

**Australian experience in the use of economic
evaluation to inform policy on medical
technologies**

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Centre for Health Program Evaluation

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FOREWORD

This working paper contains material prepared for a conference on 'Economic evaluation of pharmaceutical and other medical technologies: from theory to practice' which was held at Duke University, North Carolina, on 30 November/ 1 December 1995. An edited version of the paper will be published in the conference proceedings.

ABSTRACT

This paper considers the role of economic evaluation of health care technologies in Australia and its relationship to policy and program decisions.

Economic evaluation in relation to policy has been best developed in relation to drug subsidy decisions under the Pharmaceutical Benefits Scheme. A key to this successful use of economic analysis has been the availability of a well developed framework for evaluation, linked to legislative provisions and clearly defined responsibilities within a government program. This application of cost-effectiveness analysis to decisions taken by the Pharmaceutical Benefits Advisory Committee is still evolving. At this stage, those responsible for the economic evaluations are increasingly having to confront the issue of the limits of such analysis in the practical policy formulation process. Considerations other than economic analysis may have major influence on some decisions.

Several case studies are presented to illustrate these points.

Australian experience with evaluation of non-pharmaceutical health technologies is mixed. Health technology assessment has been undertaken in Australia for a number of years, providing advice to policy areas, administrators and users of technologies. In a number of assessments, resource allocation was considered in some detail, although this did not always include economic analysis.

Generally these assessments have been framed as advisory documents providing input to policy and program areas that have a more diffuse legislative and administrative framework than that applying to evaluation of drug listing applications under the Pharmaceutical Benefits Scheme.

Case studies are presented on the assessment of organ transplantation programs, breast and cervical cancer screening, magnetic resonance imaging, shockwave lithotripsy and related technologies and cardiac pacemakers.

Some general points that emerge are the importance of factors other than economic evaluation in the decision making process, and the need to make policy and administrative decisions on the basis of limited data. It seems likely that policy on health technologies will continue to be influenced by a range of technical, political and societal factors, as well as by economic appraisal.

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The Australian Health Care System

The Australian health care system

Population and health status. The Australian population is about 18 million and is highly urbanised. The main concentration is in the south east of the continent, predominantly in the coastal zone. The standard of health is generally high. In 1993, life expectancy at birth was 80.9 years for females and 75.0 years for males, and death rates continue to decline. Compared with the USA, age-standardised death rates for neoplasm are similar, those for circulatory and respiratory diseases somewhat higher and those for injury/poisoning lower. Infant mortality is also declining, with a rate in 1993 of 6.1 per 1,000 live births (Australian Institute of Health and Welfare 1995). A 1993 survey estimated that 18% of Australians were disabled in some way (Australian Institute of Health and Welfare 1994a).

Some of the major concerns with health status are the same as those in a number of other developed countries. They include the major causes of illness and death - heart disease, stroke and cancer. Some problems which are more specific to Australia include high rates of skin cancer, including malignant melanoma, associated with exposure to high levels of sunlight, and asthma. Like other countries, Australia has experienced differentials in health status which are strongly linked to employment and socioeconomic status. Most major causes of death show strong occupational trends. In addition, numbers of serious chronic and recent illnesses, and average days of reduced activity reported by men and women, rise as equivalent family income decreases.

The health care system. The health care system in Australia involves three levels of government - Commonwealth (Federal), State and local - and both public and private providers of services. Governments take a major role in the financing of health services, but most medical and dental care and some other professional services are provided by private practitioners on a fee-for-service basis.

The Commonwealth government is primarily concerned with funding programs and the development of broad policies. It influences policy-making and health services through financial arrangements with State and Territory governments, provision of benefits and grants and through the regulation of health insurance. State and Territory governments have major responsibility for the public provision of health services, including public hospital systems, mental health services and public health regulation. At the State and Territory level there has been a trend towards the creation of central agencies with varying degrees of delegation of responsibility to regional or area authorities.

A mechanism for the different Australian governments to discuss matters of mutual interest concerning health policies and programs is provided by the Australian Health Ministers' Advisory Council (AHMAC), comprised of the heads of the various health authorities and the chair of the National Health and Medical Research Council.

The Commonwealth supports benefit schemes covering medical, pharmaceutical, hospital and nursing home services, funded through government budgets. Many other programs, including health promotion, have involved provision of conditional grants to the States and Territories. Since 1984, a universal health insurance plan known as Medicare has been in operation. The Health Insurance Commission (HIC), administers the Medicare program and also a Pharmaceutical Benefits Scheme.

In 1992–93, health care expenditure in Australia was \$34.3 billion, representing 8.5% of GDP and an average of \$1,944 per person. The Commonwealth Government provided \$15.1 billion, State and local governments \$8.1 billion and the private sector \$11.1 billion. (Australian Institute of Health and Welfare, 1994a). The largest component of recurrent health expenditure (43%) is allocated to hospitals.

The Medicare program has a dominant place in the funding and control of many health technologies. For each technology included under items on the Medicare Benefits Schedule, a proportion of the cost is met through Commonwealth reimbursement. If a technology is not included in the Schedule, typically costs will be met by the patient, with private insurance cover being relatively limited. Once a technology is included in the Medicare Benefits Schedule private providers are more likely to acquire it, knowing that payment for use will be covered by insurance. For some high cost technologies, funding has been provided through government grants, with very limited private sector involvement.

Pharmaceutical Benefits are provided for prescribed therapeutic drugs purchased at retail pharmacies, with the items being listed in a schedule. Unsubsidised prescribed items can also be bought in pharmacies, and many drugs are available over the counter without prescription. Safety net arrangements apply to limit the amount paid by a patient in any calendar year.

The Pharmaceutical Benefits Scheme currently includes around 1,600 products representing about 530 drug substances. The Scheme covers about 65% of prescriptions in Australia (over 115 million a year), with the other major area of pharmaceutical use being within public hospitals. In 1992/93, expenditure under the Scheme was \$2.2 billion, of which the Commonwealth government contributed over \$1.5 billion. In comparison, expenditure on private prescriptions was \$263M and hospital drug use cost \$274M (Australian Institute of Health and Welfare, 1994a). The Pharmaceutical Benefits Scheme therefore has a dominant place in influencing the use of pharmaceuticals in Australia. As a result of shifts in the levels of patient copayments, over 80% of the Scheme now funds prescriptions for pensioners and other concessional patients (Graham 1994). Between 1980-81 and 1990-91 average expenditure per person on prescription drugs increased by almost 240%, about twice the increase in the Consumer Price Index, and there is continued strong growth.

Assessment and control of health technologies. Australia has had difficulty in producing coherent mechanisms to shape policy and fund and place health care technologies. The situation is complex because of the mix of responsibilities of different levels of government and the balance of private and public funding for medicine. Introduction and diffusion of health technology in Australia is determined by a complex interaction of market forces, public funding and regulation. Non-government groups including professional societies, equipment suppliers, consumer organisations, third party payers, local service administration and medical specialists have a significant influence.

In some areas, such as introduction of pharmaceuticals, there have been strong legislative provisions and regulatory control. More commonly, the major method of control is financial through budgets for hospitals and clinic services (at the State level), setting the rates of reimbursement for items funded through the Medicare and Pharmaceutical Benefits Scheme programs or in allocation of grants for specific technologies or services. It is generally recognised that these are crude and imperfect ways of influencing the diffusion of technology and that control by regulation can only be partial (Hailey, 1995).

Coverage of health technologies by the assessment process is still comparatively limited. Hailey (1993) has commented that there are 'islands' of assessment and fully informed policy, with the mainstream of health technology deployment evolving through less formal mechanisms. This is perhaps inevitable until assessment is linked more systematically to resource allocation decisions and undertaken more widely within hospitals and other institutions.

Economic evaluation as a component of health technology assessment is less well developed. Also, some economic studies of health technologies have been in the context of consultants' reports and little information is available on these. Salkeld et al. (1995) have drawn attention to the small numbers of published economic evaluations of Australian health care and the limitations to their quality. Approaches to increasing the impact of health technology assessment, particularly with regard to economic analysis, have been discussed in detail by Drummond et al. (1991) and Antioch et al. (1995). For the most part, such improvements have yet to occur in Australia, and a number of the case studies presented in this paper reflect both the more limited evaluation approaches that have been taken and the realities of applying assessment findings to a complex health care system.

Pharmaceutical technologies - some general points

The approach in Australia to evaluation of new pharmaceutical products parallels those developed in the USA and Sweden, with comprehensive data being required from manufacturers to describe chemistry and quality control, animal and human safety and efficacy for each product. Following detailed assessment within the Commonwealth Department of Human Services and Health, pharmaceuticals which meet evaluation requirements are approved for use by the Australian Drug Evaluation Committee (ADEC). There is no economic evaluation component to this process.

Economic evaluation of pharmaceuticals in Australia has been dominated by the requirements associated with drugs proposed for listing under the Pharmaceutical Benefits Scheme. Control of these drugs is achieved through a Pharmaceutical Benefits Advisory Committee (PBAC) which makes recommendations on which products should be listed on the Pharmaceutical Benefits Schedule. All products considered would have first received clearance through ADEC. The PBAC is required to take into account the cost effectiveness of drugs when making such recommendations. Determinations on prices are made by a separate body, the Pharmaceutical Benefits Pricing Authority (PBPA), which is serviced by the Department of Human Services and Health.

Starting in 1993, industry applications for listing under the Pharmaceutical Benefits Scheme have had to include formal evidence of cost effectiveness of products. The basis for use of economic analysis in this context has been outlined by Evans et al. (1992), with instructions to manufacturing industry being included in guidelines on submissions to the PBAC issued by the Commonwealth Department of Human Services and Health (1992) which have subsequently been updated. The PBAC is advised on the content of submissions by an Economics Sub-Committee. PBAC recommendations on listing are made to the Health Minister, and Cabinet approval is required if expenditure of more than \$10 M per year is involved. If it is considered necessary to lower the price of a drug for it to become cost effective, this becomes a domain of negotiation.

The Australian guidelines are intended to be flexible and pragmatic while being linked to theoretical foundations. Some issues in the early application of this approach were the shortage of expertise in such analysis, selection of comparative therapies, degree of accuracy of estimates of incremental health benefits and consistency of levels of evidence (Mitchell, 1993). The viewpoint of the analysis is societal, the preferred comparator the treatment most likely to be replaced, medical evidence based on effectiveness is sought and incremental and sensitivity analysis are required (Drummond 1995).

Other significant features, as noted by Sloan & Conover (1995), are that only direct costs are required, and that there is a strong preference for effectiveness to be demonstrated through results of randomised trials, preferably "head to head" studies. There is provision for including estimates of indirect economic outcomes, but "...changes in productive capacity as an outcome of therapy are not encouraged in submissions to the PBAC" (Commonwealth Department of Human Services and Health 1995). The reasons and implications of this viewpoint have been discussed by Sloan &

Conover (1995). There continue to be sensitivities as to the potential consequences of the effects of inclusion of indirect costs on the results of analyses which may be influential on government policy. In part, this may be because some analyses involving indirect costs will take a wider perspective than that which may typically apply to the ambit of responsibilities of health portfolios.

The guidelines have recently undergone further revision (November 1995), though most of the changes relate to reorganisation of the document and provision of additional explanation. The discount rate to be used remains at 5%, except for calculation of the cost to the Pharmaceutical Benefits Scheme budget, where a rate of zero is to apply. Cost effectiveness and cost minimisation are the usual forms of economic analysis and cost benefit analysis is not encouraged. There have so far been only a handful of submissions which have include cost utility analysis.

