector machines in Sydney and Melbourne. Numbers and distribution of machines were considered at some length in the assessment. The appraisal of realistic machine time requirements for Australia, drawing on early US experience, was particularly valuable in forming judgments as to the level of resources that might initially be needed. Adoption of recommendations in the report concerning numbers and placement of lithotripters, certainly influenced practice and the health status of many people. Analysis by the AHTAC (1991) has suggested that use of ESWL has resulted in annual savings of around \$7M to the health care system and gains of 69 person years through avoidance of hospital stay from other treatment.

The assessment has been followed up, firstly with a brief technology update by the NHTAP and more recently with a comprehensive overview of renal stone therapy by AHTAC. Follow up in terms of systematic collection of Australian primary data was less successful, notably because no funding was allocated to such activities. Both public hospital units made available patient data to the national assessment body, but these were incomplete and did not reflect a coherent body of experience. The private ESWL unit in Sydney has published accounts of early experience and clinical details on small series of patients, but again there was no systematic, comprehensive collection of data.

The original NHTAP assessment provided useful source material for subsequent appraisals of options conducted by State Health Authorities, notably in South Australia and Western Australia. While policy was influenced by the assessment, it is apparent that there have been various imperfections in the way that this technology has been introduced to Australia. Although Australia has avoided the over-provision of ESWL experienced in several other countries, to date access has been imperfect, with few people from the smaller States travelling for such treatment. The AHTAC considers that levels of open surgery for renal stones remain unacceptably high. While systematic collection of data in this area has been limited, considerable comparative information is now available to policy areas (which need to consider how to react).

Assessment of ESWL in its application to treatment of gallstones has also had some successes. The initial assessment was again undertaken before introduction of the technology and was initiated by NHTAP because of trends overseas. The Panel saw this application of ESWL as less promising than the treatment of renal stones and recommended introduction of only one machine in the context of a clinical trial (NHTAP, 1988). This recommendation was accepted and a trial is still in progress - comparing the costs and clinical efficacy of biliary ESWL with those of open and laparoscopic cholecystectomy. A randomised controlled trial design would have been desirable, but

proved not to be feasible, because of lack of acceptance by clinicians and the probability that randomisation would not have been achievable.

In this case assessment has clearly influenced policy and to some extent practice. The health status of a number of people has been influenced by such treatment. However, while the current trial will further define the place of this technology, the major concern to policy makers must now be the new technique of laparoscopic cholecystectomy which is diffusing very rapidly in Australia, and seems likely to have a much more dominant role than lithotripsy for treatment of gallstones.¹⁹ The Royal Australasian College of Surgeons has proposed interim guidelines for this newer technology, but it is unclear what the effects of them might be (noting the findings of Greer; see the discussion in Section 2 above).

The evaluation of biliary lithotripsy includes a cost utility analysis which will draw both on the cost data provided by the hospital and a qualitative research project involving detailed interviews with a number of patients and their families. These projects will provide an opportunity to develop methodology for use in further evaluation.

(ii) Office Pathology Testing

Over the last few years technologies have developed for pathology testing outside the laboratory setting. Equipment includes so-called 'dry chemistry' analysers which have been suggested as standard equipment for settings such as GP's offices. The potential target for such technology is very large and virtually open-ended, with the high level estimate being suggested by usage in the USA, where around 25 per cent of all pathology services are now performed outside laboratories.

In Australia, the initial assessment was carried out by a working party of the Health Ministers' Advisory Council well before any significant introduction of these desktop analysers into the country (Hailey et al, 1984). The assessment was requested following a Health Ministers' conference at which concern was expressed that this technology could raise costs and lower the quality of pathology services. A subsequent trial was funded because of these concerns, assessing the performance achievable with these analytical systems under non-laboratory conditions. Such assessments are still uncommon, with most appraisals being undertaken by laboratory-trained staff, who would not usually be employed to perform these tests in the decentralised setting.

The trial included a detailed evaluation of actual usage of such desktop analysers in GP's surgeries and in hospital ward side rooms. Considerable information was obtained on the performance achieved by non laboratory-trained users of this technology, and the level of usage and degree of substitution for pathology tests ordered from laboratories. The evaluation of GP usage was based on a crossover design comparing pathology ordering by a number of practices in Melbourne and Sydney. Information was also obtained on possible outcomes of testing - in terms of changes in biochemical parameters in patients and opinions of GP's and patients concerning the presence of the technology in the surgery (NHTAP 1989, Dunt et al 1991).

Resource considerations were not addressed in any detail, but the findings gave a clear suggestion that under the conditions of the study, while there was some substitution for

¹⁹ Initial data from the trial suggest that the efficacy of biliary ESWL seems limited under the Australian conditions, where the preferred adjuvant substance for dissolving gallstone fragments is not available (St Vincent's Hospital, 1991).

tests ordered from laboratories, desktop pathology testing would overall be additive to normal pathology services. In addition, substantial concerns emerged as to possible levels of accuracy and precision achieved by naive users without strong technical backup.

This series of studies influenced policy in that the pathology laboratory accreditation provisions for services funded under Medicare were extended to include the non-laboratory situation. This has had the effect of forcing non laboratory users of pathology tests who wish the services to be funded through Medicare to comply with minimum standards of performance laid down by the National Pathology Accreditation Advisory Council. The cost of obtaining accreditation and the level of reimbursement for tests under the Medicare Benefits Schedule has tended to limit the diffusion of this technology in Australia with the proportion of total pathology services performed in this way still being less than one per cent.

