MONASH UNIVERSITY

THESIS ACCEPTED IN SATISFACTION OF THE
REQUIREMENTS FOR THE DEGREE OF
DOCTOR OF PHILOSOPHY

ON..... 5 July 2002 .....

.....[redacted].....

Sec. Research Graduate School Committee

ADDENDUM

PART A:

p.10 reference 8: a sub-title should be added to read "Evans, R. G. (1984) Strained Mercy The Economics of Canadian Health Care". Toronto, Buttersworth

p.16 second para, line three: "Figure 1" should be "Figure 2.1"

PART B:

p. 67 footnote 37: delete reference to (Olsen, Smith et al 1999).

p. 68 last line: delete "(Hodgson and M.R. 1982) and read "(Hodgson and Meiners 1982)".

p. 71 last para: Comment: the assertion that CEA neglects social justice may be seen as contentious by some economists. This issue is covered at length in Chapter Five and was mentioned briefly in Chapter Four (p. 55-56). It raises the issue of whether equity weights attached to QALYs are a feasible proposition, as well as the exclusion in CEA of considerations of social justice beyond distributional justice (i.e. who receives the QALY).

p. 72 last sentence: delete "..health status as the main objective of the health sector." and read "..a combination of health status and length of life as the main objective of the health sector."

p. 73 and p. 76: Comment: the reference to CUA as "technical analysis" may seem a little unusual to some economists, but was explained in Chapter Two (pp. 21-25). This characterisation reflects discussion in the priority setting literature where the term "technical approach" is used to refer to approaches to priority setting where reliance is placed on rational decision rules and technical data sets, rather than on the process by which decisions are taken (such as the need for stakeholder involvement; the contested nature of rationing; the role of judgement; etc).

p. 96 quotation from Mill: delete "..human being satisfied.." for "..human being dissatisfied.."

p. 100 third para: Comment: Over and above the equity rationale for government involvement addressed in this section, there is also an important class of efficiency reasons referred to as "market failures". The efficiency rationale was addressed in Chapter One pp. 2-6.

p. 102 first para: Delete reference to (Olsen 1997).

p. 200 mid page: Comment: In reference to the statement "..in normative economics the conclusions are untestable", it should be noted that the conclusions could be tested in terms of whether they are consistent with the assumptions. It is also possible to test any factual assumption. However, the transition from a positive to a normative statement requires a value judgement and this cannot be empirically or logically "tested".

PART C:

p. 216, title to Chapter Eight: insert "Selected" to read "Selected Models of Priority Setting Proposed by Non Economists". As noted in the text it would be impossible in a brief review to cover all the approaches and their various permutations.

PART D:

p. 285, first para: Comment: it may seem like a contradiction for average costs to be employed in MEEM, while criticising league tables in Chapter Nine for reporting average CEA/CUA results. As noted in the text, however, reliance on average cost and outcome data is common in economic evaluation and its validity must be considered on a case-by-case basis having regard to how heterogeneity in the illness/patient profiles is handled; the fixed cost/variable cost balance and the decision context. Further, the key problems noted with league tables from a priority setting perspective, was not their reporting of average CEA/CUA ratios, but rather their potential for methodological confounding and lack of recognition for various issues impacting on "due process".

p. 313, references: references 50-52 are all Richardson (2001). Standard practice suggests reference 50 be amended to Richardson, J. (2001a); reference 51 to Richardson, J. (2001b); and reference 52 to Richardson, J (2001c).

p. 328, second dot point: Comment: the statement that "equity weights would be used in a positive direction only" reflects a common misunderstanding. As soon as positive weights are added to the benefits received by some groups, by definition, the un-weighted groups will become negatively weighted relative to the weighted groups.

p. 340, first para, last line: the formula for calculating YLL is missing. Insert

$$" YLL = \frac{1 - e^{-rLE}}{r} - \frac{1 - e^{-rMST}}{r} "$$

p. 368, past para, second last sentence: "..can be can be..". "be can" or "can be" can be deleted!

APPENDICES:

No changes.

The Macro Economic Evaluation Model (MEEM): An Approach to Priority Setting in the Health Sector

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Faculty: Business and Economics

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Submitted: May, 2001

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Summary of Thesis

This thesis addresses the topic of priority setting in health care – that is, it analyses the ways in which choices are made about the allocation of scarce health sector resources between competing demands – and is presented in five parts. In Part A the origins, setting and context for the topic are presented. The question of whether there is a need for priority setting is discussed, together with key issues that reflect the ongoing debate about how to set priorities. While the literature reviewed in Part A suggests that the importance and need for priority setting is clearly established, the central question of how priority setting is to be achieved remains strongly contested. Parts B to E of the thesis focus on this central question of what constitutes an appropriate approach to priority setting in health care.

The thesis provides two significant contributions to the resolution of this question. First, in Part B, a checklist is developed to help identify the features of an ideal approach to priority setting. Ten criteria are developed based on four key considerations, viz: economic theory; ethics and social justice; lessons from empirical experience; and the pragmatic needs of decision-makers. The checklist represents a significant contribution to our knowledge on this subject, particularly given the current level of disagreement about the appropriate approach to priority setting. While there are well-accepted checklists to guide the conduct of traditional micro economic evaluation, there are no comparable checklists that reflect the particular decision context of priority setting, involving the assessment of multiple options for change. This thesis is the first time that criteria from such a broad range of considerations have been brought together to develop a framework for priority setting that is both realistic and theoretically sound. The needs of decision-makers are kept in focus throughout the thesis because its fundamental purpose is to develop a framework for priority setting that will be adopted by decision-makers – a framework which is broader than one which focuses exclusively on the issues considered by narrowly defined economic theory or economic orthodoxy.

In Part C of the thesis, existing models of priority are assessed against the checklist. Models proposed by non-economists are reviewed, as well as models proposed by economists. It is concluded that while there are current models for priority setting with considerable merit in relation to some of the criteria, none of the approaches reviewed perform well against all the criteria. This assessment gives added weight to the second contribution of this thesis; namely, to develop and trial a model of priority setting that satisfies all the criteria in the checklist.

The Macro Economic Evaluation Model (MEEM) is described in Part D, together with an overview of its development, potential uses and case study applications. Because problems associated with data needs are a dominant theme that emerges from the empirical evidence, a chapter is dedicated to the question of how the information needs of MEEM were made tractable. It is important to note that the major case study of MEEM was not a theoretical exercise, but rather a real priority setting problem involving the development of Australia's national cancer control strategy. The case study was subject to real time and policy

constraints and, consequently, it provided a sound basis for assessing whether or not MEEM constitutes a rigorous and sensible approach to priority setting.

The merit and performance of MEEM was assessed in two ways. First, a formal assessment is presented using the explicit evaluative criteria of the checklist. Second, an informal assessment is presented based on the reaction of those who sought the cancer control evaluation, as well as the feedback from the broader research community. MEEM performs very soundly in both assessments. The thesis concludes by noting that two further major case studies in mental health and cardiovascular disease have been commissioned on the strength of the cancer study, and that this represents an important external endorsement of the practical value and acceptability of MEEM.

Part E of the thesis contains supporting documentation explaining the MEEM approach. Appendix One provides a list of publications released during my candidature that are based on research undertaken in developing MEEM. Appendix Two provides further detail on aspects of the major case study, particularly in relation to the macro evaluation of the options for change.

Candidate Signed Statement

I hereby declare that this thesis does not contain any material that has been accepted for the award of any other degree or diploma in any university or other institution. To the best of my knowledge the thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis. I declare that I have had sole responsibiiity for the research concept and design, for the conduct of the research (except where otherwise set out in the Acknowledgements) and for the drafting of the entire manuscript.