Pharmaceutical technologies - case studies

Participants in the assessment and decision making processes associated with the PBAC program face legal constraints on divulging information regarding the detail of economic assessments and reasons for acceptance or rejection of a product for listing. Very little is available in the public domain on the details of the various evaluations or the reasoning behind the decisions on listing. In the case studies included here (Table 1), it has been necessary to make inferences regarding the various evaluations and decisions, based on limited published information, changes to the Pharmaceutical Benefits Scheme and information supplied by several individuals. However, even with such limited information, a number of interesting points emerge on the application of cost effectiveness analysis in this area.

Table 1: Pharmaceutical products considered for listing in the
Pharmaceutical Benefits Schedule, and some evaluation issues

Pharmaceutical	Issues
Dornase alfa	Few relevant data available. PBAC view that effectiveness was limited; insufficient offsets through savings on hospitalisation, antibiotics. Decision overruled by Minister.
Sumatriptan	Disagreement on price for non life threatening condition. Equity.
Interferon alfa 2b	Uncertainty on permanence of remission; intermediate endpoints; listing subject to monitoring.
Finasteride.	Poor cost effectiveness ratio; intermediate endpoints; choice of comparator.
Salmeterol xinafoate	Decision influenced by willingness to pay judgment; industry view of additional benefits through reducing hospitalisation
Gonadotrophic - releasing hormone products.	Decisions on price influenced by indications and availability of other drugs.
Fluoxetine	Seen as worth while addition, disagreement/ negotiation on price/restrictions
Filgrastim.	Indications widened following new evidence
Terbinafine HCl	Generation of substantial additional market following listing. Future additional costs through required pathology testing.
Paclitaxel	Listed, though trial design and consequent data had a limitation
Cladribine	Expensive drug listed as clearly more cost effective than comparator
BCG-TICE	Cheaper, more effective than older treatment
Erythropoietin	Listed, but not subject to cost effectiveness analysis, decision by Ministers.
Alglucerase	Very high cost, could not justify under guidelines, handled through act of grace payments outside the program.

Dornase alfa Dornase alfa (Pulmozyme) is a drug designed for the management of cystic fibrosis and acts by breaking down secretions in the lungs, thereby improving lung function. There is no proven effect on the progress of the disease, but the treatment helps in alleviating respiratory distress. The issue here, from the perspective of the PBAC, was the high price sought in relation to the comparatively limited benefits that could be identified. The cost effectiveness ratio, based on the incremental cost per patient free of a chest infection at 24 weeks, was very high (over \$60,000). Benefits through improved lung function as measured by spirometry were limited to a mean increase in FEV-1 of 6%, compared with placebo. There was also a reduction of 28% in the number of chest infections requiring treatment with parenteral antibiotics. Costs of treating a patient exceeded \$13,000 a year, according to a media release (Commonwealth Department of Human Services and Health 1994) and were not matched by identified savings through avoidance of hospitalisation and antibiotics. There seemed to also be benefits in terms of symptomatic relief, though these had not been quantified.

The view of the PBAC was that the drug produced limited benefit for patients with cystic fibrosis, through improvement in lung function. The Committee considered that the changes in respiratory tract infections, pulmonary function, quality of life and other outcomes which were associated with use of dornase alfa were of modest clinical significance. A review process in the Department considered the price of the drug to be excessive for the degree of benefit likely to result from its use. A decision was therefore taken not to list this product. The determination in this case was made by the Minister for Health, on the advice of the PBAC, and was associated with extensive media exposure. A second application by industry was rejected and a third deferred pending advice from the Minister.

There was further negotiation between the company and the Department, with one option canvassed being conditional listing, for example restricting subsidy to those cases where change to FEV-1 was greater than 10%. Such an increase was determined by the PBAC as providing a favourable outcome of treatment, and use of such a criterion might reduce the caseload by about a third (and increase the benefit obtained).

There has been considerable industry dissatisfaction with the position taken by the PBAC. The estimate of cost to budget by the PBAC assumed a 'worst case' with the drug being prescribed to all cystic fibrosis cases. The industry position was that only about a third of these would in fact be users, given what was known about the proportion who would respond to treatment with Pulmozyme and problems with compliance.

The industry view is that the cost effectiveness analysis undertaken for Pulmozyme had little meaning, and that it was necessary to use the only outcome available from clinical trials at that stage to meet the requirements of the guidelines. The revised guidelines appear to offer more flexibility but there is still a perception that breakthrough drugs are at a disadvantage because there will often be limited data available. Industry also advised the PBAC that it was not possible to identify favourable responders to dornase alfa prior to treatment, and that it was necessary to administer the drug for two weeks to ascertain the response. The FEV-1 value is regarded by industry as a crude measure which excludes a number of patients who may benefit through reduction in respiratory infection and/or quality of life.

This protracted process has now been brought to a conclusion by the present Minister overruling the recommendations from the PBAC, and giving a directive that the drug will be listed from the beginning of 1996. The major influence on this decision appears to have been pressure from the public. The Pharmaceutical Benefits Scheme subsidy will apply after an individual has been shown to be a responder to the drug, with industry agreeing to meet the costs of the two week trial period. The Department appears to be seeking to continue price negotiations through the PBPA.

Considerations other than application of the results of cost effectiveness analysis have driven this process. These include the nature of the condition being treated and the public profile it generates, the lobbying efforts by support

groups and the fact that the total number of patients is small (about 200 new cases a year) so that the consequent addition to the budget would not be too great. Some of the additional arguments are illustrated by a recent newspaper article on a 21 year old fibrocystic whose use of Pulmozyme reportedly greatly increased functional status and decreased the need for lung transplantation (Ferrari, 1995). This individual was reported to be using sales of chocolate to raise funds for purchasing the drug.

The experience with Pulmozyme indicates the need for continuing dialogue between evaluators, industry and policy areas.

Sumatriptan. Sumatriptan was a new drug for treatment of migraine. The evaluation considered that it was an effective treatment, and superior clinically to the comparators used. However, agreement on price was not reached with the company. The suggested price to meet cost effectiveness criteria was a fraction of that requested and listing was denied. Nor was the Minister prepared to agree to a proposal that expenditure by the Commonwealth be capped, with the company supplying the drug free of charge after expenditure reached \$50M.

This is a somewhat different situation to that in the Netherlands where a decision was taken to subsidise this drug, but only to the same price level as that of its competitors and with a substantial patient copayment. In the current Australian arrangements there is no provision for varying patient copayment in this way. This an option that potentially could be considered by government - if current policy were to be changed it might be useful to link a drug such as sumatriptan to a sliding scale reimbursement, with the patient paying a greater proportion of the cost than would be the case under current legislation.

One consideration for the PBAC is that there is an equity issue, with many migraine sufferers being unable to afford the unsubsidised drug. As against this, the perception of the Committee was that migraine is not a life threatening condition and that other treatments are available.

Price negotiation is continuing with the company and is taking account of further work to define the oral dose-response curve. The original formulation was a 100mg capsule, but 25mg and 50mg formulations are now being manufactured, and offer equal efficacy and fewer side effects. On a pro rata basis the cost per treatment would seem to be substantially decreased.

Finasteride Finasteride, a drug for use in the management of benign prostatic hyperplasia (BPH), was essentially considered unacceptable for listing because of limited evidence of effectiveness, in terms of changes to urinary flow and symptom scores. After consultation with the PBAC, the company initially submitted an economic evaluation based on modeling, which considered the impact of finasteride on the use of surgery (TURP). This was not seen as acceptable and the PBAC requested a comparison with watchful waiting, based on available evidence of effects on urinary flow and symptom scores. There was some feeling in the PBAC that the technical advance achieved with this drug was not matched by its impact. The Committee was also mindful that the cost implications of listing were significant, given the high prevalence of prostatic hyperplasia.

An industry view is that there should have been a greater acceptance of the realities of collecting more definitive long term data and that the PBAC position was focused primarily on the cost to the program budget. An application from the company that a restricted listing be granted on the basis of finasteride being available to a small, appropriately selected group of men with moderate to severe symptoms, for whom surgery is inappropriate, was not accepted.

Dawson (1995) has pointed out some of the difficulties with the use of surrogate endpoints. In considering treatment of BPH, assessment of outcome should include the reduction in the need for surgery. However, finasteride had only been shown to affect intermediate outcomes such as urinary flow, prostatic volume and symptom score. Only small

differences in these due to finasteride had been detected in large scale studies. A question was whether a small change in urinary flow was associated with a reduction in symptoms such as nocturia and frequency, which are more relevant to patients.

As an illustration, Dawson considers the consequences of the statistically significant increase of 17% in urinary flow produced by the drug. If a patient passed 1,500 mL of urine a day at peak urinary flow rate, he might be able to gain an extra 23 seconds away from the toilet. This translates to an extra day away from the toilet over 10 years' treatment, at a cost of \$7,500. Dawson also drew attention to the absence of head to head trials with the cheaper, earlier generation drug prazosin.

Finasteride has also been briefly considered in the context of assessment of other technologies for management of BPH (Dankiw & Hailey, 1993). This included preliminary economic comparison of drugs, microwave treatment, lasers, stents and surgery using a cost minimisation approach. On the assumptions made, treatment which included the use of drugs did not compare very favourably with other approaches (Table 2). However, a subsequent paper, which included some consideration of indirect costs, has noted that data on outcomes remain limited, and that there is scope for increased efficiency in the use of surgery (Hailey et al, 1995).

The assessment was a source document for an evaluation by the Australian Health Technology Advisory Committee (1994) and was helpful in indicating that further clinical and economic data were needed and that the issues were complex. A recommendation from the AHTAC study was that new technologies for treating BPH should have adequate trials before being introduced into routine clinical practice. The AHTAC report was widely disseminated, but its influence on policy and practice is unclear. It is interesting to speculate whether current eligibility of laser treatment for Medicare Benefits would have been approved had the technology been subjected to the level of economic evaluation required for listing of products in the Pharmaceutical Benefits Schedule.

Table 2: Comparison of treatment costs for different options for managing benign prostatic hyperplasia*

Option	Treatment cost for a cohort over 5 years, \$M	Cost per person treated to health programs, \$
Surgery	122.5	5,400
50% surgery, 50% microwave	89.5	3,600
Laser	55.3	2,400
70% surgery, 30% drugs	135.9	6,000
50% surgery, 50% watchful waiting	69.6	3,000

* Costs refer to a cohort of 22,730 cases, corresponding to the national annual caseload of men initially treated surgically, followed over a five year period.

Source: Hailey et al, 1995

Alpha interferon. The listing of interferon alfa 2b for the treatment of chronic hepatitis C was linked to a decision that patients should be monitored to establish that the disease was cured and not dormant. A problem here was the use of a surrogate outcome with limited data. There were only 30-40 cases that had been followed to three years and it was uncertain whether there was long term remission from the disease for about 20% of those taking the drug or a

slow relapse. More recent data from US studies would suggest that the level of remission might be only 10%, which will have obvious effects on the cost effectiveness ratio.

Shiell et al. (1994) have published a cost effectiveness study of the drug in the treatment of chronic active hepatitis C, using a Markov modeling approach to simulate costs and outcomes in hypothetical cohorts of patients treated with and without the drug. Using conservative assumptions based on Australian experience, treatment with alpha interferon was estimated to result in a discounted cost per life year gained of \$33,230 in patients with cirrhosis at the start of treatment and \$71,950 in those without advanced liver disease. The results were sensitive to the effective response rate in patients with cirrhosis at the start of treatment and to the life expectancy of patients without that condition.