The influence of the assessment is limited in areas where Medicare funding does not apply. Only in Victoria, where there is appropriate State legislation, does accreditation extend to other 'desktop' situations such as cholesterol testing in supermarkets. Effects of the assessment on containing expenditure on a further form of pathology testing were probably real, but need to be seen in the context of the overall cost of pathology services in Australia which could be as high as a billion dollars a year. Further assessment of this form of testing is warranted, but is only being considered in a limited way at this stage. It remains an open question as to whether the assessment has significantly influenced health status. Hailey and Lea (1990) have suggested that, overall, the potential cost impact of near-patient testing has yet to be matched by convincing evidence of corresponding benefit.

(iii) Magnetic Resonance Imaging

Magnetic Resonance Imaging (MRI) is a diagnostic technique with high capital and operating costs with potentially open-ended application which could well rise to several hundred thousand examinations a year. It offers unique diagnostic information, but in many situations has the potential to be additive to existing methods.

The Australian assessment was initiated by the NHTAP because of the potential large impact of MRI on health care services. A synthesis report, based on overseas information and opinion from Australian radiologists, was completed well in advance of any introduction of the technology (NHTAP, 1983). The report eventually led to a large scale evaluation of MRI over several years which collected data from five machines in public hospitals. Throughout the assessment there was a high level of cooperation and support from the Royal Australasian College of Radiologists.

This assessment was undertaken primarily to give governments a picture of the capabilities, limitations and costs of MRI as it existed in the mid 1980's. The scope of the evaluation was very broad - indeed probably wider than any other study of MRI. It included use of a minimum data set to collect information on every patient presenting for examination (a similar approach was used in Switzerland); a collection of cost data from each hospital according to an agreed protocol; and a series of more detailed assessments on smaller groups of patients in which the accuracy of the technique and to some extent its effect on patient management was examined.

The cost data was collected on an accounting basis; a model that had limitations, but which was adopted with the agreement of the Federal Department. It succeeded in capturing actual hospital data and pointing to differences between the participating centres, in terms of the costs of operating various types of MRI scanner and in the variety of staffing and

operational practices. On the basis of the clinical data obtained in the trial, linked to appropriate reports in the literature, a consensus statement was issued on the efficacy of MRI examinations (NHTAP 1988b).

In addition, the NHTAP issued in 1990 a further synthesis report drawing together its opinions on the current place of MRI in Australia (NHTAP 1990). More recently, the AIH has issued a report on use of contrast media in MRI examinations (Hailey and Crowe 1990) and the consensus statement has been updated and issued by AHTAC. AHTAC is currently considering the evidence for costs and effectiveness of MRI in the examination of joints. Given the continued evolution of MRI and its application to other types of examination, it seems likely that follow up of this technology will continue for some time.

This long sequence of assessments (over more than eight years since planning commenced) certainly influenced policy on the mode of introduction of MRI into Australia. Controlled introduction of this high cost technology linked to detailed assessment provided excellent experience and information, cost-savings and models for the future. Government expenditure on MRI in the early phase of its introduction in this country was overwhelmingly directed towards areas where the technique had a large comparative advantage over other methods, in the context of hospital installations with patient populations having high disease prevalence, and with specialist referral only. The assessments have had some influence on practice; from the evidence available through the NHTAP and from other Australian work it appears to have influenced the health status of many people (e.g. Sorby 1989).

However, in policy terms this technology seems at the cross-roads as far as Australia is concerned. The NHTAP made recommendations concerning further distribution of the technology at additional units in hospitals which had major neurosurgical caseloads, and routine collection of usage data by those units in the public sector (NHTAP 1990a). While there has been some move towards putting in place additional public sector units, it was not until the recent Federal budget that further support for public sector MRI installations was announced, following directly from the NHTAP assessments. The delay in the announcement of this government policy in part reflects the involvement of coordinating departments in the budgetary process. In the meantime there has been significant activity by the private sector to install additional scanners, even in the absence of government reimbursement, leading to potential concentrations of resources (such as three scanners in Tasmania) which seem hard to justify. Hailey and Crowe (1991) have noted that widespread acquisition of MRI implies a major opportunity cost to the health care system, and doubt that Australia can afford the luxury of wide proliferation of MRI facilities.

(iv) CT Scanning

CT scanning is included here as an example of assessment undertaken of a technology that was already widely diffused. The NHTAP originally decided to undertake an overview of CT scanning in Australia as a follow-up to the MRI assessment, to give further perspective to the place of the newer technique. CT scanning is an important diagnostic technology with virtually open-ended usage and a target of perhaps 500,000 examinations per year. The NHTAP report (1988c) included information on the numbers of CT services, distribution of scanners and expenditure on this technology under Medicare and through the public hospital system.

The Panel confirmed the importance of the technology, but noted that while its growth had been very rapid in Australia, this could not be accounted for in terms of replacement of older techniques. There appeared to be a lack of information as to how CT was used in

Australia, particularly outside the hospital setting which provides the most common situations where CT is of major benefit to patient management.

The Panel recommended a study involving both private and public sector CT units to obtain information on the types of cases being examined with some indication of the effect of CT results on decisions affecting patient management. The other major recommendation was that the relevant professional bodies should develop guidelines for GP's and others who ordered CT scans, as an aid to rational usage of an expensive resource.