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5/5/2001

(Robert C Carter)

5/5/2001

Acknowledgements

First and foremost I would like to acknowledge with gratitude the guidance and feedback on draft chapters provided by my supervisor, Professor Jeff Richardson. His insightful comments, patience and moral support have been a constant source of inspiration and comfort through the years of my candidature.

Priority setting can be a challenging topic, particularly when the development of a new approach is attempted that involves large data sets and a 'real life' case study. The size and scope of the research work attempted in my candidature for this thesis is such that its completion required the assistance of others, particularly in relation to the supporting data sets that fed into the MEEM approach, and the conduct of the major case study. I would like to acknowledge this assistance, particularly in the development of the cost-of-illness database (Chapter Eleven) and in the conduct of the major case study (Chapter Twelve). The details of this assistance, together with any financial assistance involved, is set out below.

The Cost-of-Illness (COI) estimates

Research for this thesis on the analysis of disease costs commenced in 1992 at the Australian Institute of Health and Welfare (AIHW). The initial work was co-funded by the AIHW and the Commonwealth Department of Health, Housing, Local Government and Community Services (as the Department was then called). I assembled a small research team to undertake the task under my direction, usually involving two statisticians and one junior health economist. The membership of the research team changed over time as the estimates and the associated methods were developed and refined. I would like to acknowledge the assistance of Kathryn Antioch, Maneerat Pinyopusarerk, Anne-Marie Waters, Lyn Conway and Ruth Penm, who were all members of that research team at various points and contributed to the development of the cost estimates.

In Chapter Eleven an overview is provided of the COI methodology (Section 11.2) focussing on the methodology utilised in the cancer estimates employed in the major case study. The brief description is based on a joint AIHW/CHPE publication (which I co-authored) released to document the methodology (Mathers, Stevenson et al. 1998). As the focus of the thesis is on priority setting, rather than COI analysis, no attempt is made to present the COI methodology in detail or to trace its development from my initial approach. A brief account of the history of the COI work is given below in order to document my contribution. References are provided to publications (many involving myself as first or co-author) where the detail of the costing approach is available.

Originally referred to as the "Macro Economic Evaluation Model (MEEM) project", COI estimates were developed under my direction for the reference year 1989/90, both in relation to direct costs to the health care system and a range of indirect costs. The MEEM project also developed a set of summary measures of disease impact in terms of potential years of life lost

(using ABS cause-deleted life tables) and health service use. I would like to acknowledge the advice and assistance of Dr Colin Mathers and Chris Stevenson with the early health outcome data sets used in first case studies. The MEEM project produced a series of reports[1] in support of the National Health Goals and Targets program (Carter and Penm 1993; Carter and Penm 1993; Carter, Pinyopusarerk et al. 1993) and the NHMRC analysis of the potential impact of various health promotion and screening interventions in clinical practice (Carter, Pinyopusarerk et al. 1993).

Following completion of these reports, I moved to the National Centre for Health Program Evaluation in Melbourne (as the Centre was then called) to pursue, amongst other things[2], the development of MEEM in a more formal way through my Ph.D. candidature. Given the important role I envisaged for the COI/BOD estimates in the MEEM approach to priority setting (refer Chapter Ten), I continued my involvement in the work I had begun through collaboration with the AIHW. Under the new leadership of Dr Colin Mathers, the AIHW project team (re-named to the "Disease Costs and Impact Study" (DCIS) to reflect the AIHW/NCHPE collaboration and my focus on MEEM) continued to develop the methodology and improve the comprehensiveness of the estimates. Work continued, for example, on a comprehensive accounting of disease costs across all chapters of the International Classification of Diseases (ICD-9) and the methodology was revised and extended to include health services accounting for over 90% of recurrent health expenditure. The revised methodology, which included new databases as they became available, was used to develop comprehensive estimates for the reference year 1993/94. A series of reports were released[3] containing the revised and updated estimates, including a report on ICD-9 Chapter Two - Neoplasms (Mathers, Penm et al. 1998) utilised in the major case study (refer Chapter Twelve).

The Major Case Study

The major case study of MEEM reported in Chapter Twelve was undertaken for the Cancer Strategies Group (CSG) of the National Health Priority Action Council (NHPAC) to assist with a review of Australia's cancer control strategy and to trial an economic approach to priority setting. It was funded jointly by the Commonwealth Department of Health and Aged Care and the Victorian Department of Health and Family Services. The detailed results have been published separately and copies are available on request from the Centre for Health Program Evaluation (CHPE) (Carter, Stone et al. 2000; Carter, Stone et al. 2000) or from the CHPE website (http://ariel.unimelb.edu.au/chpe/). The full report runs to 227 pages and is presented in summary form in Chapter Twelve, supplemented by key extracts provided in Appendix Two (Part E). The results of the case study have also been integrated into the proposed National

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[1] Members of the research team were encouraged to develop and first author associated papers for publication, viz: (Antioch, Waters et al. 1992; Conway, Pinyopusarerk et al. 1993; Antioch, Waters et al. 1995; Antioch, Waters et al. 1995; Waters, Jelfs et al. 1996).

[2] I accepted the position of Deputy Director of the Health Economics Unit, as the former occupant (A/Professor Helen Owens) had left to take up a position with the Industry Commission.

[3] See, for example, (Mathers, Penm et al. 1998; Waters, Mathers et al. 1998; Mathers, Vos et al. 1999).

Cancer Strategy, which has been distributed for public comment and feedback by the CSG (Cancer Strategy Working Group 2001).

The timing of CSG's review, together with the size of the task, required that I put together a small team of researchers to assist me in implementing the economic approach to priority setting I had proposed. The members of the research team, their time commitment, together with our respective contributions are set out below.

Members of Research Team for the MEEM/PBMA Trial

Project Director: A/Professor Robert Carter, Centre for Health Program Evaluation (CHPE). Wrote the project submission for the study and negotiated its implementation and funding. Wrote the detailed evaluation protocol for the technical analysis, directed the application of the evaluation methods, and assisted in preparation of all intervention briefing papers. Guided the Working Group (refer membership Appendix Two) through all aspects of the MEEM/PBMA priority setting process, involving a series of meetings over a nine month period. Wrote-up the trial results, including the published reports, drawing on the technical analysis contained in the intervention briefing papers and Working Group decisions.

Senior Project Officer: Ms Christine Stone, Epidemiologist, seconded from Public Health and Development Division, Victorian Department of Human Services, full-time (6 months). Assisted with the project organisation, documentation and reporting formats. Led work on the colorectal cancer screening briefing paper; the skin cancer prevention briefing paper and commenced work on the skin cancer diagnosis paper.

Project Officer: Ms Jane Hocking, Epidemiologist and Public Health Trainee on Placement, Public Health and Development, Victorian DHS, full-time (3 months). Led work on the cervical cancer screening briefing paper and commenced work on the PSA testing paper.

Project Officer: Ms Cathy Mihalopoulos, Research Fellow (Health Economics), CHPE, part-time (2 months). Led work on the two Psychosocial Care briefing papers

Project Officer: Mr. Steven Crowley, Senior Lecturer (Health Economics), CHPE, part-time (1 month). Led work on the fruit and vegetables briefing paper.

Project Adviser on equity weights: Dr Stuart Peacock, Senior Lecturer (Health Economics), CHPE. Prepared briefing paper on development of the equity weights.

Project Adviser on DALYs and @Risk simulation software: Dr Theo Vos, Public Health and Development, Victorian DHS. Assisted project staff in use of DALYs and @Risk simulation software for sensitivity testing. Assisted with preparation of the tobacco control and fruit & vegetables briefing papers

References

1. Antioch, K., A.-M. Waters, et al. (1992). Disease Costs of HIV/AIDS. 24th Annual Conference of the Public Health Association of Australia, Canberra, Public Health Association of Australia.