The cost effectiveness of the drug depended critically on the validity of assumptions made on long term effectiveness. It was therefore suggested that its use might best be restricted and the long term response of patients to treatment closely monitored. This position is very similar to the policy that has been put in place by the Department following advice from the PBAC. Collection of ongoing data is the responsibility of the companies concerned. A major benefit through systematic accumulation of data is the potential for input for a randomised trial - for example with patients being allocated to treatments of 6 months or 12 months.

It is of interest that two letters in response to this paper (Turnbull et al, 1994) took opposing views on the approach and results, one considering that the analysis was unduly conservative and the other that it might have underestimated costs and overestimated effectiveness. In response, Shiell et al. comment that the responses highlight the difficulties with using decision analysis to estimate cost effectiveness of treatments where the benefits have not been fully evaluated in clinical trials. They also restate that the most critical problem is that the true rate of the drug's long term effectiveness is unknown and extremely sensitive to different assumptions about its value. Also, cost effectiveness is likely to vary among patient subgroups. Finally, they suggest that explicitness in the decision making process, more than the final cost effectiveness ratio, is the real strength of economic evaluation and decision analysis.

This is a case where the evaluation and policy processes are having to learn to manage a difficult situation with limited data and changing indications of effectiveness.

Fluoxetine The antidepressant fluoxetine provides an example where restrictions on use under the provisions of the Schedule were eased. Originally, use was not permitted unless tricyclic antidepressants had first been tried. This condition no longer applies and the drug is available for treatment of major depressive disorders where other therapy is inappropriate. This is much less restrictive, and leaves the responsibility far more with the prescribing physician as to whether to use a preparation which is about ten times the cost of amitriptyline and other tricyclic antidepressants.

The approach on price levels has apparently been to link negotiations to the price of other antidepressants, such as the monoamine oxidase inhibitor moclobemide, taking a cost minimisation approach. The cost to the Pharmaceutical Benefits program appears to have been a major consideration.

Some clinical considerations were that though drugs of this type were in some ways not as effective as the earlier tricyclic antidepressants, they were less toxic and better tolerated. Other factors were the perception that there had not been much new for the treatment of depression psychosis for many years, and that there were important societal issues with the effects of depression on patients' families. At a more pragmatic level, the Department was having to live with the realities of the prescribing trends for this class of pharmaceuticals, which were being supported by the medical profession. The assessment and policy approaches to this drug have gone beyond consideration of cost effectiveness - there has been a political judgment as to what extent to 'hold the line'.

Filgrastim. Consideration of indications for filgrastim, a granulocyte colony stimulating factor, have had separate, contrary effects. Restrictions were imposed for its use as an antineoplastic associated with bone marrow transplantation, and in treatment of some other types of malignancy. However, following evidence of benefit in severe chronic neutropenia, there was some easing of restrictions, and it is now permitted for use in certain patients with congenital, chronic or chronic cyclic forms of this condition.

The company was unable to show that the drug had any influence on mortality. Arguments on cost effectiveness related to its ability to shorten hospital stay and reduce the use of antibiotics. Essentially, a cost analysis was involved. A sensitivity analysis was undertaken and the decision on price guided by the estimate of where there was a break-even situation. The approach to use of this drug has been in line with US Oncology Society guidelines, with selection of patient groups based on a break even point calculation. Evidence-based material had been applied to a decision making process.

Salmeterol xinafoate This drug is an anti-asthmatic which is listed but with restrictions on the type of condition for which the government subsidy is paid. The intention was to restrict support for an expensive product to those asthmatic cases who were most likely to benefit from treatment with it, rather than several other widely used anti-asthmatics. This product is therefore available for use only for patients with frequent episodes of nocturnal asthma who are receiving treatment with oral corticosteroids or maximal doses of inhaled steroids. At \$45, the benefit is about four times higher than that for older drugs such as salbutamol. The drug is a long acting agent which can prevent overnight bronchospasm; there is no effect on the overall disease pattern.

The PBAC decision was related to a perception by its Economics Subcommittee of a willingness to pay - on balance it was judged that \$7-9 per night free of interrupted sleep was reasonable value for money. An industry perception is that the drug would have additional benefits through helping avoid further consultations and hospitalisation episodes, and that there would be major benefits in terms of well being. However, there seems to have been little information on such aspects during the period of assessment.

Levporelin, goserilin, nafarelin The listings of these gonadotrophic - releasing hormone products in the Schedule give an insight on the account taken of different indications in reaching pricing decisions. Levporelin acetate intramuscular injection is listed for the treatment of advanced prostatic cancer with a benefit of \$434. Similarly, goserilin is listed for use as a subcutaneous implant for treatment of advanced prostatic cancer and for advanced breast cancer in pre-menopausal women with a benefit of \$385. In contrast, nafarelin acetate, which is used as a nasal spray for short term treatment of visually proven endometriosis, has a benefit of \$96. This brings it into the same range as the longer established treatment for this condition, danazol, which has two listings (capsules of different strengths) at \$70 and \$100. The inference is that the price set for nafarelin acetate has been closely tied to that of the comparator used in the cost effectiveness study.

Terbinafine Terbinafine hydrochloride has been listed as a treatment for nail bed fungal infections. It was clearly shown to have superior cost effectiveness to the existing treatment (griseofulvin) and is also easier to use. The availability of a Pharmaceutical Benefit for this drug has now generated a substantial previously untapped market, consisting of cases that were previously untreated (Table 3). As a result, government expenditure on treatment of this condition has increased considerably. The treatment is effective, though cost per cure is still fairly high at several hundreds of dollars. Given the high prevalence of tinea infections, and the likelihood of recurrence, use of the drug may continue to grow, though recent sales have started to level out.

A further point is that provision of terbinafine hydrochloride under the PBS arrangements is subject to proof of the nature of the infection. From 1 February 1996, each new case involving use of the drug will requires a test.

performed in an accredited laboratory which is supervised by a pathologist. Microscopic identification by a dermatologist will no longer be sufficient. These new arrangements will result in an additional cost to the government of \$24 per patient, with a total of perhaps \$1.4M per year. It will be interesting to see whether in future there will be a acceptance of testing performed in physicians' offices, given the increasing availability of near-patient testing technology for fungal infections.

This situation gives an interesting challenge to the policy process. The guidelines and cost effectiveness analysis may have little to say about the basis for future decisions on the level of government subsidy which will apply to use of this drug.

Table 3: Use of drugs under the PBS for treatment of nail bed fungal infections

Period	Number of prescriptions		
	Griseofulvin	Terbinafine HCl	Total
July-Dec 1993	62,000	Nil	62,000
Jan-June 1994	50,000	15,000	65,000
July-Dec 1994	39,000	38,000	77,000
Jan-June 1995	39,000	44,000	83,000

Costs to Commonwealth Government, 1994/1995: griseofulvin: \$0.8M, terbinafine HCl : \$9.2M

Future annual cost of pathology tests: \$1.4M

Source: Sandoz Australia Pty Ltd

Anti-cancer preparations Three anti-cancer preparations give examples of products which clearly met the cost effectiveness guidelines and were accepted for listing. BCG-TICE vaccine powder for intra - vesical administration was accepted for treatment of bladder carcinoma. It was dominant over the earlier treatment using doxyrubicin, being both more effective and less expensive. Cladribine, even with a benefit price of \$4,658, was an easy listing decision, being more effective, safer and cheaper than the alternative interferon treatment, for a small group of patients with leukemia.

Paclitaxel was also considered to be an effective cancer treatment - for ovarian carcinoma- and was listed. A complication in the evaluation was that data were based on a trial in which the design specified crossover of non-responders in the comparator arm (mitomycin C) to paclitaxel treatment, whereas there was no crossover from the paclitaxel arm. This may have overestimated the effectiveness of the new drug.

Alglucerase Alglucerase is a very high cost drug for the management of a rare condition, Gaucher's Disease, associated with deposition of lipid material within the spleen and anemia. Advice from the Economics Subcommittee was that this treatment would never meet PBAC requirements, with costs per QALY being several hundred thousand dollars. However, it was recognised that a small number of cases (perhaps 20 a year) would benefit from using this drug. In this case, the matter has been handled by funding the drug outside the program, through act of grace payments negotiated with the Department of Finance.

Erythropoietin Erythropoietin is included here as an example of an expensive drug which was approved for use under different administrative arrangements, prior to implementation of the guidelines, and which has not been subject to a cost effectiveness analysis. It is listed in the Schedule for treatment of anemia associated with chronic renal failure when treatment is initiated in a hospital with a renal dialysis unit.

Following concerns by States at the rapid growth in the use of expensive specialised drugs provided through the public hospital system, discussions by health ministers and AHMAC led to agreement on funding for such services and establishment of a Highly Specialised Drugs Working Party (HSDWP). The HSDWP selects drugs for inclusion in the funding arrangements, and monitors their use. Criteria for selection include need for ongoing medical supervision, treatment of chronic medical conditions in an identifiable patient group and high unit cost. Commonwealth funding for erythropoietin was provided in 1991 through grants to the States and the drug was included in the Pharmaceutical Benefits Scheme arrangements under restricted conditions.

Various centres have adopted measures to reduce the dose to the lowest level suitable for maintaining benefit in each patient, thus achieving savings (Australian Health Technology Advisory Committee 1992). Studies such as these seem to have had little impact on the actual decision making processes on prices and availability of the drug. Policy considerations were in the context of setting agreed prices for a product that was considered essential by governments for specialised programs. As responsibility for its supply was shared between Commonwealth and States, there was the complication of involvement of different jurisdictions. Price setting appears to have been established on the basis of negotiation between the PBPA with the manufacturers, taking account of their margins and experience in other countries. Monitoring and adjustment of the budget took account of expenditure by hospitals.

Overview. The use of economic evaluation in informing decisions on whether to provide funding for drugs through the Pharmaceutical Benefits Scheme is now well established. This is a rare example of a public sector policy and administrative process concerned with medical technology being routinely informed and influenced by economic assessment. Considerable experience has now been gained and draw on the lessons of over 150 submissions containing economic evaluations.

The perception of the PBAC and those who advise it is that during the first two years of operation of the economic evaluation provisions, progressive improvement has been seen in the quality of the submissions coming from industry, and that good experience has been gained with evaluation and policy formulation procedures. Good features of the present program are quite clearly specified procedures, a process of dialogue with industry and professional organisations and a short turn around of submissions, with evaluations being completed within six weeks of receipt (although associated Departmental administrative procedures take much longer).

There are, however, some less certain aspects. At this stage, those responsible for the economic evaluations are increasingly having to confront the issue of the limits of such analysis in the practical policy formulation process. In many cases, the cost effectiveness analysis results, and consequent recommendations, may be components in a negotiation process with industry, professional bodies and support groups which takes account of other factors. In the future, the policy areas within the Department of Human Services and Health may well need to consider their position on the choices to be made where new products meet the provisions of the guidelines but raise major allocative issues because of their potential cost to the Federal health budget. Harris (1994) comments that some listed drugs and some surgical procedures may have a cost per life year saved in excess of \$100,000, and that the answer to which of these should be funded is a political one, as economics has little to say about whether a life year is worth that amount.

A continuing pressure on the Health portfolio will be the demands for efficiencies and savings emanating from the Department of Finance. Much of the purpose of the economic evaluation initiatives has been to achieve savings to the Pharmaceutical Benefits Scheme budget, and continuing success in achieving such comparatively restricted aims will be necessary if the program is to survive with adequate evaluation resources in a climate of fierce bureaucratic competition within and between Federal agencies. The economic evaluation program clearly also has other objectives, and there is a real commitment to assisting the choice and appropriate use of effective pharmaceutical technologies. Nevertheless, the focus seems more on a single program than on appraisal of broader health goals and

targets, despite the inclusion of advice in the guidelines on presentation of information on the impact of new products on overall government costs.