The effect of the assessment has been mixed. The NHTAP report provided a useful source document for a number of purposes, but the first major recommendation has not been accepted, Federal and State Governments deciding not to fund a major assessment of the sort proposed. Apart from the usual considerations of competing priorities for scarce evaluation funds, there was perhaps some feeling that CT scanning was sufficiently mature and commonly used not to require further appraisal. While this may be an understandable reaction on the part of some policy areas, it raises serious concerns regarding the prospect of rational control and usage of mature technologies that are widely distributed, are a major cost to the health care system, and have the potential for inappropriate use. The data point to continued substantial increase in this type of examination. Follow up to the NHTAP report has been minimal. A small study at Flinders Medical Centre funded by RADGAC has been conducted, but information from it will be limited. There may have been a partial influence on policy regarding reimbursement but this is unclear. It is doubtful, whether the NHTAP assessment has so far significantly influenced practice or health status.

However, the second major recommendation made in this assessment was accepted by the professional bodies concerned, and guidelines have now been produced under the auspices of the Health Care Committee of NHMRC (NHMRC 1991). As suggested in the NHTAP report, the guidelines are intended for use by GP's and others who order CT examinations and are seen as an aid to encouraging rational use of technology and as a contribution to medical education. Production of such a document reflects creditably on the professional bodies concerned. Its impact will take some time to assess, may be long term and will depend on the method of presentation of the document, any further updates and active support of the strategies proposed by professional bodies.

No economic analysis was attempted in this case by the NHTAP or by other Australian bodies. Economic analysis of CT, and indeed any assessment of this technique after the very early years of introduction overseas, seems almost non-existent. These gaps in information point to serious concerns about rational assessment, control and policy after introduction of significant health care technologies.

(v) Cervical Cancer Screening

Assessment of cervical cancer screening in Australia involved a series of pilot projects which were monitored and coordinated by a Steering Committee appointed by the Australian Health Ministers' Advisory Council. The assessment reflected a major commitment to improvement in women's health, and concern over the scope and effectiveness of existing services for this widespread serious disease. The target group here is very large, perhaps 1.2 million women per year in Australia.

Cervical screening services were already in place in Australia, but in many respects were unsatisfactory. The role and efficacy of such screening services had been well established in other countries and offered the possibility of preventing up to 90 per cent of squamous cell cancers. The evaluation steering committee considered the existing approach in depth

and developed options for national strategies for more cost effective programs (AHMAC 1991).

The Committee identified problems with the existing approach in Australia which included deficiencies in program design, coverage of target population (including special needs groups), provision of services and monitoring/quality control. It was noted that the majority of women who develop invasive cervical cancer were inadequately or never screened. Problem areas were evaluated in some detail in the pilot projects, although the Committee pointed out that all of these were hindered by lack of a data base and any comprehensive monitoring system. Areas covered in the pilot projects included strategies to increase participation of women in screening programs, accuracy of screening procedures, and adequacy of screening in different population groups.

Particular areas of concern identified with respect to low effectiveness and cost-effectiveness in existing services included the interval at which women were screened, the age group to be screened, costs of laboratory testing and the high proportion of screened women who received further investigation.

The Committee outlined options for change and supported these with a detailed economic analysis covering both financial cost and cost-effectiveness aspects. Cost to governments of the approach recommended by the Committee was actually less than the estimated cost of continuing with the current approach. The size and timing of these potential cost savings varied by scenario, and eventually disappeared as participation levels were forecast to increase over current levels. Comparison of the economic cost per life year saved with the organised approach recommended by the Committee gave estimates of \$44,654 (current approach) and \$30,782 (recommended approach) respectively and were subject to a sensitivity analysis. The Committee also considered funding mechanisms for a national program.

This comprehensive series of assessments has significantly influenced policy and the various findings have been taken up by the Federal Department with ongoing development, in consultation with State authorities, of a national program. Details of the arrangements will be determined in part by the extensive analysis undertaken in the original assessment, though it is uncertain how closely subsequent costings in policy initiatives will follow the results of the economic evaluation. It is still too early to judge whether the assessment has significantly influenced practice or health status. The strong expectation would be that both would be substantially influenced should the recommendations put forward in the assessment report be adopted and implemented.

Overall, the assessment provides a relatively rare example of significant resources being allocated to evaluation of existing health care technology. This situation arose from strong political commitment, the seriousness and prevalence of the condition in question and the widespread perception of inadequate performance from existing programs. There was a strong 'opportunistic' element in this assessment, as it was "piggybacked" onto an evaluation of breast cancer screening. It is debatable whether it would have been put in place in its own right.

(vi) Bone Mineral Assessment

Evaluation of bone mineral assessment, a technique promoted as a means for detecting developing osteoporosis in peri or post menopausal women, was requested by the Federal Department of Health because of uncertainties concerning its costs and effectiveness. The target group is large, perhaps of the order of 40,000 per year if bone mineral assessment

were to be used on a population screening basis. Some bone mineral assessment services were already in place, but assessment by NHTAP was undertaken before any wide diffusion of such services (NHTAP, 1986).

The initial assessment by the Panel looked at the different methods of assessment, paying particular attention to their technical strengths and limitations, the rationale for bone mineral assessment and potential costs and impact. It was concluded that the widespread routine use of this technique for detection of developing osteoporosis should not be supported - a position accepted by the Department.