2. Antioch, K., A.-M. Waters, et al. (1995). Disease Costs of Tuberculosis and Syphilis in Australia. Canberra, AIHW.

3. Antioch, K., A.-M. Waters, et al. (1995). Disease Costs of Hepatitis B in Australia. Canberra, AIHW.

4. Cancer Strategy Working Group (2001). Priorities for Action in Cancer Control: 2001 - 2003. Consultation Draft - January 2001, Cancer Strategy Working Group, Commonwealth Department of Health and Aged Care.

5. Carter, R. and R. Penm (1993). The Cost of Injury in Australia. Canberra, AIHW/NCHPE Research Report.

6. Carter, R. and R. Penm (1993). The Economics of Cancer in Australia. Canberra, AIHW/NCHPE Research Paper.

7. Carter, R., M. Pinyopusarerk, et al. (1993). The Economics of Cardiovascular Disease in Australia. Canberra, AIHW/NCHPE.

8. Carter, R., M. Pinyopusarerk, et al. (1993). The Economics of Disease in Australia: Interim Report for the NHMRC Working Party on Prevention Programs. Canberra, AIHW/NCHPE.

9. Carter, R., C. Stone, et al. (2000). Trial of Program Budgeting and Marginal Analysis (PBMA) to Assist Cancer Control Planning in Australia: Full Report. Melbourne, Centre for Health Program Evaluation.

10. Carter, R., C. Stone, et al. (2000). Trial of Program Budgeting and Marginal Analysis (PBMA) to Assist Cancer Control Planning in Australia: Summary Report. Melbourne, Centre for Health Program Evaluation.

11. Conway, L., M. Pinyopusarerk, et al. (1993). The Public Health Significance of Drug and Alcohol Abuse in Australia. International Symposium on the Economics of Drug and Alcohol Abuse, Canberra, Commonwealth Department of Health.

12. Mathers, C., R. Penm, et al. (1998). Health system costs of cancer in Australia 1993-94. Canberra, Australian Institute of Health and Welfare & The National Cancer Control Initiative.

13. Mathers, C., C. Stevenson, et al. (1998). Disease costing methodology used in the Disease Costs and Impact Study 1993-94. Canberra, AIHW.

14. Mathers, C., T. Vos, et al. (1999). The Burden of Disease and Injury in Australia. Canberra, Australian Institute of Health and Welfare.

15. Waters, A-M., P. Jelfs, et al. (1996). Tobacco Use and its Health Impact in Australia. Canberra, AIHW.

16. Waters, A-M., C. Mathers, et al. (1998). Health System Costs of Cardiovascular Disease and Diabetes in Australia, 1993-94. Canberra, AIHW.

Preface

My interest in the Macro Economic Evaluation Model (MEEM) started in the early 1990's in response to a quite specific problem but has since been sustained by a number of broader considerations – particularly the sheer scale of the economic evaluation task required to make a real impact on resource allocation.

The specific problem related to a task that, at the time, I was not able to resolve to my satisfaction. I was a member of a Working Party convened under the auspices of Australia's National Health and Medical Research Council (NHMRC) to examine what advice should be promulgated to medical practitioners in the field of periodic health checks. The Working Party was attempting to develop guidelines covering screening, counselling, immunisation and chemopropylaxis based on epidemiological evidence of efficacy, together with other socially relevant criteria. The number of potential interventions numbered well over 150 and it wasn't long before Working Party members turned to me for input on how the economic credentials of the various candidates could be assessed and integrated into their report. I have been trying to answer that question (and versions of it in other policy contexts) ever since!

This thesis represents my attempts at providing a method to answer that question.
While a little late for the Periodic Health Checks Working Party, I am comforted by the knowledge that their question of how to prioritise multiple interventions in a limited time frame is still very relevant today. In fact, my major case study for this thesis (Chapter Twelve) was undertaken for another Working Party, that on this occasion, I could help in a more concrete way.

My problem in advising the Periodic Health Checks Working Party was twofold. First, many of the interventions under consideration had not at that time been evaluated from an economic perspective. The cost-effectiveness literature was (and still is) very incomplete and the epidemiological filter was not likely to reduce the interventions to a number that could be evaluated through conventional economic methods within the time and resources available. Trolling the available cost effectiveness literature provided some help, but that still left many gaps, together with a range of issues involved in utilising the "League Table" approach to priority setting (refer Chapter Nine) – particularly comparability of study methods and context.

My second problem was that economic analysis requires a comparator, with the most meaningful from a policy perspective being current practice. The available evaluation literature was focussed more on effectiveness than efficiency, and where cost-effectiveness studies were available, very few involved the Australian setting. What was required was comprehensive information on health care expenditure patterns in Australia in a form that could be related to current care patterns and options for change. Unfortunately, the information then available was not in this form. The Australian Institute of Health and Welfare

published information on health care expenditure, but it was classified by institutional setting (hospitals; nursing homes; etc) and by broad non-institutional categories (medical services; pharmaceuticals; etc), with no linkage to the diseases/conditions to which the expenditure was related. The inability to describe expenditure on current practice, even in general terms, made it virtually impossible to provide the economic advice that the Working Party needed with any level of rigour.

What was required, it seemed to me, was a new and innovative approach that was based on economic principles, but which worked at a multi-project level, rather than on an individual project level. The challenge was to develop a theoretically sound framework that was broad-based, which could encompass all pertinent interventions to the research question, but which was feasible in terms of data requirements and the research effort required. Solving this challenge gave rise to MEEM.

MEEM started life as a technical approach – i.e. focussed on decision rules and associated algorithms (see Chapter Two) – to resolve the problem of evaluating multiple interventions in the area of health promotion and/or illness prevention. The concept of benefit was based on health gain only, measured using changes in cases detected/prevented and/or mortality. Since this initial focus in the early 1990's, MEEM has evolved in a number of ways, reflecting my continual involvement in priority setting tasks – in particular Program Budgeting and Marginal Analysis (PBMA) and disease specific modeling – together with ongoing study of the theoretical and empirical priority setting literature. More specifically, MEEM evolved in four basic ways, viz:

- First, the technical specification of decision rules and the associated arithmetic was tempered by an appreciation of the importance of "due process" – that legitimacy comes from both an acceptance of the logic behind the decision rules, together with the decision-making process by which the outcomes were derived;

- Second, empirical evidence from a variety of sources highlighted the importance of judgement in arriving at sensible priority decisions, as opposed to decisions based on the automatic application of decision rules;

- Third, the narrow definition of benefit which focussed only on health gain was broadened to reflect considerations that are important to decision-makers and the general community - such as equity, importance of the problem, evidence base, and acceptability/feasibility; and

- Fourth, the initial focus on health promotion and illness prevention was broadened to encompass the complete disease pathway from prevention through to palliation.

The result of this evolution is a more robust and practical macro evaluation model that has passed the test of practical application in one major case study. While success in one setting does not establish validity in other settings, it does represent an important test of the hypothesis that MEEM meets the challenge of providing a theoretically sound framework that is broad-based, can evaluate multiple interventions, is feasible in terms of its data requirements and the research effort required, and is acceptable to stakeholders. The signs are very positive, not only from those involved in the case study and community feedback, but because two further major applications of the MEEM approach are underway in mental health and cardiovascular disease, based on the strength of the case study. The work to date does lend credence to the claim that MEEM is a valuable contribution to the evaluation toolkit.

Related to the development of MEEM, but an outcome of consequence in its own right, is a checklist of ten criteria to help answer the question: "What constitutes an "ideal" model of priority setting?" The checklist, presented in Chapter Seven, has similarly evolved and broadened to reflect my assessment of the considerations that should guide models of priority setting. An assessment of economic theory is important to provide a sound theoretical framework. An assessment of ethics and social justice is necessary, because of its fundamental importance in making normative judgements. The lessons from empirical experience and the needs of decision-makers are also important, because the fundamental purpose of a checklist is to guide the development and/or selection of models of priority setting that will be used by decision-makers. This thesis is the first time, to my knowledge, that criteria from such a broad range of considerations have been brought together to develop a framework for priority setting that is both realistic and theoretically sound.