An industry view is that the focus of government and the Department of Human Services and Health is on cost containment, and that the government effectively hides a large part of the cost by forcing pharmaceutical companies to accept prices that are low by international standards (Australian Pharmaceutical Manufacturers' Association, 1995). The Australian Pharmaceutical Manufacturers' Association has suggested that insufficient weight is given to savings through use of new drugs in other areas of the health portfolio, including decreased reliance on palliative care. While the new guidelines are not a major theoretical departure from the earlier version, there is some concern that the expansion of requirements and the description of informational needs might become unduly prescriptive. As mentioned above in relation to Pulmozyme, a further concern is that there may be an undue burden on proof of efficacy of breakthrough drugs with the preference for randomised trials over the duration of the period of effect of the intervention (Grobler, 1995).

Overall, the perception by industry is that it is in a weak position in its relationship with government, and that companies are tending to take an overly conservative approach to the prices and claims they include in submissions, in the knowledge that there will be a high degree of control imposed by the bureaucratic process, supported by its technical advisers. Some of this situation relates to historical events in the relationship between pharmaceutical industry and the Federal health portfolio, but in part reflects more recent trends to greater use of economic advice to determine the basis on which government funding will be allocated.

Despite the control exercised by Commonwealth Government over their price and distribution, information about pharmaceutical drug use in Australia is poor (Australian Institute of Health and Welfare, 1992). As a consequence, there are some limitations on the information generally available to the PBAC in undertaking economic appraisal, and some restriction on feed back after a drug has been listed. A suggestion from industry sources is that this situation increases the tendency for the Department to think of drug pricing and availability in terms of impact on the Pharmaceutical Benefits Scheme budget rather than considering overall effects on health care.

Non pharmaceutical technologies

Australian experience with evaluation of non-pharmaceutical health technologies is mixed. Systematic regulatory appraisal of medical devices is less well developed than the program for pharmaceuticals and does not include economic assessment. There is no regulatory control of procedures.

Health technology assessment has been undertaken in Australia for a number of years, providing advice and recommendations to policy areas, administrators and users of technologies. Much of the assessment work directed towards the technologies considered in this paper was undertaken under the auspices of national advisory bodies, and in reports prepared by the Australian Institute of Health and Welfare (AIHW). The National Health Technology Advisory Panel (NHTAP) was established by the Commonwealth in mid-1982 and was subsumed by a new body, the Australian Health Technology Advisory Committee (AHTAC) in 1991. AHTAC is a committee of the National Health and Medical Research Council. Further details of these bodies and their activities have been given by Hailey (1995).

Recommendations and data from the assessments have influenced policy on whether or not to fund technologies, levels of funding, indications for use and placement of services. There has also been a useful influence on practice, though data here are more limited. In a number of assessments, resource allocation was considered in some detail, although this did not always include economic analysis. The more common type of approach was to include cost analyses without proceeding to full economic evaluation. However, many of the concepts embedded in models of economic assessment of health care technologies were taken into account (Drummond et al. 1992).

Solid organ transplantation

Organ transplantation services are well established in Australia, and their distribution and use has been influenced by a number of assessments. However, formal economic analysis has played a minor role, with there being a greater focus on costs of services whose use had been accepted by governments following strong representations from professional bodies and the public. Even the cost data available have severe limitations and are not always consistent between hospitals or inclusive of all significant components.

Renal transplantation. Provision of services for treatment of end stage renal disease is largely the responsibility of State governments. End stage renal disease treatments were the subject of an early cost effectiveness study by Doessel (1978). This clearly established transplantation as the preferred method of treatment. Quality adjusted costs per life year for cadaveric and living donor transplantation were \$662 and \$565 respectively, at a discount rate of 4%. In comparison, the corresponding values for home dialysis and hospital dialysis were \$2,454 and \$4,184.

Results such as those of Doessel informed opinion within health services, and there has been little argument regarding which treatment should desirably be offered. Recent information from the Australia and New Zealand Dialysis and Transplant Registry

(Table 4) confirms the superiority of transplantation in terms both of survival and quality of life. From data available to AHTAC (Table 5), it is clear that transplantation is the preferred treatment on cost grounds, with hospital hemodialysis the most expensive of the alternative approaches..

However, while renal transplantation is recognised as the preferred method of managing end stage renal disease, dialysis remains the dominant treatment method in Australia because the organ donation rate is low (currently 13.5 organs per million population per year). The transplantation rate has increased by 17% over the last decade, while that for dialysis has grown by 45% (Disney 1993). Much of the discussion on this area of health care services has been in terms of increasing the rate of organ donation, and optimising use of different forms of dialysis.

Table 4: Outcome data for end stage renal disease treatment, 1993

Treatment	Rate per million	Five year survival		Patients able to perform normal activities, %*
		35 - 54 years years	> 65	
Transplantation	27	83	65	85
Dialysis	192	64	50	50

* Karnovsky Scale categories 100 and 90

Source: Disney, 1993

Table 5: Comparative costs of treating end stage renal failure*

Treatment	First year cost, \$	Subsequent cost per year, \$
Transplantation	15,100	4,400
Home dialysis	38,000	14,200

CAPD	29,100	27,100
Dialysis with self care	35,500	27,400
Hospital dialysis	48,800	48,800

* 1991 dollars

Source: AHTAC, 1992

Major themes in service delivery guidelines developed by AHTAC (Australian Health Technology Advisory Committee 1992) were the need to increase the rate of organ donations for transplantation, increase home dialysis and minimise maintenance dialysis in hospitals. It is too soon to say whether the AHTAC recommendations have had much impact. State health authorities appear to be making efforts to decrease the number of hospital dialysis cases. The Australian Coordination Committee on Organ Registries and Donation has attempted to increase organ donations, but there has so far been no change to earlier trends.

The New South Wales Department of Health commissioned a study to provide advice on optimum size and throughput of renal transplantation services, following concerns at the number of hospitals that were performing transplantations and the consequences to budgets and outcomes. The resulting report (Shiell et al. 1991) was somewhat inconclusive because of the limited data available. Estimated short run economies of scale through concentrating services would be limited (for example 2 to 7% reduction in average costs with a 50% increase in throughput). There appeared to be a significant positive relationship between outcome and throughput, but the study was unable to make related recommendations because of the small number of cases from each hospital and the possible significance of other variables. The State Department seems not to have found this analysis to be of much practical help, and remains concerned at the number of transplantation centres.

A more directive position was taken by AHTAC (Australian Health Technology Advisory Committee 1992), which considered a minimum of 30 transplant operations per year at each centre to be desirable and recommended that centres which are not performing 20 operations per year should either cease transplantation altogether or increase their commitment. If this guideline was applied in New South Wales, four of the hospitals included in the study by Shiell et al. would be affected. As things stand, those hospitals appear to be maintaining their transplantation services, arguing that the costs are offset by efficiencies at individual institutions and that outcomes are satisfactory. Responsibility for auditing such claims seems to be moving towards the regional administrative areas in the States.

Heart, lung and liver transplantation. The history of these transplantation technologies in Australia has been somewhat different to that of renal transplantation as they have been considered in the context of limited numbers of units supported initially under a Nationally Funded Centres policy. This policy is applied by AHMAC and is aimed at ensuring access to approved high cost, low demand services and avoiding unnecessary duplication of resources. Typically, only two or three centres in the country might provide such services. Support is provided on a relatively short term basis, with renewal of funding being subject to review of the technology and of the centres that are providing it. The expectation is that in many cases nationally funded centre status will be discontinued as the technology becomes well established.

Administration of funding arrangements is handled by an AHMAC reference group comprised of officials from health authorities. Each technology funded in this way is eventually reviewed by AHTAC to determine whether support from the program should continue or if the technology should be regarded in future as a superspecialty service funded by individual States.

Heart, liver and lung transplantation programs have been the subjects of a series of assessments by AHTAC under the provisions of the policy (Australian Health Technology Advisory Committee 1991-1995). Efficacy of the heart and liver transplant services has been monitored over many years, and has proved to be acceptable when survival data are compared with those from transplantation centres in other countries (Hirsch et al. 1995). Lung transplant survival data also compare favorably with overseas results, though survival has been somewhat lower than for heart and liver replacement procedures, and the performance of the centres concerned is still improving (Australian Health Technology Advisory Committee 1995).

The situation on cost data is less satisfactory, and both AHTAC and the AHMAC reference group have had difficulty in obtaining accurate, comparable information from the transplantation centres (Australian Health Technology Advisory Committee 1995). Hirsch et al. (1995) have noted that there are substantial additional costs associated with transplantation which are met from other government programs. Many discussions on costs of transplantation have been highly selective. They have ignored, for example, the cost of blood supplies which have tended to be regarded as a free good and not as an expensive and logistically demanding component. AHTAC has moved to put in place a standard protocol for specification of costs, but this has taken a long time to formulate and seems not yet easily applicable. In the recent appraisal of lung transplantation programs, one hospital was unable to apply the protocol, and estimated costs per transplant at the three centres concerned varied appreciably (\$65,090, \$86,600 and \$96,900). There do not appear to be good data on the cost to health services of supportive care for patients who do not undergo transplantation.

Under the Nationally Funded Centres policy, 1992-93 costs were set by the AHMAC reference group at \$81,440 for adult heart transplants, \$89,584 for pediatric heart transplants and \$122,160 for liver transplants. These included costs of preoperative work-up, donor organ retrieval, surgery, immediate postoperative care, the first six months' immunosuppression and patient transport and accommodation. Essentially these were 'best estimates' by AHTAC and reference group officials on the basis of limited information, and were accepted by AHMAC for the purposes of operating the programs.

The liver and heart transplantation services have now been dropped from the Nationally Funded Centres program, following reviews and recommendations by AHTAC (1994), and in future individual State governments will have responsibility for their funding. Drawing on imperfect Australian hospital data, information on cyclosporin use and costs, and a study in Québec, AHTAC has estimated that the cost of heart transplantation followed by an average of nine years post-transplant survival is likely to be at least \$160,000 (Australian Health Technology Advisory Committee 1995). Average annual cost to the health system is estimated to be of the order of \$15M if 95 patients are transplanted each year (corresponding to expected organ donation rates). Costs would increase if the average survival time exceeded nine years, and there will be additional costs through long term complications. The Committee also drew attention to the further costs that might arise through use of mechanical assist devices as a bridge to transplant. It will now be a matter for State governments to take such estimates into account when allocating future budgets, and to consider areas where there may be changes in costs.

There has been very limited Australian information on quality of life aspects, though one study reported that heart transplant recipients enjoy a high quality of life and showed no evidence of mood disorder (Jones et al. 1992). This study suggested that retraining might be necessary if the 22% of recipients who were on invalid pensions were to return to the workforce.

An issue which will continue to demand attention is the feasibility of establishing transplantation units in smaller centres of population. This has been a difficult area for less populous States. Residents of South Australia and Western Australia have been disadvantaged by being at considerable distances from transplantation units, but potential caseloads are small (perhaps ten heart and ten liver transplantations per State per year), so that the viability of units is uncertain. In the recent guidelines, AHTAC has maintained the approach taken in earlier assessments, recommending that transplantation units should not be established unless an annual caseload of 20 or more is expected.