A follow up assessment was undertaken after three years (NHTAP, 1989), again at the request of the Federal Department, to consider any new developments in relation to the role and clinical effectiveness of bone density measurement techniques. Significant developments included a new method of measurement which substantially improved performance and harder evidence on the efficacy of hormone replacement therapy (HRT) as a means for slowing down bone loss — an example of important technical change over a short period of time.

The follow up assessment looked in some detail at the newer approach and possible reasons for undertaking such investigations. It laid stress on the need for appropriate quality control, but recommended that bone mineral measurement would be appropriate in a number of specific situations. However, the Panel did not support a population screening program, taking into account the limited evidence of correlation between low bone mineral values and subsequent fracture and the possibility that the bone density value would not be a major factor in risk benefit analysis for HRT. It was considered that, while in a number of cases the technique would have a valid role in assisting decision making, there needed to be substantial clinical justification for bone mineral measurement based on consideration of risk factors and reservations on the use of HRT.

This second assessment considered issues related to the potential cost effectiveness of bone density measurement in terms of a decision tree model. It was pointed out that data were lacking for most nodes of the decision tree (a common situation with many health technologies) and hence any estimate of potential number and total costs of bone density measurements were conjectural. Nevertheless, rough national cost estimates were derived and elements required for any subsequent cost effectiveness analysis were identified.

Further assessments are now in progress under the auspices of AHTAC. These include a meta-analysis of available prophylactic approaches and bone mineral assessment techniques, and a longer term study on bone densities and fracture rates in a cohort of women in the Dubbo area. In addition, an economic analysis is to be undertaken by the AIH.

This series of assessments appears to have influenced policy, albeit in a limited sense through denial of reimbursement for routine screening - although the wider indications for assessments described in the second NHTAP report may also have been influential (while being hard for policy areas to assimilate). The assessments would seem to have partly influenced practice in that they have acted as a brake against possible inappropriate dissemination and use of bone mineral measurements. It is not clear at this stage that there has been any direct influence on health status.

(vii) Automated Implantable Cardiac Defibrillators

An assessment of automated implantable cardiac defibrillators was undertaken recently by

the Australian Institute of Health (Cowley et al, 1990) because of a perception that this was an emerging technology in Australia which was expensive and had the potential to make a substantial impact on the health care system, if diffusion accelerated to the extent predicted by some analysts. The AICD is a device to terminate potentially lethal cardiac arrhythmias and prevent sudden death. The present target population in Australia might be between 250 and 1000 per year.

To date there has been little use of this device in Australia so that the assessment was undertaken before significant diffusion. The assessment reviewed the current status of the AICD; considered current and potential utilisation in Australia; and cost and cost-effectiveness in comparison with alternative treatments. The analysis included an economic assessment of costs per life year saved by AICD implantation and medical therapy, together with assessments of potential total costs to the Australian health care system.

The economic analysis used a modelling approach and did not draw on primary Australian data. The report noted that it would be highly desirable for an Australian trial to include a detailed cost analysis and to study cost-effectiveness. The assessment concluded that AICD was a high cost technology with significant benefits for selected patients, that further study would be needed before its indications were extended and that it should continue to be implanted only in specialised centres at major teaching hospitals.

The impact of this assessment is not yet clear. There has been apparently minimal consideration of support for the AICD within policy areas, although funding of such devices will already be of some concern to State health authorities and hospitals. The assessment has been followed by at least one trial of the AICD in an Australian hospital which is expected to include costs and economic analysis, so that some follow up assessment is in progress. The effects of the assessment on practice and health status at this stage are uncertain but probably minimal. The evaluation of AICD represents an "early warning" exercise in regard to a specific technology with a relatively small target group but with potentially significant costs to the health care system.

(viii) Liver Transplantation

Liver transplantation is a major surgical intervention which has been made feasible by a number of technical developments in areas such as anaesthesia and immunology. The target group for Australia is small, at around 100 patients a year, although this could be larger if selection criteria were changed. The cost of the procedure and follow up are high, but so are the costs of treating and caring for patients who would die of liver disease should transplantation not be available. This series of assessments provides an example of the evolving approach in Australia to consideration and introduction of high-cost medical services.

The original consideration of liver transplant facilities was undertaken by a clinical committee serviced by the Federal Department and which made recommendations to the Federal Minister. The Committee was set up following performance of transplants on Australians at overseas centres with the assistance of act of grace payments and a perception that the technique was developing in other countries, although worldwide patient numbers were small at that stage. The Committee consulted extensively with interested groups in Australia and recommended commencement of a pilot program in Sydney. This recommendation was informed by the perception of Australian surgeons that survival rates overseas were at an acceptable level and that sufficient expertise and facilities for liver transplant should be available in Australia.

It is worth noting the pressures on the assessment and policy process at that time through media reports and the availability of a consensus development conference statement from the US National Institutes of Health. Some emotive electronic and print media reports on Australian liver transplant candidates were a feature. The NIH consensus statement had indicated there should be broader application of liver transplantation, although with some qualifications; it appears that, in part, the NIH position was informed by the pressure from professional groups and public relations campaigns in the U.S. (Rettig, 1989). The Australian evaluation prior to introduction of the technique, was at a relatively basic level, synthesising leading overseas reports and domestic opinion.