I close this preface with the observation, that in my view, there has been a tendency for economists to have a methodological "one size fits all" approach to the variety of decision contexts that confront policy-makers – and that method has been a reliance on detailed project specific evaluation. While such project specific evaluation is undoubtedly very important, its role may have been overplayed and this may have contributed to the limited impact that economic evaluation has had on policy decisions – a problem which economists around the world have bemoaned. The essential contribution of this thesis is develop and trial an explicit "macro evaluation" approach – i.e. an approach to evaluation developed specifically for the priority setting context where multiple interventions are being assessed.

PART A: THE RESEARCH QUESTION

Chapter One: The Need for Explicit Priority Setting

"There is every reason to expect that the management of scarce resources will remain one of the defining characteristics of all health care systems." (p. 108) (Klein, Day et al. 1996)

1.1 Introduction:

The need to make choices about the allocation of resources between competing demands exists in all health care systems and is increasingly being seen as an issue of growing importance. In this chapter the importance of priority setting is examined, together with the reasons why policy-makers in a number of countries are now addressing the issue with renewed interest. Three reasons are discussed, viz:

- The rejection of the "free market" as the mechanism of choice to allocate health sector resources and the consequent need for an alternative mechanism;
- The growing evidence that the deployment of current resources is far from optimal; and
- The continued growth in health care expenditures, both in absolute terms and as a percentage of GDP.

1.2 Definitions

Before exploring these issues, it is worth pausing briefly to clarify terminology – in particular use of the words "rationing" verses "priority setting" and "explicit" verses "implicit" approaches to priority setting.

Rationing is a word whose semantic origins covey a sense of reason (i.e. same Latin rootstock as rationality) but which in practice is emotionally laden. David Hunter, for example, uses the term rationing in the sense of patients being denied effective treatments due to funding restraints, rather akin to wartime rationing (Hunter 1997). Similarly, David Hadorn argues that the withholding of care that is acknowledged to be necessary due to inadequate resources "can legitimately be called rationing" (Hadorn 1991; Hadorn and Brook 1991). This has led some authors to suggest restrictions on the way the term is used. Rudolf Klein and colleagues (Klein, Day et al. 1996), for example, argue that the word should be reserved to describe the process by which resources are allocated to individuals at the point of service delivery. The more neutral term of "priority setting", could then be reserved to describe the process of determining the budgets and their distribution to institutions and services, which constrain the decisions about care for individual patients. Joanna Coast et al. (Coast and Donovan 1996), on the other hand, seek to restrict the use of the term "priority setting" to

denote the use of explicit systems for the distribution of scarce health care resources. They argue that "while implicit choices will inevitably affect the final distribution of resources, they are not part of the process of setting priorities."

Others, such as Chris Ham (Ham and Coulter 2000), see little point in drawing such hard and fast distinctions between the terms "rationing" and "priority setting", as the terms are often used interchangeably. Certainly in the literature, the two terms are often employed synonymously to describe the variety of ways in which choices in health care are made, whether they affect individuals, communities or countries. For this reason, while I have sympathy for the various semantic distinctions proposed, Ham's position is adopted in this thesis.

Next to the distinction between "implicit" and "explicit" rationing. Implicit rationing is sometimes mistakenly equated with an absence of rationing, while explicit rationing is assumed to mean the introduction of a policy to ration health care. In this thesis, the term "implicit" is used to describe the approach to rationing where neither the decisions themselves nor the basis for those decisions are clearly expressed. "Explicit" is used to describe the alternative approach where both the decisions and the basis on which they are arrived at are clearly specified. This means that explicit rationing may encompass the technical methods that include decision rules, together with approaches that emphasise the process by which decisions are taken. This distinction between approaches that emphasise rational decision rules and those that emphasise the correct process is an important theme to emerge from the theoretical and empirical literature. It is discussed at greater length in Chapter Two. Note also that this definition of explicit is broader than that used by some authors ((Redmayne, Klein et al. 1993)) where explicit is used in the narrower sense of specifying a list of conditions and/or treatments that will not be treated and/or made available.

1.3 Rejection of the free market approach in the health sector

In the orthodox neoclassical theory of prefect competition, the free market is relied upon to answer the three fundamental economic questions that all societies must answer – i.e. what should be produced? (allocative efficiency); how should it be produced? (technical/productive efficiency); and who should receive it? (distributive equity). Economists often argue, therefore, that if there is no impediment to the free operation of markets, the market mechanism will ensure that resources are allocated to minimise opportunity cost and maximise community welfare (Donaldson and Gerard 1993). However the assumptions built into the traditional "market" model are unlikely to occur in the real world, and in health care there are reasons why markets might "fail". There is an extensive health economics literature in which the reasons for market failure in health are presented and discussed ((Culyer 1971; Sen 1977; Evans 1984; McGuire, Henderson et al. 1988; Le Grand, Drapper et al. 1992; Rice 1998; Hurley 2000)). The existence of market failure provides an efficiency rationale for government

intervention (and hence a role in priority setting), over and above any equity rationale that may motivate government action.

In recent years, there has been a surge of interest in reforming the organisation and delivery of health care systems by replacing government regulation with a reliance on market forces. This has led several economists, particularly Thomas Rice (Rice 1998), to provide authoritative reviews of the traditional market model, its underlying assumptions and applicability to health. These authors (Fuchs 1996; Evans 1998; Reinhardt 1998; Hurley 2000) have challenged in particular, the implicit assumption behind the resurgence of interest in market competition, that "economic theory" demonstrates that competition in health care will lead to superior social outcomes. They argue persuasively that the belief in the superiority of market-based systems stems from a misunderstanding of economic theory as it applies to health. Rice summarises the position thus:

> *"As will be shown, such conclusions are based on a large set of assumptions that are not met, and cannot be met in the health sector. This is not to say that competitive approaches in this sector of the economy are inappropriate; rather, their efficacy depends on the particular circumstances of the policy being considered and the environment in which it is to be implemented. There is, however, no a priori reason to believe that such a system will operate more efficiently, or provide a higher level of social welfare, than alternative systems that are based instead on government financing and regulation. This argument is further bolstered by the fact that so many other developed countries have chosen to deviate from market-based health systems." (p. 3) (Rice 1998)*

While the various assumptions behind the traditional market model can be set out in considerable detail (for example, see (Rice 1998)), their essence is as follows. Consumers and producers of goods are assumed to have perfect information about the opportunity costs and the value of the goods being produced and consumed; individual consumers and producers are assumed not able to influence price; and the benefits from consuming the goods are assumed to accrue only to the individual consumer. In short, the perfectly competitive market would be characterised by informed consumers able to effect demand, and a competitive and responsive supply system. In reality, however, there are:

- uncertainties, both in relation to the need for and the effectiveness of health care (and the insurance solution in turn poses the dangers of moral hazard and adverse selection);
- asymmetry of information between producers and consumers, which leads to an agency relationship between producer and consumer, and the danger of supply induced demand;
- externalities and merit good characteristics in health care (i.e. one individual's consumption of health care is likely to affect other individuals' welfare, either because of reduced risk of infection or harm, or because individuals have

concern for the well-being of others and health care needs can be catastrophic) ; and

- pure public good characteristics in health care that make it difficult to leave production and distribution to the free market (i.e. "non excludability" makes it difficult for markets to work, while "non rivalry" makes it unnecessary – such as environmental protection that produces clean air).

The existence of market failure means that if the allocation of health care resources was left to the market, too little of some goods and too much of others would be produced. Because the market cannot be relied on to allocate health care resources efficiently, there is an efficiency rationale for governments to intervene in the funding and provision of health care (Evans 1984; Rice 1998). Consequently, there must be some mechanism for determining how much to spend on health care and how to allocate health care resources between different services.