Pancreas transplantation Pancreas transplantation in association with renal transplantation is being undertaken on small numbers (about 10 per year) of Type 1 diabetic patients with renal failure. This service is offered in Sydney under the Nationally Funded Centres policy. The decision by AHMAC to support this service was taken on the basis of advice from AHTAC which recommended that the technology should be provided at one centre only to ensure a high

level of expertise. Detailed cost data were not available for consideration. Levels of funding for the service was subsequently determined by the AHMAC reference group on the basis of cost estimates provided by the hospital.

Mitchell et al. (1993) cited per patient costs of transplantation as about \$40,000 plus \$9,000 per year subsequent to the procedure, in addition to the costs of renal transplantation. In contrast to these figures, a detailed cost study by Smith & Hall (1993) estimated an average cost to the hospital in 1993 of \$98,397 per patient transplanted, based on a predicted patient throughput of 14 with 10 actually proceeding to transplant. Some account was taken of this work by the AHMAC reference group, but the funding actually approved under the Nationally Funded Centres policy was of the order of \$60,000 per patient for a throughput of 14 per year. The decision on costs seemed to reflect officials' views on the level of hospital overheads that were justified, and a bargaining process between representatives of different jurisdictions. Funds were committed without much consideration of economic analysis.

Mitchell et al. (1993) note that the high costs of pancreas transplant compare with an annual cost of about \$300 per patient for insulin and that ultimate assessment of cost effectiveness will depend on demonstration of prevention of complications and of decreased mortality.

Overview. Hailey (1995) has commented that the impact of health technology assessment in treatment of end stage renal disease has been limited to date and that the influence of the guidelines prepared by AHTAC will depend on how the suggested targets are viewed by State health authorities and professional groups. There seems to have been some movement by State governments to put in place a more efficient mix of dialysis services, in the absence of opportunities to make greater use of transplantation as the preferred option.

The assessments by AHTAC on heart, liver and lung transplantations have been successful in influencing decisions by AHMAC on services provided under the Nationally Funded Centres policy (Hirsch et al. 1995). AHMAC accepted all the recommendations put to it by the advisory body. Decisions on the budgets for these services have drawn heavily on the advice given in the various assessment reports. However, economic input has been limited, and continues to have a rather minor role in the formulation of more recent service delivery guidelines. The quality of cost data available to the national advisory body has generally been poor. It has taken a long time to put in place a standard protocol for cost collection by hospitals and this is still not fully implemented.

Decisions on transplantation services have typically been driven by considerations other than cost effectiveness. Governments continue to be sensitive to taking 'hard' decisions on treatments for conditions which will be fatal, and perhaps rather publicly so, if not treated. 'Trial by media' has been a real influence over some years. One perception is that this climate may start to change as governments continue to confront issues of rising costs of treatment and widening demands on budgets, and allocative decisions become more pressing.

Screening for breast cancer and cervical cancer

Impetus for economic appraisal in these areas was related to the fact that they were new and expensive programs, and that there was particular sensitivity in government to possible inappropriate use of screening technologies. These large initiatives in women's health were likely to need substantial resources, and there was pressure to minimise any cost inefficiencies, which were evident for existing services.

Breast cancer screening Small scale breast cancer screening services were established in Australia during the mid-1980's. Between 1984 and 1988 use of mammography services increased in all age groups, but women over 65 made least use of them although the death rate associated with the disease was highest in that group (Australian Health Ministers' Advisory Council, 1990a).

In 1988 AHMAC established a National Breast Cancer Screening Evaluation, which drew on a number of pilot projects based on some established screening services, and included a detailed economic assessment. The evaluation took account of strategies used in other countries and of concerns at 'de facto screening' (opportunistic examinations, usually under Medicare, without regard to the age of the woman, full history or the interval since the last mammogram).

Estimated annual reduction in deaths from breast cancer if a screening program were introduced ranged from 13% with a participation rate of 55%, to 23% if all eligible women participated. Cost per life year gained was estimated to be between \$6,600 and \$11,000, a range which suggested that a screening program appeared to be good value for money, on the basis of comparison with the costs and benefits of other health care interventions. A sensitivity analysis showed that this result was reasonably robust. It also compared favorably with results for programs in other countries and was clearly superior to a de facto screening scenario (Australian Health Ministers' Advisory Council, 1990).

The committee conducting the evaluation recommended, on the basis of both scientific and economic evidence, that mammography screening be introduced and made available to all eligible women. The program should select women on the basis of age alone. Mammographic screening should be made available for women aged 40 years and above, but recruitment strategies should be targeted at women aged 50-69 years. Screening should be made available as widely as possible to women in the target group with the intent of re-screening them every two years.

The report considered that an organised program would be acceptable to Australian women, could match cancer pick up rates from elsewhere and would be cost effective. It recommended careful monitoring and evaluation of any screening program and stressed the need for good quality control. The assessment also considered quality of life aspects and the need for appropriate counseling, noting the problems for women who have false positive results.

There are important practical and ethical issues in addition to such cost-effectiveness considerations. Although evidence of benefit from screening women who were less than 50 was poor, the introduction of a screening mammography program which excluded women aged 40 to 49 would encounter the practical difficulty that women in this age group would obtain mammography outside the program. Since such mammography could lack many of the features required of a national program, for example a high standard of quality control, it would probably be less effective.

Economic aspects of breast cancer screening have subsequently been considered by Carter et al. (1993). Their analysis also suggested that screening all women aged 50 to 69 every two to three years is reasonable value for money. For women aged 40 to 49 the mortality benefit and cost-effectiveness is less clear, and they suggested it would be prudent to allow, but not actively pursue, screening in this age group until further evidence was available.

Almost all the recommendations made in the assessment report were accepted by AHMAC. The machinery of appraisal involved a process of scrutiny and discussion within the Commonwealth Department, and subsequent negotiations with States and Territories and professional groups on organisational and cost aspects. In March 1990 it was announced that the Commonwealth would contribute \$64M over three years towards establishment of a national program. By 1993 all States and Territories had made commitments to population-based screening for eligible women. The national program fully funds screening and assessment services through to confirmed diagnosis of breast cancer and is independent of the Medicare Benefits Schedule.

Monitoring of the program has been undertaken by an evaluation committee which provided its first report to the national advisory body at the end of 1994 (Department of Human Services and Health, 1994). The review process included a cost study (Carter & Cheok, 1994) to determine whether the funding approach was still appropriate and to estimate the costs of services in remote areas that were not considered in the original assessment. The authors

stress the importance of keeping the cost analysis in perspective, noting the need to keep in mind equity and effectiveness objectives when considering the cost performance of various screening centres.

The cost analysis indicated that funding for screening units in urban areas seemed sufficient, but that centres that provide screening services to rural and remote areas of Australia were underfunded by about \$20 per woman screened. These results were based on examination of currently used mobile screening services and did not include other, possibly more cost effective options for providing services in remote areas. The report has also listed a number of issues, for example staffing policies and approaches to remote film processing, where consideration needs to be given to cost effectiveness. The recommendations from the cost study were accepted by the coordinating committee, and AHMAC, and have been picked up in second triennium of program funding.

Evaluation of the national program is continuing, with input from health economists, but there will now be a greater focus on process and outcome measures, following the earlier emphasis on establishment of infrastructure. Tasks will include developing better links with cancer registries and improving data collection.

The relatively low rates of recruitment nationally remain a concern. The phase one evaluation report recommended that mammography utilisation under Medicare should be given a high priority in the next phase of the evaluation. The report mentions that preliminary analysis of Medicare data suggests that claims for bilateral mammography peaked in 1992/93 and appeared to be declining in 1993/94. However, data that have become available since the report was completed indicate that in fact there was a small increase in Medicare-funded mammography services between 1993/94 and 1994/95. As much of the Medicare expenditure seems likely to be in respect of de facto screening, it appears that there is still some way to go before the national program has as prominent a place in breast cancer screening as is intended by governments.

Outcomes from the screening program will take some time to become well defined, though an interesting early indication is that in New South Wales there has been a moderately strong shift to detection of smaller tumours and localised disease in 50-59 year old women, compared with earlier age groups and with other types of cancer (Kricke et al, 1995).

Cervical cancer screening Assessment of cervical cancer screening in Australia has followed a similar path to breast cancer screening. A major evaluation, funded by AHMAC (Australian Health Ministers' Advisory Council, 1990b), looked closely at an existing technology and made recommendations based in part on economic evaluation, which set conditions for a national program.

The economic analysis indicated that the cost estimates for an organised approach to cervical cancer screening compared favorably with the current approach. This was largely because of savings stemming from the adoption of a two or three yearly screen, compared with annual screening. Cost per life year saved using the proposed approach was estimated as \$30,782, compared with about \$45,000 under the then current arrangements. Comparison was also made with published data on the cost effectiveness of other types of interventions.

The AHMAC evaluation committee estimated that 700 to 750 cervical cancers were prevented each year, using existing services, at a cost to the community of \$165M. There was the potential to prevent a further 700 cancers a year through improvements to screening and follow up. Areas of difficulty included program design, recruitment, quality assurance, interval and age of screening, and the proportion of women receiving further investigation.

The committee drew attention to the increase in marginal costs per life year saved in going from a three year to a two year screening interval. However, while a three year interval was considered optimal from an economic perspective, two year screening was recommended so as to "... balance considerations of cost effectiveness and acceptability to the medical community and to women. Without this acceptability, it is unlikely that the very

significant gains in cost effectiveness of moving from an annual interval to a two year interval, would be achievable" (Australian Health Ministers' Advisory Council 1990b).

The committee also discussed the large marginal cost per additional life year saved (\$767,777) if the 18-24 year age group was included in a screening program, but nevertheless recommended that commencement age for screening should stay at 18 years, or within one year of first intercourse, whichever is later. This was linked to a recommendation that there should be informed public debate on the issue with a view to achieving a consensus on a possible later commencement age. The assessment recommended continuation of screening to 70 years (extending an earlier limit of 65 years derived from a consensus conference) noting that inclusion of the 65-69 year age group might result in additional 124 cancers detected per year and would improve the cost effectiveness of a national program.

Other major subjects of recommendations were performance of pathology laboratories, organization of registries and options for follow up of minor abnormalities. Comment was made about the need to increase the rate of recruitment.

The report was accepted by AHMAC and funding made available for a national screening program, with coordination through a unit within the Department of Human Services and Health. Consideration of the economic assessment and its implications was undertaken within the Department and in consultation with other jurisdictions and professional and consumer groups.

As with the breast cancer screening program, the cervical cancer initiative has been subject to further appraisal. A follow up inquiry (Rome 1993) made further recommendations on screening standards, and also requirements for registries and histological follow up. However, concerns at quality of testing remain, and development of standards for cytology services has been greatly delayed. Registry linkage is taking a long time, with some States yet to commit funds and having concerns regarding privacy provisions.

A detailed cost study of management protocols for women with abnormal smears was undertaken as part of the ongoing review (Braggett et al. 1993). Costs were determined from the perspective of government as the financing authority for the program. Costs to women and their families, and outcomes of the different management options, were not addressed. This work was therefore not a cost effectiveness study, unless it is assumed that outcomes are equal under the different options, in which case it could be regarded as a cost minimisation study from a financial authority perspective. The most expensive option was an 'active/ active' approach (immediate colposcopy plus biopsy and subsequent observational management), though this was only 5.5% higher than the least costly option of management by repeated smears until treatment is necessary. Cost of management of abnormalities detected in women under 35 years of age is about twice that for management of women older than 35,

This cost analysis probably helped the decision process, though the differences revealed were not dramatic, and clinical considerations were probably more important. Also, there is still a lack of knowledge as to real cost factors in routine clinical practice, with some feeling by the Department that an empirical study will be needed.