The recommendation that a pilot project be supported was accepted by the Federal Government. However, in the event liver transplantation was first introduced at another centre as an initiative of the hospital concerned, supported by the State government. The site designated as a national centre commenced transplantations about a year later. While the approved national pilot centre eventually established a successful program, the first "unofficial" liver transplant unit appeared to make much of the running during the initial introduction of the technology into Australia and built up a significant national and international reputation. The third liver transplant unit, which commenced operation in 1988, was again essentially a local initiative. All three centres are now recognised by AHMAC as appropriate units to attract nationally funded centre status. This decision has apparently been based on clinical experience reported by the units rather than on any detailed evaluation.

Liver transplantation services are now being considered by AHTAC in the context of policy for nationally funded centres, to determine whether further diffusion of this technology is appropriate. Concurrently, a detailed costing exercise on the existing units is being undertaken for AHMAC by consultants. The current appraisals will help to set future directions for this technology, but are being put in place some time after the services have become established. Opportunity to change established directions may be limited.

The current AHTAC assessment has been assisted by the clinical data collected by each of the existing units (made available through a combined registry arrangement). However, available clinical and cost data have some limitations and detailed evaluation is not feasible. It remains the case that these expensive services are in place and operating without evaluation according to any defined protocol.

The initial appraisal undertaken by the clinical committee evidently influenced policy in that the need for the original single unit was accepted. However, the policy was not implemented consistently. Policy makers seem to have been pushed by the institutions concerned and by other pressures from the public, professions and media. It is possible that the original evaluation and the current assessment by AHTAC will influence health status, but it seems likely that any effect will be at the margin. The main determinants of health status for this group of patients will be the practices and procedures built up over the last few years by each of the existing centres.

(ix) ECMO

Extracorporeal membrane oxygenation (ECMO) is a technique of last resort for children, particularly neonates, with severe respiratory problems. The target for this technology is very small, perhaps no more than 100 cases per year in Australia with the present range of indications. Nevertheless, this is a high profile group and the technique represents a prominent topic in neonatal care.

The initial push for assessment came from the professions through a consensus conference organised by the Australian Association of Paediatric Teaching Centres (Robertson, 1990). There was strong support for additional funding for ECMO, including research on its efficacy. Use of consensus conferences in health technology assessment has not been undertaken frequently in Australia; and there was interest in general approach and methodology as well as the specific subject under discussion. The conference panel took into account Australian caseload and some differences in the type of patient in comparison with the USA. It recommended restriction of ECMO to the existing two centres in Sydney and Melbourne; and appropriate evaluations to monitor the technique's outcomes and costs, recognising that there were inadequate data on these and on resource requirements.

The organisers of the consensus conference approached AHMAC, which requested NHTAP to examine the costs and financial benefits of the proposal that support for ECMO be limited to not more than two centres. The NHTAP assessment (NHTAP, 1990), drawing on available information from the two ECMO centres, made estimates of projected national caseload and of both gross and marginal ECMO related costs for scenarios of one or more units. The Panel concluded that ECMO was an augmentation to paediatric intensive care which appeared not to be very high cost. Marginal costs might be no more than \$500,000 a year nationally or perhaps \$6,000 per case. The Panel concluded that there were good reasons to limit the number of ECMO centres to not more than two as the technology was still evolving, appropriate minimum caseloads were needed to maintain expertise, and conventional therapy (which was also developing) might provide a valid alternative in many cases.

The NHTAP assessment can be taken to have directly influenced policy. It was considered by AHMAC which decided to recognise ECMO as a specialised service, but not to fund it under the Nationally Funded Centres program. Together, the consensus conference and the subsequent NHTAP report have probably had some influence on practice. It is unclear whether there has been any effect on health status, as a result of these appraisals. At this stage it is also unclear whether there will be further assessments.

(x) Some Reflections on These Assessments

As in other countries, the most obvious areas of success in terms of policy being informed by assessment have come when considering possible introduction of a technology. In these circumstances, government agencies will often be well placed to act as a gate-keeper, providing conditional support for a limited number of units and procedures, and insisting on evaluation as a precondition for more widespread dissemination of the technology. The mechanisms available and their influence on the usage of technologies become less certain after diffusion. The complexities of the Australian health care system have led to the major policy tool being financial e.g. use of the Medicare Benefits Schedule (inclusion or denial of a fee, link to accreditation) and provision of special grants. Of course, policy areas may not always be inclined, or able, to act on the advice provided to them.

As suggested by Hailey, Cowley and Dankiw (1990), the assessments have served a useful educational purpose. Reports from all of the assessments have been made widely available to health authorities, professional bodies and other interested parties in Australia, have served to promote informed debate on health technology matters and are an important basis for educational activities. In our view, these evaluations have done more than merely delay the allocation of resources by funding authorities; they have contributed

to the more rational introduction and usage of various technologies.

It has to be acknowledged that the evaluations have had methodological limitations. In all of the above cases pragmatic approaches have been taken to capture available information in time to provide sufficient information for practical decision making at the policy level. Constraints on the evaluations have included the resources available, the time within which decisions were required, the availability of data and the degree of cooperation from institutions and individuals. Continuing concerns include the comparative vulnerability of assessment bodies (and some policy areas), the reality that only limited numbers of technologies can be considered and the low levels of on-going monitoring and follow-up evaluation.