It is important to acknowledge, however, that in responding to market failure, governments often create impediments to the free operation of markets (such as licensing requirements that impact on freedom of entry and/or funding arrangements that bias choice). The possibility of "government failure[1]" clearly exists as the mirror image of market failure. It is quite possible that government intervention may further distort rather than ameliorate problems associated with market failure and/or that governments may carry out their priority setting tasks inefficiently. Historically, it has in fact been the need to develop tools and decision aids to assist government in making resource allocation decisions in place of the market that has given rise to the growth in economic evaluation and related decision theory oriented approaches. Thus while the presence of market failure is a necessary pre-condition to justify government intervention on an efficiency rationale, it is not a sufficient condition unless any government failure involved is less distorting than the market failure it is trying to address. In this context it is opportune that economists and policy-makers in a number of countries are addressing the issue of priority setting with renewed interest.

It also important to recognise that while "market failure" may provide an efficiency rationale for government intervention in the health sector, it is by and large not the main reason why governments become involved. Rather than pursuing efficiency, most governments intervene for reasons associated with equity and social justice. Market-based systems ration access to health care on the basis of ability-to-pay and/or people's ability to acquire health insurance. Under this system individuals are required to set and fund their own priorities. Societies generally choose not to use this system of allocation for health care – among various reasons, chief is the widespread concern that citizens have access to health care in

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[1] Sometimes referred as the "dead hand" of government in comparison with Adam Smith's reference to markets as the "invisible hand".

accordance with their needs, not in accordance with their ability-to-pay. Thus in all developed countries a form of health care insurance is made available, and in most countries there is also government intervention, albeit to varying extents, to regulate the production and distribution of health care. Having intervened initially for largely equity-based reasons, most governments would still seek to avoid and/or minimise the possibility of government failure. The dominant presence of governments in health care markets, whether for efficiency and/or equity reasons, shifts the prime responsibility for priority setting from the individual to politicians, bureaucrats, managers and clinicians; and places it on the policy agenda. Often, it must be said, important aspects of priority setting are left to doctors, and decisions shaping patient access to health services are made implicitly in the privacy of the clinician's consulting rooms. Implicit decision making, however, has come under increasing pressure in the face of resource constraints, evidence of significant small area variations in service and rising patient expectations.

1.4 Evidence of market failure

Also important to the recent focus on priority setting has been the growing perception that resources allocated to health services are not deployed in an optimal fashion. Weinberg has described this as arising from an "intellectual crisis" in the scientific basis of clinical practice – "a situation in which clinicians commonly do not know the best treatment regimen and in which clinical decisions are based on personal (doctor) preferences or inadequately justified judgements" (quoted in (Richardson 1998)).

Evidence of inefficiency has taken two main forms, viz:

- first, the compilation and publication of results from cost-effectiveness studies that suggest a significant potential for improvement in allocative efficiency (Department of Health 1994; Tengs, Adams et al. 1995); and

- second, widespread evidence of small area variation in procedure rates for the same intervention not explicable by differences in population characteristics. This evidence has been documented both within a number of countries [Paul-Shaheen, 1987 #236](Ham 1988; Leape, Park et al. 1990)[Folland, 1990 #235](Renwick and Sadowsky 1991; Richardson 1998; Richardson and Robertson 1998; Richardson, Robertson et al. 1998)[Goddard, 1998 #234] and between countries (McPherson 1990).

McPherson demonstrated that the rate at which well-defined procedures are delivered per 1000 population vary by surprising amounts between similar developed nations: 519% for hysterectomy; 579% for cholectystectomy and 431% for appendectomy (McPherson 1990). The research of Renwick and Sadkowsky (1991) and Richardson and Robertson (1998)

suggests that similar practice variations exist in Australia. These differences give strong prima facie support to the view that, relative to best practice, some populations are being significantly over-serviced, while others are being significantly under-serviced. Such evidence of inefficiency underpins the quest for a priority setting mechanism able to identify desirable resource shifts.

1.5 Controlling the growth in health care expenditure

For most governments, including those countries reviewed in Chapter Six, there is a cost containment element to their interest in priority setting. The Swedish Parliamentary Priorities Commission (The Swedish Parliamentary Priorities Commission 1995) concluded, for example, that:

> *"Prioritisation due to resource constraints has always existed and will always be necessary in the caring sector. If the issue has risen to the top of the international agenda of debate about health care it is because those resource constraints have become more severe under the twin pressures of governments seeking to restrain the growth of public expenditure and rising demand for health care as the result of demographic and other trends."(Quoted in Klein p. 100 (Klein, Day et al. 1996))*

While from an economic perspective the appropriate level of health care expenditure is essentially a matter of social choice [Richardson, 1988 #1], governments remain conscious of the taxation implications of their health policy. While there is no inevitability about the level or source of health care funding, there are nonetheless genuine reasons for concern. In the first three post-war decades the rate of economic growth in Australia was sufficiently high to support a rising trend in demand. But with the slowing of GDP growth in the 1980's and 1990's there is reason to question whether the economy can sustain a continued growth in health expenditure into the 21st century. In particular, to question whether the government can continue to underwrite an expansion of the health sector at its historic rate.

Underlying the concern over expenditure growth are a number of more fundamental developments that have a bearing on the performance of health care services. Three impacts on demand are usually highlighted (Richardson 1998; DHAC 1999a). First, there are the demographic changes, including the ageing population and the decline of the population of working age. While often overstated, these demographic changes will undoubtedly increase the demand for health care and limit the ability of health services to respond to this demand (Duckett and Jackson 1999; Richardson and Robertson 1999; DHAC 1999b). Second, advances in health care technology and medical science will also give rise to growing demands for health care services. The pace of innovation is not slowing and poses significant implications for the funding and provision of services. Third, the expectations of a more educated and informed population are rising as those who use services demand higher standards of care.

Another less discussed factor, is the productivity impact of labour intensive verses capital intensive sectors of the economy. Health care is a labour intensive industry, with approximately 70% of the health budget spent on salary and wages in most countries. It is therefore an industry where productivity tends to rise more slowly than the rest of the economy; yet salaries and wages tend to rise in line with productivity-driven increases in the rest of the economy. Hence there tends to be a persistent rise in the cost of delivering any given bundle of health care services. Investment in new health care technology may extend the limits of the possible, or improve quality, but only rarely does it contribute to a decrease in costs. Those systems with more government control over salaries and wages in the health sector – like the UK, Sweden or Australia – are conspicuously more successful in containing cost inflation than those like the United States which rely more on the free market. But the long-term trend is similar everywhere: the cost of providing any given level of health care tends to rise over time.

In a period when the scope for increasing expenditure is limited and under close scrutiny, there is a need to search for ways of using existing budgets more efficiently. Certainly, most would accept that the population cannot expect Medicare to deliver unrestricted access to all possible medical care. A related concern is the desire to ensure access to available services on an equitable basis.

1.6 Money or science to the rescue?

Most commentators, particularly economists, see rationing as inevitable. From this perspective the relevant issues are who should take the decisions about allocating resources, how they should be made and what criteria should be used. Some, however, contest the inevitability of rationing. For those of this view, an appeal is usually made to science to eliminate waste or for resolution through increased funding or to a combination of both.

The appeal for more funding reflects a view that government parsimony is to blame, that health care budgets reflect neither demand nor need, but rather a series of ad hoc political decisions. There is no magic formulae, however, which allows governments or their critics to determine the "right" or "appropriate" level" of funding (Klein, Day et al. 1996; Richardson 1998). Nor does appeal to international comparison resolve the issue. Higher expenditure in other countries may reflect a range of factors, such as higher salary and wage rates, health sector resources being used less efficiently, different disease patterns, different income levels, or different social choices. International comparison certainly doesn't support a conclusion that spending eliminates the need for priority setting or rationing. American scholars (Fuchs 1974) (Mechanic 1979), for example, were among the first to draw attention to the issue of rationing, despite the fact that the proportion of the national income devoted to health care is considerably higher than any other country. As Klein comments, "the literature on rationing speaks with an American accent" (p.99) (Klein, Day et al. 1996).