Braggett et al. also considered newer technologies developed as potential replacements for the Pap smear test. The evaluation indicated that most of these were still developmental and that their inclusion in the national program would increase costs for limited gains in reliability. This advice was accepted by the program coordinators.

The recommended interval for Pap tests is currently set at two years. As implied in the original assessment, this is something of a compromise, which evolved out of discussions held between health authorities and the medical profession after completion of the evaluation. The finding that a three year screening interval would be most cost effective. prompted fierce debate, with the Australian Medical Association pressing for a one year interval. There is

some feeling in the Department of Human Services and Health that it would be desirable to go to the three year interval, but that this is likely to be unrealistic on political grounds, given pressures from the medical profession and growing concerns at litigation. The recommendations on age of screening remain the same, and there has been no attempt to raise the minimum recommended age.

An analysis of Medicare data (Dankiw, 1994) has shown that age-specific rates of screening remain high for the 20-24 year age group and significant for women under 20. Short intervals between tests are seen also in other age groups. As indicated in Table 6, almost 22% of women participating have an interval of 12 - 18 months, only a small decrease since the start of the national program (many of the tests with an interval of less than 12 months would be due to repeat exams because of failed sampling). A factor driving this pattern is the current open ended nature of Medicare reimbursement. There are no restrictions on numbers of tests for which a benefit will be paid; possibly modification of referral patterns would be achieved if women had to pay full costs of tests at intervals of less than two years. It is interesting that in this case the Commonwealth Government has been unwilling or unable to apply this most obvious policy instrument.

There have been small increases in the proportion of women over 60 years of age in the screening program, while the proportion in youngest age groups has dropped slightly (Table 7). Overall participation rates remain low.

A recent Danish analysis (Gyrd - Hansen et al. 1995) has reached similar conclusions to the earlier Australian study regarding the interval and age groups for screening and the benefits through increasing participation rates. The indications from cost effectiveness analysis are quite clear, but may not readily be translated into practical programs. The reality in Australia seems to be that patterns of practice have a big influence on ages and intervals of screening, with women in younger age groups being frequently seen by their GPs and others on matters such as contraception. Women may well be given advice on screening and opt to stay in a routine with frequent tests. Also, particularly given recent publicity, GPs may be nervous at deferring exams because of anxiety at possible litigation should an abnormality subsequently be detected.

Table 6: Interval between Pap smears in screening services

Interval, months	Per cent of all women screened		
	1987/ 88	1990/ 91	1992/ 93
< 12	18.4	23.0	19.7
12 - 18	18.9	22.5	21.7
19 - 36	25.0	22.0	29.9
> 36	37.7	32.5	28.7

Note - a) Medicare data
b) National program commenced in 1990/91
Source: Dankiw, 1994

Table 7: Age distribution of women having Pap smears

Age group	Cancer incidence, per 100,000	Per cent of women screened	
		1987/ 88	1992/93

15 - 19	0.6	5.0	4.1
20 - 24	2.6	13.4	12.3
25 - 29	9.8	17.9	14.8
30 - 44	20.7	42.2	42.4
45 - 59	19.5	17.0	20.4
60 - 64	22.2	2.8	3.5
65 - 69	31.5	1.7	2.5

Note: Medicare data

Source: Dankiw, 1994.

Overview. Australia's experience with breast and cervical cancer screening provides good examples of policy and programs being influenced by economic assessment. It is interesting that substantial resources have been committed to assessment of older, well established technologies. Cost effectiveness analysis provided assurance that the proposed programs were realistic, and gave a useful framework for program parameters such as age and interval of screening. However, the success in influencing policy areas was somewhat qualified by the need to gain acceptance by the medical profession and other groups. Practice conservatism and consideration of other factors by doctors and their patients seem to be affecting the operation of the national programs, particularly in the case of cervical cancer screening.

Magnetic resonance imaging

Policy on the introduction, distribution and use of magnetic resonance imaging (MRI) in Australia has been strongly influenced by health technology assessment, which has included some consideration of economic aspects. Most of this linked activity was associated with the assessment program put in place when the technology first became available in the country. There have been few subsequent evaluation initiatives.

Australia's program for introduction and evaluation of MRI had its origins in a synthesis report by NHTAP (National Health Technology Advisory Panel 1983), which recommended that MRI should be assessed before any widespread diffusion was contemplated. This position was accepted by governments and funds made available for evaluation. This support for rational introduction was prompted to some extent by concerns at the level of use of CT scanning that had developed.

The study was carried out at five public hospitals which collected cost data according to a defined protocol; a minimum data set, completed on every patient, which included radiologists' assessment of the benefit of MRI at the time of examination; and more detailed follow up studies on selected groups of patients to assess the usefulness of MRI in diagnosis and management of specific conditions (National Health Technology Advisory Panel 1990, Hailey & Crowe 1991).

Apart from giving basic process detail, such as time of examination, the minimum data set was useful in providing indications of usefulness of MRI, and a notable result was the high diagnostic yield achieved. Overall, 63% of head and 73% of spinal examinations showed abnormal pathology, reflecting the casemix in the teaching hospitals and a policy of specialist referral of patients. The combined clinical experience from the assessment led to a consensus statement on the place of MRI in Australian health care, which considered over 40 specific applications of the technology (Australian Health Technology Advisory Committee 1991a).

An example of the more specific clinical studies which gave indications of the efficacy of MRI is that reported on 2,810 consecutive examinations in Sydney (Sorby 1989). The accuracy of MRI in a number of conditions was

considered in detail and clinical impact assessed on the basis of opinion from referring clinicians. Impact of the technique was apparent in 104 cases where surgery was avoided; 55 where invasive procedures were avoided; 151 where MRI led to surgery or improved surgical planning; and 175 where a correct diagnosis was established after incorrect results from CT or other tests.

A study in Perth considered follow up of 1,119 consecutive patients who had been referred by specialists for imaging of brain or spine (Hailey et al. 1993). MRI made a dominant contribution to final diagnosis with neoplasia and vascular disorders but was less significant for white matter disease, including multiple sclerosis. MRI affected patient management in a high proportion of spinal examinations and in cases of cerebral neoplasm, with less contribution of the cases with cerebral vascular disorder and white matter disease. Subsequent experience at the hospital is that for some cases, such as pituitary neoplasm and suspected acoustic neuroma, MRI has replaced older types of tests and is not additive to them.

The costing approach used and the results obtained have been summarised by Hailey & Crowe (1991). Components included were costs of depreciation on site and equipment, salaries and allowances, maintenance, consumables and indirect hospital costs. Annual costs varied appreciably between the five units (\$1.08M to \$1.82M), reflecting differences in equipment prices, varying policies on staffing and different requirements for maintenance. Scans performed annually per staff member varied from 256 to 515, the range reflecting differences both in numbers of staff and routine hours of operation. The NHTAP noted that it would be desirable to consider a standard approach to the staffing of MRI units (National Health Technology Advisory Panel 1990).

In reviewing the cost data, comment was made on the need to consider approaches to the replacement of equipment (Hailey & Crowe 1991). Points noted included the expected decrease in capital cost of MRI scanners, the potential for longer depreciation cycles for some types of equipment and the need for both software and hardware upgrades to maintain state of the art imaging capability. Such upgrades might cost up to \$1M over a ten year period.

NHTAP noted that the data from the study gave a broad indication of the cost of MRI examinations in a public hospital setting, in the circumstances of an assessment program using particular types of equipment. Further detailed consideration would be needed to estimate realistic costs of MRI examinations in other settings, or with newer types of equipment.

Some indications of the potential cost effectiveness of MRI could be gained from the trial data when applied to selected areas of use. Table 8 gives data for costs associated with diagnosis of six conditions for which MRI was known to be particularly promising. In the judgement of the radiologists in the study, availability of MRI would produce savings through eliminating the need for more invasive alternative examinations and associated need for hospitalisation. The cost data used drew on results from the trial and the levels of reimbursement under Medicare for other types of services. Overall, use of MRI would result in savings, when investigation of these conditions was considered.

Table 8: Estimated hospital costs for investigation of certain conditions, with and without MRI ¹

Suspected condition	Number of cases	Cost without MRI, \$` 000	Cost with MRI, \$` 000	Saving if MRI used, \$` 000
Acoustic neuroma	217	89	146	(-) 57
Syringomyelia	552	638	388	250
Cavernous hemangioma	163	173	110	63
Posterior fossa tumour	676	391	454	(-) 63
Pituitary adenoma	199	240	134	106
Cervical spinal myelopathy	118	84	79	5
Temporal lobe epilepsy	340	241	229	12
Totals	2,265	1,856	1,540	316

1. Cases from five teaching hospital MRI units over one year, representing 21% of caseload

Source: Crowe and Hailey, 1989

There are some obvious qualifications to be made in regard to such estimates. Firstly, the projected savings would only be achieved if MRI did in fact replace other diagnostic methods, rather than being used in addition to them. Also, even in a teaching hospital environment, examinations for these conditions were responsible for only 21% of the caseload. Comparative costs of this nature would have been less favorable for other types of exams.

Following recommendations made by the Panel (National Health Technology Advisory Panel, 1990b), governments agreed on a policy to develop a network of teaching hospital MRI units in centres with major neurosurgical responsibilities. Essentially, policy areas accepted the view of the Panel that MRI was now established as a useful diagnostic technology in many examinations of the head and spine. The initial conditions for funding and use of public sector MRI units drew on the cost data derived in the assessment and on the consensus statement and other material relating to the types of examination for which MRI was seen to have a comparative advantage.

Numbers of units, their placement and budgetary details were then settled in negotiations between health authorities. Decisions on placement of additional MRI units in the public hospital system have been made by State governments on the basis of apparent clinical requirements, general increases in caseload and the role of the hospitals concerned as leading institutions in the regions where they are located.

A further short study considered the role of gadolinium contrast media in MRI examinations (Hailey & Crowe 1992). Assessment of available data indicated that effectiveness in terms of influencing patient management and outcome were inadequately defined, but it was considered that the contrast material would be helpful in 20 -30 % of examinations in teaching hospitals. A problem solving approach would be needed if gadolinium was to be used efficiently. Annual national costs might range from \$0.4M to over \$10M after further diffusion of MRI, and there might also be increased costs to services (perhaps 1-5%) through increased length of examinations. It was suggested that an assessment of the cost effectiveness of gadolinium - enhanced MRI would be desirable.

The advice on the usefulness and costs of the contrast material were picked up by the Department of Human Services and Health and incorporated into the funding arrangements for public hospitals. However, no support was forthcoming for a cost effectiveness study.

The initial decisions on levels of funding for the public sector MRI units drew on the cost data obtained in the assessment. Subsequent variations to funding through grants provided by the Commonwealth appear to have been made on the basis of notional global budgets and negotiations between officials, rather than on any evaluative basis. A feature of the present arrangements is that funding is provided on the basis of 3,500 examinations per year at each unit. As hospitals receive no additional funding if they carry out further exams, there is a disincentive to operate MRI units at maximum efficiency. The policy appears to be linked to concerns regarding local budgets, and sparring between different levels of government, rather than on rational application of evaluation principles. The arrangement are seen by some States as unduly inflexible, as at present it is not possible to enter into contracts with private radiology for the provision of services. Thus, public patients in northern Queensland would have to travel a considerable distance to the nearest public hospital facility rather than being eligible for State-funded examinations performed at a private unit.

Following one of the recommendations by NHTAP, the public hospital units have routinely collected data on numbers and types of services and provided these to the Commonwealth. However, such data appear to have been used purely for audit purposes in the context of the funding arrangements and there has been no attempt to link this information to further evaluation.