4. FACTORS LIKELY TO INCREASE THE IMPACT OF HEALTH TECHNOLOGY ASSESSMENTS

In addressing this issue, it is first necessary to consider what is meant by 'impact'. Typically, policy decisions will be influenced by a number of inputs, of which technology assessment will be only one. Therefore, unique measures of impact may be difficult to define. In some situations it is relatively easy to identify the role of technology assessment.

For example, the United Kingdom government commissioned a study of the costs and benefits of heart transplant (Buxton et al 1985) prior to its decision to expand the number of centres. Furthermore, it waited until interim results of the study were available before making its decision, which was in line with the study's recommendations.

In other situations the measures of impact may be more subtle. Hailey et al (1990) propose a number of measures of the impact of assessments, relating to a range of possible government actions. However, they point out that some effects of technology assessment, for example influences on expectations and behaviour patterns in users and providers of services, may be quite long term. For example, evidence on the relative ineffectiveness or inefficiency of a given technology may accumulate over time and users' decisions may not be dependent on a single study.

Despite the problems in measuring impact, it is important to consider what factors are likely to increase the impact of a given assessment. We identify seven specific factors below, each of which is discussed in turn.

(i) Quality of Study

Those undertaking assessments of health technology usually pay particular attention to the quality of studies. For example, the criteria for a good economic evaluation in health care have been set out as a 10-point checklist by Drummond et al (1987). However, it is possible to overstate the importance of good study methodology, since this is usually only a necessary, but not sufficient, condition for impact. It is unlikely that good methods alone will convince the opponents of the recommendations of a particular assessment. Rather, good methods are more important in defending the study from attack by those who oppose the conclusions. Where the conclusions of an assessment are generally popular, confirming many individuals' prior beliefs about a particular technology, methods are less likely to be subjected to close scrutiny.

(ii) Timeliness of Study

It is often argued that, for an assessment to have an impact, it needs to be timely. The timing of health technology assessments is no easy matter. Buxton (1987) has argued that, because of the rapid pace of technological change in medicine, it is 'always too early, until suddenly it's too late'. Certainly, there are key stages in the diffusion of technologies where important decisions are to be made and where study results are more likely to be used. These include decisions about allowing entry of the technology into the health care system, the placement and distribution of specialist units and allowing third party reimbursement. In such situations it may be better to provide timely, if imperfect, data on costs and benefits, rather than definitive data after the decision has been made. However, it remains important that the imperfect data are not seriously misleading in their implications.

The other aspect of timeliness relates to the broader economic and political environment within which technology assessments are conducted. For example, it is easier for governments to make controversial decisions at some stages of a parliament rather than at others. Similarly, the data from a technology assessment may become available at a time when other recent events suggest a particular decision. It is clearly wrong to view the results of health technology assessments and their implementation as being quite independent of the decision making context prevailing at the time they become available.

(iii) Local Validity of Study Results

There is a general shortage of resources for health technology assessment and it will not be possible to undertake a given study in every setting. For example, with emerging technologies, decision makers are often reliant on assessments undertaken in the United States. In such cases the opponents of study conclusions may argue that the situation prevailing locally is different from that in which the study was undertaken. There are often differences in clinical practice, local health service organisation or relative prices that could affect whether a given technology is cost-effective in a given setting. The obvious solution would be to repeat the study using local data, but where this is not feasible it may be possible to extrapolate from results obtained elsewhere - where necessary taking account of major differences by suitable modifications. For example, one study of a new drug technology has been undertaken in a way that would facilitate such extrapolation (Drummond et al 1991).

(iv) Decision Maker Involvement in the Study

In a review of health technology assessments undertaken in the United Kingdom, Drummond and Hutton (1987) noted that the vast majority were conducted by independent researchers with no obvious link to the decision making process. Whereas the independent researchers may minimise the potential for bias in study methods, it is much more likely that the results could be ignored by key decision makers, either because they are unaware of the studies concerned or because they do not address what the latter define as the relevant issues. If the decision maker is involved in the study, perhaps by commissioning it or being involved through an advisory committee mechanism, there may be a greater chance of impact. If this process works well, the study will be more likely to address the relevant questions. Furthermore, having been involved in the design and conduct of the study, it may be harder for the decision maker to distance himself from the conclusions, or fail to act on them.

Of course, decision maker involvement is no guarantee that the study will have an impact.

Ways can be found to ignore 'inconvenient' results. Indeed, decision makers may want to apply criteria that were not addressed in the health technology assessment, such as the impact on employment in a depressed region if the plant manufacturing a particular technology were to close. There may even be a cost to the decision maker in being involved.

(v) Dissemination of Study Results

If technology assessments are to have an impact then the results of studies need to be widely known. The results of studies undertaken by independent researchers are not widely disseminated; often the researchers view publication in a learned journal as their main aim. Other dissemination activities, such as interviews with the media or seminars for key decision makers, generally have lower priority than beginning the next study. Decision maker involvement can often encourage dissemination, since certain activities can be specified as part of the research contract. However, there are also concerns that certain sponsors might suppress results if the research contract allows this. For example, this issue has recently been raised in the context of research sponsored by the pharmaceutical industry (Hillman et al 1991).

(vi) Availability of Policy Instruments

In order for studies to have an impact, decision makers need to have the appropriate mechanisms for influencing the diffusion and use of health technologies. Haan and Rutten (1987) have specified a range of policy mechanisms within the European Community, Hailey et al (1990) have outlined some possibilities for Australia and we consider various mechanisms in this article. In general, there is no shortage of available instruments, but it is important that researchers consider how the results of their study could be used. Our examination of specific health technology assessments in Australia leads us to conclude that the major policy instruments have been financial.