Those countries that have taken priority setting seriously enough to appoint special commissions (refer Chapter Six) all vary in the level of health care expenditure and the way in which health care is organised. Neither greater generosity in the financing of collective health care systems, nor their replacement by systems driven by individual preferences[2], can provide a way of escaping the dilemmas of collective choice. Even if more funds were made available for health care in Australia, decisions between competing claims on resources would still have to be taken. While the reality of priority setting seems independent both of the level of funding and the structure of any particular health care system, the form that it takes, the way it is perceived and the degree of visibility certainly vary from country to country.

It is also significant that developments in health care delivery systems have not obviated the need for effective approaches to priority setting. While initiatives such as purchaser/provider split, managed competition and managed care have all been introduced to promote allocative and technical efficiency, these arrangements require information from priority setting models to facilitate discriminating purchasing and utilisation of public health services. These developments in health service funding and delivery are thus complementary to, and not an alternative for, a formal approach to priority setting.

The appeal to science is made on the basis that resources are at present being wasted because they are not being used effectively or efficiently and that scarcity is therefore largely self-induced (see, for example (Roberts 1996)). In the 1980s and early 1990s the assumption was that improving management practice could eliminate waste. By the mid-1990s, however, the consequent rise in spending on management was, in itself, seen by many as an example of waste. The emphasis switched to increasing efficiency by invoking what Klein called "the new scientism" (Klein, Day et al. 1996) or more broadly known as evidence-based medicine.

In the UK, for example, health authorities were exhorted to purchase only procedures with demonstrated beneficial outcomes. Clinical practice was to be based on the systematic, scientific evaluation of the effectiveness of health care interventions. Countries around the world have focussed on the development of clinical guidelines and academic centres have been set-up to synthesise and to diffuse the results. While there is certainly an important potential in this evidence-based medicine (EBM) movement to improve resource allocation, it is important to recognise its limits. Advocates of EBM caution against having unrealistic expectations of what cost savings it can deliver. Sir John Scott, a leading medical academic in New Zealand, for example, comments that while he has been preaching the doctrine of EBM for the past 35 years he is now more realistic about the benefits (St John 1997).

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[2] As experience in the United States demonstrates, the government would still have to provide insurance for those who cannot afford to do so for themselves and there would still be a need for political decisions as to the appropriate level of funding.

There are a number of issues at stake here:

- Randomised trials are not appropriate in all circumstances and the experiential learning of the medical profession should not be too readily dismissed;
- Evidence of efficacy from well-conducted trials is not the same as evidence of effectiveness in real life settings, where interventions are applied on a mass scale by clinicians less skilled in the techniques concerned;
- Evidence about effectiveness is not the same as evidence about cost-effectiveness and does not tell us anything about allocative efficiency;
- The expectation that guidelines and protocols can be used to promote "best buy" purchasing needs to rest on a practical understanding of the professional decision-making process, including the need for flexibility in application to individual patients and the inherent variation and uncertainty in clinical practice; and
- The potential to release resources through the elimination of ineffective practices, whilst an important initiative to pursue, will not take away the need to make choices between competing uses for the available budget.

To quote the Director of Public Health of the Cambridge Health Commission in the United Kingdom (Zimmern 1995):

> *"[E]ven if purchasers were able to remove at a stroke all procedures agreed to be inefficient and ineffective, the resources released would almost immediately be consumed by the tide of unmet need for the remaining efficient and effective interventions. Thresholds for referral would drop and patients, previously shielded from the health care system by the gatekeeper GP, would benefit."*

Overall, therefore, it does not seem plausible to assume that the mobilisation of science will necessarily – or even probably – dispose of the necessity for making difficult choices in the allocation of resources. Priority setting in health care may not be new, but it is increasingly seen as an issue of growing importance. The combination of constrained resources and increasing demands has led policy makers in a number of countries to address the issue more directly than in the past. As a consequence there is a search for new policy instruments alongside the continuing use of waiting lists and clinical discretion as methods of rationing. This has led politicians and managers in a number of countries to address the challenge of rationing more explicitly by setting up committees and expert groups.

In conclusion, as Alan Williams argues, priority setting is now no longer simply a matter of eliminating ineffective health care, but an inescapable problem with important equity implications; viz:

"[T]he recent rapid growth in effective health care has led us to the point where no country(not even the richest) can afford to carry out all the potentially beneficial procedures that are now available, on all the people who might possibly benefit from them. So priority setting can no longer be a matter of eliminating ineffective activities (that is, it is now more than a matter of becoming more efficient in the low-level sense of getting on to the production possibility frontier). Priority setting now has to deal with the much more contentious high-level efficiency problem of choosing where to be on the production possibility frontier, that is, which mix of efficient activities to select from those that are open to us. This is a matter of allocative efficiency rather than technical efficiency and, inevitably, contains equity considerations, that is, views as to how the welfare of one person is to be weighted against the welfare of another person." (p.173) (Williams 1988)

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Chapter Two: Key Issues that Set the Context for Priority Setting

"There is a sense in which priority setting is what economics is all about.... If economists cannot make a contribution to the process of priority setting, it is hard to see to which other aspects of health care economists can contribute." (Mooney 1994)

"Explicit rationing sounds fine in theory – who could possibly be against it in an ideal world? But the world is not ideal. It is messy, turbulent, ambivalent, and as Handy notes, full of paradox which is 'inevitable, endemic, and perpetual' (Handy 1994)(p. 17). The trick is not to seek to eliminate paradox, but to manage it." (Hunter 1997)

2.1 Introduction:

In this chapter the key issues that provide the setting and context in which priority setting takes place are presented. These issues provide an important touchstone to reality that will be referred to in various chapters throughout the thesis. The list is drawn from the work of a number of authors prominent in the field of priority setting[3]. The key issues are:

1. Understanding the choice between implicit and explicit approaches to priority setting;
2. Recognising the importance of the different levels at which priority setting takes place in health care;
3. Understanding the debate between technical and process oriented approaches to explicit priority setting; and
4. Resolving the question of whose judgement should be included in the priority setting process – particularly attempts to consult and involve the public.

2.2 Implicit verses explicit approaches to priority setting

In recent years there have been many calls for priority setting in health care to be based on rational and explicit approaches (Klein 1995; Maynard 1996; Ham 1998). Economists[4], proposing various methods of economic evaluation have played a central role in meeting this call. At times the assumption seems to be that explicit rationing is unquestionably a good thing – implying openness and honesty, and paving the way to a more efficient, equitable and democratic health service. It is important to recognise that while explicitness has important virtues, there are also legitimate problems that need to be acknowledged. These fall into one of two categories. First, there is criticism of the assumption that the path of explicit priority

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[3] These authors include ((Fuchs 1984; Hadorn and Brook 1991; Mooney, Gerard et al. 1992; Klein 1995; Mechanic 1995; Coast and Donovan 1996; Klein, Day et al. 1996; Maynard 1996; Richardson, Segal et al. 1996; Ham 1997; Hunter 1997; Mechanic 1997; Robinson 1999; Daniels 2000; Ham and Coulter 2000).

setting is a practical and feasible path to follow. Second, there is genuine debate as to whether there are some levels of decision-making where it may be intrinsically undesirable to make rationing explicit.