At the time of writing, government funding remains channeled only to public sector units and reimbursement is not available for further services provided by private radiology. In terms of future involvement of private radiology there is something of a policy gap. For a time limited numbers of 'overflow' cases from public hospitals were performed at designated private units with government funding, but these arrangements have now been tailed off.

Despite the policy on limiting government funding to support of public sector services, the number of private radiology MRI scanners have increased substantially since the end of the assessment (Hailey and Crowe, 1993). For most private units caseload has been limited and dominated by workers' compensation cases. By early 1992 there were 7 public and 16 private units in Australia or 1.3 per million population - a somewhat lower proportion than those in several European countries but now increasing to perhaps 48 units (2.7 per million population) by end 1995. There is concern in policy areas that the proliferation of MRI could eventually lead to provision of services that are not cost effective and that much of the spread of the technology will have been outside the immediate influence of health authorities.

Future policy may be informed by an assessment by AHTAC that is currently in progress, though this is focusing primarily on clinical indications for MRI examinations and does not have economic evaluation as a main focus. The Royal Australasian College of Radiologists is also sponsoring an independent review of the technology, in which economic issues will be considered.

Overview. Though there was no formal cost effectiveness analysis, the cost and efficacy data and their analysis in the original assessment of MRI were highly influential in determining policy on the initial support for the technology in Australia. The assessment was useful in setting the 'starting conditions' for the new technology (Selby Smith et al. 1994). The assessment permitted a relatively structured approach to the 'first impressions' phase for an imaging technology, where there will be a need to make an early choice of promising potential applications which have some comparative advantage relative to other technologies (McDonald & Hailey 1995). The assessment has continued to be useful as source material through the first few years of operation.

Unfortunately, there has been no follow up to further establish the place and cost effectiveness of MRI, as was suggested in the assessment reports. The proposal by NHTAP for development of a data base on the evolving role of

the technology has not been realised, and an opportunity to build on the useful start made with the original assessment has been lost.

There still seems a reluctance by governments to commit funds to evaluation of diagnostic imaging technologies, even though their use and benefits in routine application remain poorly defined, and cost to the health care system through Medicare and public hospital budgets is around a billion dollars a year. Health authorities have seemed more generally concerned with managing budgets as best they can in balance with usually non-quantified demands from the medical profession. It is noteworthy that CT scanning, the technology that triggered earlier concerns and was a factor in the development of health technology assessment initiatives, continues to diffuse widely with little evidence of cost effectiveness. A call by NHTAP for a study to determine the use, costs and benefits of that technology were not heeded. There are now over 370 scanners in Australia (20.6 per million population).

Possibly the position of the policy areas is linked in part to the difficulties of evaluating diagnostic imaging technologies. There are still comparatively few studies which have addressed the influence of versatile imaging methods such as MRI on patient management decisions and health status. There continue to be methodological problems in defining outcomes and in incorporating information on how imaging methods are actually used in the algorithms of patient management. There is also a need for debate on how available measures of management impact, including quality of life considerations, can be presented so as to usefully influence the policy process (McDonald & Hailey 1995).

Shock wave lithotripsy

Renal lithotripsy. The introduction of extracorporeal shockwave lithotripsy (ESWL) in Australia was closely associated with an assessment by the National Health Technology Advisory Panel (1985). This was one of the earliest of the Australian health technology assessment initiatives, and included some consideration of expected costs and benefits. The impact of this and subsequent assessments at the Federal level has been briefly reviewed by Selby Smith et al.(1994).

The assessment was requested by government as a result of pressure from urologists for introduction of ESWL and was completed prior to the arrival of the technology in the country. The NHTAP assessment compared lithotripsy with open surgery and percutaneous nephrolithotomy. In addition to considering costs of treatment, the assessment report discussed impact on patients and families in terms of loss of income and other disruption to normal lifestyle and noted the possibility of future developments, including cheaper forms of the technology.

The Panel derived estimates of cost of treatment at different patient throughputs, and noted the substantial efficiencies that would be gained if these were in excess of 1,000 patients per year. Experience at the first ESWL units in the USA indicated that such caseloads were readily achievable. On that basis the estimated caseload for Australia of around 3,000 per year could in principle be met by two or three machines. There were clearly disadvantages for patients from the smaller States if the machines were to be located in large centres of population. If two machines were placed in Sydney and Melbourne, location of a third unit in a smaller State would avoid some transportation costs and inconvenience, but the equipment would probably be underutilised. The need for provisions for appropriate patient referral and transport were suggested. Table 9 summarises the cost estimates derived for different treatment options, which suggested an advantage for the new technology.

Table 9: Estimated costs of treatment of renal stones

Technology	Cost per treatment, \$	Savings per treatment through
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			earlier return to normal activity, \$	
	Low	High	Low	High
ESWL, 1,000/ year	3,390	4,605	836	1,003
ESWL, 1,400/ year	3,130	4,200	836	1,003
Percutaneous nephrolithotomy	2,975	3,300	428	501

Source: National Health Technology Advisory Panel, 1985

The assessment directly influenced policy development by Commonwealth and State health authorities, leading to the installation of two public sector machines in Sydney and Melbourne, funded through government grants. No reimbursement was available for private treatment. Apart from a private practice machine in Sydney, there was no further procurement of the technology until 1990. By then, capital costs had started to fall, with various machines becoming available. Also, the hospital stay associated with ESWL treatment was decreasing. The smaller States gave consideration to procurement of lithotripters and there were some further purchases in the private sector. A factor influencing the smaller States was that patient transfer arrangements to the existing units remained imperfect and expensive.

An example of evaluation of this technology at the State level is the study by Harris (1989) in Western Australia. This was commissioned by the Western Australian Department of Health to inform the decision on whether it would be appropriate for this small State (population 1.3 million) to acquire the technology. The time and expense for patients to travel to centres on the Eastern seaboard was an important consideration.

Hospital discharge data and literature sources suggested that the caseload for ESWL in the State should be no more than 320 per year. Two scenarios were developed, using different capital costs for the machine, as the major cost component. ESWL was more expensive than current treatment under either scenario, but would be capable of making cost savings if favorable assumptions were made about the number of bed days saved by the new treatment. These assumptions were that current techniques were associated with a hospital stay of 7 days and that there would be one day stay for the lithotripsy procedure. On that basis, an annual saving of over \$500,000 could be projected.

The analysis also pointed to developing trends elsewhere to use ESWL on an outpatient basis and for capital costs to decrease as newer machines entered the marketplace. If there was not acceptance either of the 'favorable' case, or that the price would fall below a break-even value of about \$1.4M, then the ESWL regime could not be shown to treat patients at lower costs than existing methods. However, some further justification could be made through considering the benefits to patients in terms of reduced morbidity and shorter convalescence. The analysis suggested that ESWL in Western Australia could be supported on cost benefit grounds, though the results were not highly favorable. A decision was then made to procure a single lithotripter for a public hospital in Perth.

One of the keys to this action by Western Australia was that ESWL was funded from a capital works program over which the Department of Health had a large measure of control, making it easier to use objective assessment in reaching a policy decision. It is of interest that the analysis was subsequently influential in convincing a private practice in Perth that the economic case for a second machine was poor, and that claims regarding likely profits by the distributors of one type of lithotripter could not be supported.

A different option was taken by the Queensland Department of Health, which entered into a contract with a private hospital which had installed a machine. The health authority was reluctant to commit capital and other funding to a new public sector facility, or contribute to proliferation of a technology which was already in place in the State.

Current consideration by the State health authority in New South Wales relates to replacement of the lithotripter at the only public sector facility in Sydney with a new machine. Relevant issues here are the age and operating cost of the existing unit, probable savings in terms of reducing hospital stay and equity of access to the technology for patients who cannot afford private services.

At the Federal level, there has been little further economic consideration of renal lithotripsy. A Medicare Benefit was eventually set for ESWL, encouraging some further procurement by the private sector, but was apparently not based on economic assessment. The current reimbursement through Medicare of about \$500 is modest and probably a quite small proportion of the total fee charged by private facilities..

A review of options for renal stone therapy following diffusion of the technology to some of the smaller States (Australian Health Technology Advisory Committee 1991) suggested that ESWL compared favorably on a per case basis with other options (Table 10) and had resulted in annual savings to the health care system of about \$7M and a gain of 69 person years through avoidance of hospitalisation.

Table 10: Comparison of costs per patient of different renal stone treatments

Treatment	Cost, \$
ESWL	1,859 - 2,995
Percutaneous nephrolithotomy	3,700 - 4,740
Open surgery	4,952 - 6,062
Transurethral procedures	2,591 - 2,949

Source: Australian Health Technology Advisory Committee, 1991.

A further review by AHTAC (Australian Health Technology Advisory Committee 1993) showed that by mid 1992, ESWL use had grown to include 39% of all therapies for urinary stones, while open surgery had dropped to 7.7%. Endoscopic procedures continued to account for most of the treatments, with rates that were relatively steady, while percutaneous procedures remained as a small proportion of these. AHTAC saw ESWL ideally as being used for a higher proportion of cases, with some concern being expressed about the access of public patients to lithotripters. The following year there was an increase in the number of ESWL procedures, which were used in 46.6% of renal treatments. There was subsequently further procurement, and the number of renal lithotripters increased to 16 by mid-1994 (Australian Institute of Health & Welfare 1994b) and is currently 20.

Australian ESWL units have never managed to achieve the patient throughputs suggested in the original NHTAP assessment. In the early stages, efficiencies were limited by hospital practices and barriers to transfer of patients from other States. The numbers of machines that are now in the country imply that there is considerable over - capacity, with an average throughput of 305 patients per year for each private sector machine in 1993. From the perspective of governments, access to the technology is good, and costs to public hospital budgets and to Medicare have not risen appreciably. The burden of overcapacity appears to be carried at present by private urology practices, and could be an influence on an apparent recent trend to further replacement of endoscopic procedures with ESWL treatment.

Biliary lithotripsy. Assessment of the application of ESWL to treatment of biliary calculi also began with an assessment by NHTAP (National Health Technology Advisory Panel 1988) . This included some consideration of cost and efficacy factors compared to the standard surgical treatment (cholecystectomy) and recommended a single - centre trial prior to any further support by governments. This was considered and accepted by the Department of Human Services and Health and led to a trial at a Melbourne hospital, jointly funded by the Commonwealth and Victoria.

The technology proved to have limited efficacy, in part because the preferred litholytic agent was not available due to regulatory constraints. In a selected group of patients with symptomatic gallbladder disease and small calculi, the successful treatment rate with ESWL was 39%, and 20% of those treated eventually had cholecystectomy (St Vincent's Hospital, Melbourne 1993). Hospital data suggested that the cost of ESWL treatment per patient was around \$5,000, compared with about \$4,500 per case for open cholecystectomy and \$3,000 per case for laparoscopic cholecystectomy. However, costs of lithotripsy increased considerably (to over \$7,000 per case) if only patients with normal follow up using litholytic therapy were considered.

The technology was also considered in a cost utility analysis by Cook et al. (1993) who showed that laparoscopic cholecystectomy was unambiguously superior to both open surgery and ESWL. This study took account indirect costs and estimated ESWL treatment at \$5,100 compared with \$6,190 for open surgery and \$4,450 for the laparoscopic procedure. Laparoscopic cholecystectomy gave a gain of 2.75 HYE per 100 patients over ESWL, and open surgery a gain of 0.25 per HYE.