(vii) Conflicts and Incentives Surrounding the Study

It has to be recognised that there are many actors in the health care system, often having different objectives. For example, if the sponsor of a particular technology assessment is the government or third party payer, it is unlikely that the sponsor's interests will be the same as those of the technology's manufacturer, or the physicians who may use the technology (or be replaced by it). In the (rare) cases where there is a commonality of interests, an evaluation producing results supportive of those interests is highly likely to have an impact. Conversely, if the evaluation produces results counter to the interests, it is much less likely to bring about change - especially if the power relationships are relatively even.

In the more usual cases, where there is a mixture of interests, two factors are likely to encourage an impact. First, it is important that the assessment identifies the costs and benefits according to the key perspectives. For example, if physicians are likely to lose income as a result of the introduction of a new technology, this is important to know. Secondly, attention needs to be paid to the incentives facing the key actors. If the total benefits from a given technology outweigh the total costs (when judged from a societal perspective) can the incentives be arranged so that no-one is worse off as a result of its introduction? Although an obvious point, the attention paid to key actors' perspectives is usually slight in health technology assessments. It is hardly surprising that some of the assessments have little or no impact. The interests of the key stakeholders should be considered; and if possible a "win-win" situation devised, so that what is beneficial from a

societal perspective is also in the interest of each major group or actor.

5. IMPROVING THE RELATIONSHIP

The following discussion assumes that the methodology of the economic and other evaluations which are undertaken will be sound (along the lines outlined in Appendix 1), that attention is given to avoiding weaknesses which tend to recur in the published literature, that progress is made in relation to the measurement of health outcomes, that the possibility of increasing the integration of clinical trials and economic evaluations is actively explored, that a range of viewpoints is considered and that attention is paid to both broad planning and more detailed clinical decision making processes.

First, we suggest that the process needs to be seen as a whole, with a range of players, all of whom can have important roles (Institute of Medicine, 1985).²⁰ However, the players are likely to be more or less involved and important at different stages of the process, which can be continuing and iterative. Dynamically, the experience of a particular group can influence its decision to participate in subsequent processes; and *how* it chooses to participate. In general, we suggest that the various players need to develop appropriate links (which often do not exist at present), to be clear about their respective roles and relationships and to develop them on a longer-term basis. Closer liaison between practising evaluators and health care planners, managers and practitioners may improve judgment about which of the alternative evaluations which might be undertaken are likely to be most relevant for future decisions on policy or practice. However, closer liaison is not likely to remove entirely the uncertainty about future developments. This may be construed as an argument for not linking decisions on which evaluations to conduct too tightly to future expectations, one view of the world or one funding source, but casting the net rather more widely. To the extent that some persons undertaking evaluations have been planners, managers or practitioners in the health care system (and vice versa) understanding of the two groups' respective problems, perspectives and contributions will tend to be enhanced.

Secondly, users - at both the planning and clinical levels - need to clarify what they want from evaluation and how they propose to use their results to improve the overall health system or the care of individual patients. For example, what are the key issues and to what extent can decisions about them be assisted by relevant and timely evaluation studies? Evaluations are a means to an end - better health care and better health status - not an end in themselves. Unless the users know what they want - and can articulate it on a continuing basis - they are most unlikely to get it. Evaluators for their part may often be in a position to draw the attention of the policy area to a new technology or application which warrants consideration. We suggest that such 'early warning' messages, perhaps tied to preliminary assessments, can be valuable, but probably only if there is a reasonable appreciation by the evaluator of the needs and scope of the policy process. Those undertaking evaluations can seek to understand more fully the objectives of those who require the results for improving policy or practice within the health care system. What choice is the evaluation directed to; and what light will the evaluation shed on the costs and benefits of the various alternatives?

Thirdly, attention needs to be given to the varying motivations of key participants in the

²⁰ The Institute of Medicine argued that the lack of a systematic approach was a major cause of problems e.g. no organisation is responsible for setting priorities for assessment of technologies; new uses of established technologies may escape assessment altogether; retrieval, collation and dissemination of already available information is inadequate.

overall process and appropriate incentives developed so that socially desirable priorities are encouraged. One aspect concerns the availability of suitably skilled labour to undertake the economic evaluations requested, which is obviously inadequate in Australia at present; demand greatly exceeds supply at acceptable quality levels. There are also issues concerning how to improve dissemination arrangements, so that results can be used promptly and effectively (at both the planning and clinical levels). Drummond and Hutton, for example, have pointed out that there have been few concerted efforts to disseminate the results of economic evaluations to physicians (other than by publication in learned journals): we agree that the influence of professional bodies and medical opinion leaders has probably been insufficiently exploited by those conducting economic evaluation and those funding health services research (Drummond and Hutton 1987).^{21,22}

Fourthly, we suggest that greater attention be given in evaluation studies to designing them in ways which maximise the chance that they will throw light, at an appropriate time, on key issues which are relevant to policy choices between significant alternatives. This process requires close and continuing liaison between evaluators and policy makers. It is also intended to increase the probability that results will be known to policy makers, so that they can make appropriate changes to policies, programs or practices. It does not mean that they will necessarily do so, since evaluation results - even in the best of all possible worlds - will only be one input to policy; but at least the evaluation results will be available for consideration and can be given appropriate weight by planners and policy makers. Related to this, and the recognition that there are numerous actors in the health care system (whose viewpoints can vary widely), is the suggestion that evaluators give more explicit attention than has often occurred in the past to ensure that their findings are distributed widely to key target groups in a form which is relevant to their needs and interests. This is not only desirable in itself, but important if diverse groups in a complex system are to understand the reasons for change and to increase the likelihood that they will be committed to it.