Clearly there are impediments to the utilisation of the economic approach that flow from the complex environment in which priority setting usually takes place. Politicians, professionals and the public usually place less emphasis, for example, on the objective of allocative efficiency than is placed on it by economists. Of particular importance in this context is the concept of political acceptability or feasibility. Any examination of priority setting at the macro or meso levels (see Section 2.3), where some system of public accountability applies, will reveal decision-makers' concerns with the political acceptability of a proposed course of action. If explicit decisions on priority setting, albeit based on strong economic evidence, are felt to be politically unacceptable they are unlikely to be implemented[5].

But what exactly is meant by political acceptability? Robinson describes an unacceptable situation to be when the proposed course of action is:

> *"[S]ufficiently unpopular and widespread among those who are expected to suffer from the decision (and among supporters) that their resultant political actions (eg lobbying, press campaigns, protest meetings, demonstrations) are likely to cause considerable social unrest. In the limit, this may led to the decision-makers losing office." (p. 23) (Robinson 1999)*

If the costs of managing the protests arising from explicit rationing jeopardise other service objectives, it may be rational to adopt policies to avoid them. These are the considerations that led Hunter (Hunter 1996) to recommend an approach to rationing based on implicit decision-making and "muddling through elegantly." Mechanic (Mechanic 1995) similarly alludes to the possible costs of explicit rationing (particularly at the micro level of decision-making) when he claims that implicit rationing is "more conducive to stable social relations and a lower level of conflict."

The political and clinical reality is that implicit rationing is more comfortable. Coast (Coast 1997) offers an economic version of this rationale for implicit rationing when she raises the notion of "deprivation disutility" imposed on those denied services and "denial disutility" on the part of those making the decisions. The comment below was concerned with the Oregon plan (refer Chapter Six), but applies equally to all forms of explicit rationing and emphasises the inherent difficulties in choosing explicitly to treat some individuals rather than others.

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[4] Economists such as (Mooney, Gerard et al. 1992; Coast and Donovan 1996; Maynard 1996; Richardson, Segal et al. 1996; Drummond, O'Brien et al. 1997; Nord 1999; Olsen, Smith et al. 1999; Richardson, Olsen et al. 1999; Segal 2000).

[5] The case study in Chapter Twelve illustrates this situation in relation to the options to rationalise Australia's national cervical cancer screening program.

> *"The greatest source of anguish in the implementation of the plan will come in learning how to live with, and to rationalise, its failure to cover some people whose condition will pull at our sympathies. This anguish will be all the greater when the victims are visible and when the accountability for their condition cannot be evaded. This is the logical and emotional problem created by any set of priorities that set limits." (p.85) (Callah[illegible] 1987).*

It may be that the utility experienced by society is greater from implicit rationing than could be gained by having any of the following: an explicit priority setting approach that maximised health gain; an explicit approach that pursued an equitable system; an explicit democratic system that included community participation; or a combination of these approaches. This is essentially an empirical question to which we do not know the answer. Explicit rationing has been rejected in favour of implicit rationing by some (Dixon and Welch 1991; Welch and Fisher 1992; Hunter 1997), with Hunter's strategy of "muddling through elegantly" the most complete presentation of the case (Hunter 1997). Some critics of implicit approaches, such as Victor Fuchs, whilst arguing strongly that rationing of care should be more systematic, are prepared to accept that at the patient-physician level implicit rationing is more acceptable (cited in Coast (Coast 1996)). Others reject a strategy of "muddling through elegantly" in any context. For most economists, who generally believe that implicit priority setting results in inefficiency and inequity, Hunter's ideas hold little attraction (Williams 1985; Mooney, Gerard et al. 1992; Sheldon and Maynard 1993; Maynard 1996; Richardson, Segal et al. 1996). For some, such inefficiency is unethical due to its opportunity cost (Williams 1985; Maynard 1996). Certainly, a basic tenet of economic evaluation is to make explicit the alternatives that may be available in any decision context, together with their costs and outcomes.

This thesis is based on the assumption that implicit rationing is less beneficial to society than setting priorities explicitly in most circumstances and that ways need to found to facilitate explicit priority setting in Australia. It reflects the economic premise that decisions should be made on the basis of explicit consideration of the relative impact of allocating resources to one use instead of another. The position of Victor Fuchs on the vexed question of decisions at the patient-physician level is explored further below, but not resolved, as the approach to priority setting developed in this thesis is designed for decisions at the macro and meso levels of the health care system.

2.3 Levels of decision-making

There is an important distinction to be made between the various levels in the health care system where priority setting decisions take place – particularly whether an explicit approach is appropriate at all levels. These choices occur at the national or macro level, at the local or meso level, and at the micro or individual level. The level of decision-making, will in turn, have an important impact on the content of the choice to be made (i.e. the research question), the actors involved in the decision process, the kind of criteria used, and the process in which those criteria are applied. Too often advocates of explicit technical approaches put their

position in a way that assumes their decision rules and methods are equally applicable across all decision contexts. This is unfortunately, often true for economists. In conventional economic evaluation of individual interventions, the importance of a clear specification of the research question (including the role of study perspective and context) and its implications for study methods is usually recognised – certainly in the critical appraisal guidelines (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997). In priority setting, however, this important aspect of clearly defining the research question is often given scant recognition – including its implications for the specification of an appropriate evaluation protocol for a multiple intervention decision context. This is evident in several of the recommended approaches to priority setting from economists reviewed in Part C of this thesis.

Those authors such as Klein (Klein 1993) who stress the importance of the decision-making process, see the position as more complicated, with priorities being set on at least five levels (Figure 1). For Klein, priority setting is not just about making one set of decisions, but recognising "the complex interaction of multiple decisions, taken at various levels in the organisation about allocating resources." In the general literature on priority setting, however, the three-tier macro/meso/micro typology is widely recognised and is sufficient for the purpose of explaining the importance of the issue, together with its relevance to the model of priority setting developed in this thesis.

Figure 2.1: Different levels of priority setting

1. Macro: the level of funding to be allocated to health services
2. The distribution of the budget between geographical areas and across whole services
3. Meso: The allocation of resources to particular forms of treatment (within services but across treatments)
4. Micro: The access to treatment choice which patients should receive (within treatments)
5. Decisions on how much to spend on individual patients

Source: Klein (1993)

2.3.1 The macro level:

At the macro level politicians determine the level of funding to be allocated to the health sector and how this should be distributed between geographic areas and major services & programs. In the Australian context this would include both the Federal and State/Territory levels of government. Decisions about the budgets for particular services and programs are taken as part of Cabinet discussion. For the Commonwealth this includes S96 grants to the State/Territories; for the States/Territories it includes resource allocations to their regional health authorities, community health centres, and major institutions. At both Federal and State level the spending departments like Health are lined up against the Treasury/Finance

departments to determine the financial envelopes within which the government funded health services operate. The decisions at this level tend to be governed by broader political and financial considerations, including the broad balance between expenditure and taxing/public borrowing requirements. Apart from broad public finance considerations, economic analysis tends to be program/strategy specific (focussed around any new initiatives or major changes), with resource allocation formulae receiving increasing consideration at the State/Territory level in the distribution of funds to regions.

Thus at the macro or health care system level, the decision-makers are usually politicians and their civil service support staff. The decision content concerns the overall level and broad distribution of the health sector budget. The priority setting approach is bargaining orientated, largely implicit, but with explicit outcomes (eg specified budget; benefit package; eligible providers; etc). Technical models of priority setting tend to have a minor or support role at this macro level. They may, however, come into their own where the development of national strategies focusing on particular problems are involved[6].

2.3.2 The meso level:

At the meso level intermediate bodies such as regional and community health authorities, insurance and sickness funds, and major health care institutions make decisions on the allocation of resources to particular forms of treatment, including the number and mix of various providers. At this level the lead decision-makers tend to be managers and administrators rather than politicians and/or their policy advisors. This is the level at which, a priori, one would expect explicit technical approaches such as those advocated by economists to be the most applicable. It is also the level at which local institutions are often asked to assess the health needs of their populations and to respond in an efficient and equitable manner. The reforms of the UK National Health Service during the 1990's, for example, vested this responsibility in district health authorities. Similar responsibilities are vested in health authorities, or sickness funds, in other European countries and elsewhere, including Australia.