These assessments indicated that biliary lithotripsy was a technology with a limited role in the treatment of gallbladder disease. At the start of these studies, it was apparent that it would be applicable to a minority of patients with symptomatic gallstones, and its place subsequently become further restricted because of the rapid diffusion of laparoscopic cholecystectomy.

Policy on the technology was shaped by the interim results from the trial. The Commonwealth and State health authorities kept closely in touch with the study, with officers from policy areas participating in meetings of the project steering committee. Health authorities decided that no further support was warranted for this approach, other than for very small numbers of cases where surgery was not an option, and that such treatment could be offered on machines that were in place for treatment of renal stones. Results from the cost utility study were too late to significantly affect policy considerations, though they provided useful input to further evaluation of laparoscopic cholecystectomy.

Laparoscopic cholecystectomy. Laparoscopic cholecystectomy, a much more significant technology than biliary ESWL, was perceived very quickly both by the medical profession and the public as an attractive alternative to open surgery for most patients with symptomatic gallstone disease and diffused very rapidly.

Early results on Australian series gave indications of the potential benefits of laparoscopic cholecystectomy through shorter hospital stay, faster return to normal activities and reduced requirement for pethidine (St Vincent's Hospital, Melbourne 1993). An analysis by Street (1993) of the impact of cholecystectomy on patient costs, including those of time off work, domestic duties, leisure activities and carers, showed significant advantages of laparoscopic cholecystectomy over open surgery.

However, data on the costs and effectiveness of the method outside major centres remain limited and the optimistic view that emerged from the early studies requires some qualification. Cholecystectomy rates have increased by 32% over historical levels since the introduction of the laparoscopic technique which now accounts for about 85% of all procedures (Hirsch & Hailey, 1995). As a consequence of the increase in surgery rates, savings to health care programs have so far been modest (Marshall et al. 1994), though the unit cost of the laparoscopic method to health programs is lower than that of open surgery. There have been savings to patients in terms of monetary costs and days lost because of surgery. However, the estimates by Marshall et al. assume that all procedures are appropriate, which is not yet certain.

Reasons suggested for these higher rates of surgery are a widening of indications to include frailer patients who would not be candidates for open surgery; use of laparoscopic cholecystectomy to definitively resolve a medical problem rather than using conservative management; use in some asymptomatic cases; and surgery following incorrect diagnosis. These factors tend to be driven by the perception of reduced risk from the new procedure, though the real risk to benefit ratio may not be well defined. Awareness of the public about laparoscopic surgery may increase pressure for use of the new method. This situation points to the need for economic evaluation to consider the overall impact of a technology on the health care system.

Assessments of laparoscopic cholecystectomy provided much useful data but seem to have had little influence on government policy or to the introduction and initial use of this procedure. However, the assessments may have been valuable in raising issues for consideration and resolution by users of the technique. Action by professional bodies, and hospital administrators, in part informed by assessment, have been more significant than that by health authorities.

While laparoscopic cholecystectomy is now widely used, diffusion of other laparoscopic surgery methods has been more modest. Hirsch & Hailey (1995) have noted that uptake of most laparoscopic methods has been influenced by considerations of effectiveness compared with open surgery, competing minimally invasive therapies, and the inconvenience and cost of technical change.

Overview. The initial assessment of renal lithotripsy successfully influenced policy formulation and helped set conditions for the initial use of the technology in Australia. At the Federal level, evaluation has had a less obvious influence subsequently. Assessments by State authorities were useful in informing local decisions on development of lithotripsy services.

Assessment of biliary lithotripsy helped to achieve a controlled introduction of the technology, but it was the process of the evaluation (and the arrival of laparoscopic cholecystectomy), rather than the results, that were of most importance. Nevertheless, a coherent process for assessment was put in place with a conditional link to government funding. The process permitted collection of Australian primary data, probably prevented additional unwarranted use of the technology and made possible economic and qualitative research studies which will be useful for future assessments.

Economic and other assessment of laparoscopic cholecystectomy has had little apparent influence on government policy, with diffusion and application of this technology being driven by other influences. It may be that responsibility for determining appropriate applications of laparoscopic surgery and establishing facilities will lie more with professional bodies and local administrators than with central health authorities. Some of the information obtained in the Australian assessments seems to have been helpful in informing the position adopted by the Royal Australasian College of Surgeons.

Cardiac pacemakers

Recent guidelines on acute cardiac interventions prepared by AHTAC (Australian Health Technology Advisory Committee 1995a) include short sections on pacemakers which consider level of use and projected future caseload. There appears to have been no other assessment in Australia which has considered this technology, other than in terms of safety issues. This is an example of a significant technology whose level and mode of use have been driven by clinical imperatives and regulatory concerns on safety, rather than by economic appraisal.

Provision of pacemakers is the responsibility of individual regions within State health services. There is unlikely to be any significant consideration of economic aspects of the technology unless there are major changes either to the unit

costs or to the numbers being implanted, in which case central offices of State health authorities would become involved. AHTAC has estimated that current annual growth rate for pacemaker implantation is of the order of 5 - 10 % (Australian Health Technology Advisory Committee 1995a). This is about half that in the USA and potentially there might further growth with consequent impacts on budgets. Potentially, this is the sort of technology where assessment at the local level could be a very useful means of assisting decisions on provision of essential services.

Economic appraisal of another technology for acute cardiac intervention, the implantable defibrillator, was undertaken to provide advice on the implications for this high cost device at an early stage of its diffusion and use in Australia (Cowley et al. 1992). A modeling approach was used, drawing in part on data from other countries. Estimates of cost per life year saved in comparison with medical therapy were made for a number of scenarios. Results suggested that the cost of the technology was acceptable if it significantly reduced the mortality rate. It was noted that there was potential for much wider use of the technology in Australia.

The AHTAC guidelines (Australian Health Technology Advisory Committee 1995) indicate that use of the technology has grown slowly to about 125 procedures in 1992/93 and is well below potential demand. Limited hospital budgets were seen as the major constraint. The impact of the cost effectiveness analysis on policy was probably limited, though as an 'early warning' evaluation exercise it may have assisted decisions on support for further studies (Selby Smith et al. 1994). As with cardiac pacemakers, policy and program decisions on the implantable defibrillator remain at the regional and institutional levels.

Discussion

The health technologies considered in this paper differ considerably in their range of application, location, method of support and administration, and in regard to other factors which may affect their use and applicability (Table 11). Cost effectiveness analysis is applicable to all the technologies as a valuable input to the synthesis process that is the mainstream of health technology assessment, and as a tool to inform policy and program decisions.

Table 11: Extent of application of technologies and other factors affecting policy and practice

Technology	Program/decision area	Size of patient population	Other significant factors
Pharmaceuticals	Government subsidy (PBS listing) , level of general use	Very high (Millions per y)	Broad areas of government priorities in health Public pressure
Organ transplantation	Level of funding for designated centres Siting of renal transplantation facilities	Small (heart & liver each ~200; renal <5,000)	Donor organ availability Media pressure Population distribution
Breast and cervical cancer screening	Age and intervals for screening Organisation and funding of program	High (~ 2 million/y)	Participation rates Patient and practice pressure to screen outside recommendations
MRI	Grant funding, reimbursement under Medicare Distribution/location of machines	High (and virtually open-ended) (500,000/y ?)	Practice competition Manufacturer competition Media pressure
ESWL	Grant funding, Medicare reimbursement, distribution/location of machines	Small-medium (~ 5,000/y)	Practice competition New competing technology in case of biliary ESWL, which may be overused
Cardiac pacemakers	Administration/ control at regional or local level	Small 4,000-5,000/y	Possible pressure on budgets if rate of use increases

As the examples given have shown, application of cost effectiveness analysis to medical technologies is still in a relatively early stage in Australia, and there are many other influences on the decision making process. A study by Ross (1995) gave an indication of what sort of factors are seen as useful by Australian health care decision makers. Evaluation - related input, including economic information, was seen as influential on decisions for allocation of resources, but to a lesser extent than other elements. More important factors were considered to be political (including government philosophy), existing policies, administrative feasibility, timing and equity. Perceived barriers to the use of economic evaluation included aspects of the decision making process (including the need for advice at short notice), lack of knowledge about economics, and difficulties with communication and timeliness

Some of the decisions on the technologies discussed here have been heavily influenced by considerations of local budget control, and political imperatives, rather than results of economic analysis. Buxton (1995) has pointed out that

there are budgetary, financial, managerial and political constraints on the application of economic principles to decisions on health care technologies. There are limitations to transfers between budgets, and decisions will be related to factors such as annual budget cycles, restrictions on borrowings and savings, and emphasis on containing certain budgets. Even cost-saving technologies are not automatically accepted. These factors seem very pertinent to the Australian situation, with the capacity for delays and inefficiencies in negotiations between different levels of government and between sectors. Evidence of cost effectiveness not necessarily be persuasive in the operating climate of a major government agency. One of the issues in the development of health care reforms suggested by Defever (1995) is that concern about the reduction of public deficits prevails over cost effectiveness. Again, this seems of some relevance to the Australian situation.

At an operational level, application of cost effectiveness analysis to decisions on health technologies in Australia has not been helped by changes in administrative arrangements for assessment agencies which have caused some loss of momentum. Though there has been a realistic balance between coverage of technologies, rigour and depth of evaluation, speed of assessment and available resources there still seems too little cooperation and coordination of activities between the small numbers of groups that are actively involved in this field (Hailey 1995). There is a need for a more integrated process of assessment, control, funding and monitoring of significant technologies throughout their life cycles, with wide dissemination of information. If this is to develop, there will be a need for better consultative machinery and further resources for evaluation.

The influence of economic assessment on policy will depend, among other things, on the background and interests of senior policy makers and administrators. Departure of such influential staff can and does have an adverse effect on rational use of assessment. On the other hand, there seems a growing awareness of the need for evidence-based assessments and decisions and that increasing pressures on health care budgets will dictate development of more rational business plans.

One of the keys to greater influence of economic evaluation is improved communication between researchers, policy makers and program managers. Evaluations may need, first, to be seen more frequently as a continuing process of comparison and adjustment rather than as a one off study and, secondly, be approached through a process of mutual adjustment rather than making one aspect of the relationship subservient to another (Selby Smith et al. 1994).

At present, at least at the Federal level, communication is not helped by the strong push for control of the evaluative process by policy areas and the restriction on open publication of some economic evaluations, including those related to the operation of the Pharmaceutical Benefits Scheme. The approach taken in the assessments undertaken by the National Health Technology Advisory Panel and the Australian Institute of Health and Welfare was that evaluation should make data and analysis explicit, being itself open to challenge and subject to change. This is not a view of the world that has proved popular with some policy areas.

Antioch et al. (1995) have suggested changes in approaches to economic evaluation of health technology, which need to be applied systematically if the standard of evaluation is to be improved. Economic evaluation approaches need to be selected having regard to the nature of the problem, time and resources available and the real requirements of the policy process. Many health technology assessment tasks will not require detailed economic evaluation. The precision of economic findings may not need to be great to appropriately influence decisions and rigorous analysis may not always be the most useful for policy areas. Major considerations are likely to be the time taken to produce results and the availability of hard data (factors that apply also in other areas of health technology assessment). Antioch et al. suggest that political impact will tend to be strengthened through timely publication of unambiguous findings, with a sharp focus on government agendas. They also draw attention to the need to disseminate results, including use of the mass media.

Such changes would help in increasing the usefulness of cost effectiveness analysis in evaluation of health technologies. However, it seems likely that use of the findings from such economic assessments will continue to often be influenced by a range of other technical, political and societal factors.

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