Finally, there are problems of timing which may require compromise from both evaluator and administrator/practitioner. For example, the planner may want an evaluation of a new health technology prior to it being widely adopted, whereas the evaluator may want to evaluate it later when more experience and data are available. A solution to such timing problems which is completely satisfactory may not always be possible, in which case a second best outcome can still be worth attempting (e.g. interim results or informal discussion based on the partially completed evaluation). Sometimes decisions cannot be delayed; and once made may not be easy to revise. In our view a process of mutual adjustment can be required, involving continuing liaison and a considerable degree of mutual trust. Furthermore, evaluations may need to be seen more frequently as a continuing process of comparison and adjustment rather than a process of one-off study. Against this background we suggest that, in general, the complex problem of better linking

²¹ The Institute of Medicine, after concluding that dissemination was one of the key functions needing improvement, concluded that "research on dissemination practices should be part of a coherent approach to technology assessment" (Institute of Medicine, 1985, p.247).

²² If these perspectives are accepted they imply a heavy burden on health system decision makers, political and bureaucratic, at both the overall planning level and the level of clinical decisions for individual patients (but perhaps particularly at the former level). The burden may tend to be heavier in a Federal compared to a unitary system, and in Australian circumstances with geographical dispersion and the distances between major centres such as Sydney, Melbourne and Canberra.

evaluations with use in health care, taking account of differing aspects of timing, be approached through a process of mutual adjustment rather than by attempting to make one aspect of the relationship subservient to the other.

Ten questions to ask of a published study

1. Was a well defined question posed in answerable form?
 - (a) Did the study examine both costs and effects of the service(s) or program(s)?
 - (b) Did the study involve a comparison of alternatives?
 - (c) Was a viewpoint for the analysis stated or was the study placed in a particular decision-making context?

2. Was a comprehensive description of the competing alternatives given (i.e. can you tell who did what to whom where and how often)?
 - (a) Were any important alternatives omitted?
 - (b) Was (should) a 'do-nothing' alternative (have been) considered?

3. Was there evidence that the program's effectiveness has been established?
Was this done through a randomised, controlled clinical trial? If not, how strong was the evidence of effectiveness?

4. Were all important and relevant costs and consequences for each alternative identified:
 - (a) Was the range wide enough for the research question at hand?
 - (b) Did it cover all relevant viewpoints (e.g. those of the community or society, patients and third-party payers)?
 - (c) Were capital costs as well as operating costs included?

5. Were costs and consequences measured accurately in appropriate physical units (e.g. hours of nursing time, number of physician visits, days lost from work or years of life gained) prior to valuation?
 - (a) Were any identified items omitted from measurement? If so, does this mean that they carried no weight in the subsequent analysis?
 - (b) Were there any special circumstances (e.g. joint use of resources) that made measurement difficult? Were these circumstances handled appropriately?

6. Were costs and consequences valued credibly?
 - (a) Were the sources of all values (e.g. market values, patient or client preferences and views, policymakers' views and health care professionals' judgments) clearly identified?

- (b) Were market values used for changes involving resources gained or used?
 - (c) When market values were absent (e.g. when volunteers were used) or did not reflect actual values (e.g. clinic space was donated at a reduced rate) were adjustments made to approximate market values?
 - (d) Was the valuation of consequences appropriate for the question posed (i.e. was the appropriate type, or types, of analysis - cost-effectiveness, cost-benefit or cost-utility - selected)?
7. Were costs and consequences adjusted for differential timing?
- (a) Were costs and consequences that occurred in the future 'discounted' to their present values?
 - (b) Was any justification given for the discount rate used?
8. Was an incremental analysis of costs and consequences of alternatives performed? Were the additional (incremental) costs generated by the use of one alternative over another compared with the additional effects, benefits or utilities generated?
9. Was a sensitivity analysis performed?
- (a) Was justification provided for the ranges of values (for key parameters) used in the sensitivity analysis?
 - (b) Were the study results sensitive to changes in the values (within the assumed range)?
10. Did the presentation and discussion of the results of the study include all issues of concern to users?
- (a) Were the conclusions of the analysis based on some overall index or ratio of costs to consequences (e.g. cost-effectiveness ratio)? If so, was the index interpreted intelligently or in a mechanistic fashion?
 - (b) Were the results compared with those of other studies that had investigated the same questions?
 - (c) Did the study discuss the generalizability of the results to other settings and patient/client groups?
 - (d) Did the study allude to, or take account of, other important factors in the choice or decision under consideration (e.g. distribution of costs and consequences or relevant ethical issues)?
 - (e) Did the study discuss issues of implementation, such as the feasibility of adopting the 'preferred' program, given existing financial or other constraints, and whether any freed resources could be used for other worthwhile programs?

Source: Department of Clinical Epidemiology and Biostatistics, McMaster Health Sciences Centre, "How to Read Clinical Journals, VII: To understand an economic evaluation" (Parts A and B), *Canadian Medical Association Journal*, 130 (1984), pp.1156-62 and pp.1428-34.

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