Research (Heginbotham and Ham 1994) on the process of priority setting has indicated the multiple pressures exerted on these organisations as they seek to determine priorities. Intermediate bodies have to balance the pressures emanating from national and state governments, local providers (doctors and hospitals) and public opinion; as well as consider the technical advice on clinical and cost-effectiveness. The priorities and approaches of these other constituencies can place considerable limitations on the role played by economic information. As Robinson has argued, this research illustrates "the wider context within which health economists have to operate." (p. 19) (Robinson 1999).

2.3.3 The micro level:

The micro level is at the point of service delivery where those responsible for providing services or making payments decide who is to get what within the resources that are available. Clinicians, for example, use their judgement and experience to decide which patients should receive treatment and how much should be done for individual patients. This is rationing in the strict sense used by Klein (Klein, Day et al. 1996) and is dominated by the implicit approach. A variety of rationing strategies can be used to control costs implicitly such as queuing, reducing the intensity of services, substituting less expensive for more costly services, and deciding whether services are necessary.

The central issue here is the potential conflict for clinicians in acting as agents and advocates for individual patients and assuming stewardship for the population as a whole. While each level of decision-making impacts on the others, clinicians still retain considerable discretion, despite the growing interest of politicians and managers at the macro and meso levels in making the decisions of clinicians more explicit.

All systems of care use a variety of rationing mechanisms at this level, but the appropriate balance is a matter of continuing debate. Rationing in the UK, for example, is carried out by physicians who are aware of the budgetary limits and ration by telling the patient that they are unable to do anything to help them, rather than explicitly stating that the resources are not available for treatment (Klein, Day et al. 1996; Ham 1998). In Australia the GP also has a gatekeeper role, but the fee-for-service funding system is more open-ended and allows the GP's greater discretion in their choice of care alternatives. In the USA rationing occurs largely through managed care in one of its many forms (Daniels 2000). In its traditional form the restraining mechanism is capitation and the need to stay within established budgets. This results in a type of implicit rationing, quite similar to the UK system, where the clinician makes judgements aware that the resources are limited. Many Americans are now affected by utilisation review, however, which includes pre-certification of admission to hospital, concurrent review of length of stay, case management of high cost cases and second surgical opinions (Daniels 2000). Depending on how managed care is administered, it commonly constitutes a form of implicit rationing in that decisions depend on the discretionary judgements of physician reviewers. Alternatively, to the extent that utilisation reviewers work with protocols and guidelines, rationing may shift to a more explicit form (Daniels 2000).

Three aspects of utilisation management in the US should be noted. First, the shift and/or sharing of responsibility from the practicing physician to others. Second, the potential to

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[6] Such as when national plans for priority disease areas are being developed (as per the case study involving the development of Australia's national cancer control strategy discussed in Chapter Twelve).

substitute a more formalised and explicit determination of care for the traditional clinical implicit decision-making. Third, the broadening of the potential conflict between the clinicians role as patient advocate and their stewardship role for the population as a whole, to include incentives for the physician to consider the cost of care against their own incomes. Daniels (Daniels 2000), for example, argues for the need for managed care organisations to demonstrate that the reimbursement of physicians is compatible with appropriate care.

Arguably, the micro level is the most contentious in terms of what role explicit approaches in general, and economic techniques in particular, might play in determining priorities. Increasingly, implicit rationing has come under attack as uninformed, arbitrary, inefficient and inequitable. Across a number of countries and in a range of disciplines, the importance of clinician decisions at the micro level is recognised. It is this that lies behind the interest in guidelines and the evidence-based medicine movement. If the key challenge in priority setting is to use scarce resources efficiently and appropriately, then influencing decisions at the micro level is seen by some analysts (Mooney 1994) as the central issue to address. The argument here, stated at its simplest, is that much of medical practice cannot be supported by the results of rigorous research, and that as a consequence there is considerable scope for improving the use of existing budgets. Support for the argument comes from evidence of wide variations in clinical practice patterns that appear not to be related to variations in medical need[7]. Sheldon and Maynard in commenting on the UK system, maintain that:

> *" If we want a service that uses the public's money to promote health in an efficient and equitable way....it is important to get involved in rationing to insure that it occurs in a responsible and just fashion rather than the current process, which is largely uncharted and the product of clinical discretion which creates major variations in practice and patient access."(Sheldon and Maynard 1993)*

The counter view is also strongly put by a number of authors. This argument recognises that medical decision-making is surrounded by uncertainty and can never be reduced to standardised routines. There are therefore inherent limits to what has been described as the "new scientism" in health care (Klein, Day et al. 1996). David Mechanic has been one of the staunchest and most articulate opponents of explicit approaches at the micro level. He argues

> *"Once decisions are removed from a dialogue between doctor and patient to a public decision-making process, such decisions easily become the turf around which social, moral and political battles are fought..... The value of implicit rationing is its capacity to respond to complexity, diversity, and changing information in a sensitive and timely way. It builds on the strength of the doctor/patient communication and sensitivity to a range of needs and preferences of patients whose life circumstances vary greatly....What administrative authorities cannot do successfully, however , is micro manage the care process, inserting themselves into decisions of who should be treated and how." (Mechanic 1997)(p. 86)*

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[7] Such as (Ham 1988; Leape, Park et al. 1990; McPherson 1990; Renwick and Sadowsky 1991; Richardson 1998)

> *" In short, rationing at the micro level must be left for doctors and patients to work out among themselves. Informal resolution must take place within explicit constraints but once the boundaries are set more is gained by muddling through than by trying to establish all the rules beforehand. Seriously ill patients pose substantial complexities and, depending on how illness, culture, and personality combine, may require different care." (Mechanic 1995) (p. 1659)*

Wherever the truth lies, it seems certain that clinicians will find themselves drawn more and more into the priority setting debate, albeit reluctantly in some cases. Some authors (eg (Sabin 2000)) believe doctors are particularly well placed to lead the debate on rationing because of the trust that exists between patients and doctors and the opportunity available to doctors to use their encounters with patients to inform and educate.

There is no one "correct" answer to the questions: "What should be our priorities?" and "How should they be determined?" The answer involves a series of value judgements which will vary depending on the individuals and groups involved. Underlying most rationing practices is some notion of equity defined as allocation according to need (see Chapter Five). The difficulties inherent in operationalising the measurement of need has seen the allocation of funds between competing services and programs pushed down to the meso level in a number of countries, to be interpreted in the light of the local context. The difficulties in giving meaning to "need" also explains, in part, the further delegation to the micro level. Discretion is related to the existence of ambiguity and the complexity of individual circumstance. The exercise of discretion in turn raises the importance of process as an important component of evaluation and priority setting. The role of values and the importance of due process are examined further below.

In summary, the role of explicit and/or technical approaches to priority setting at the micro level will remain contentious for some time to come. The decision content, involving individual access to health care, is inherently emotive, complex and value-laden. Explicit approaches to priority setting have important implications for resource allocation at this level, both in regard to outcomes and due process. The impact is likely to be both direct (eg via best practice guidelines; utilisation review; and/or various points systems for access to surgery) and indirect (i.e. via the consequences of decisions made at the macro and meso levels). Resource allocation decisions utilising the approach developed in this thesis could be reflected in the purchasing decisions at the meso level; the budget and planning decisions at the macro level; or incorporated into best practice guidelines. Should circumstances arise where utilisation management applied in Australia, then the proposed approach could be used directly to aid decisions in that setting. Similarly, should Divisions of General Practice and/or the various Colleges become involved in planning exercises that involve economic evaluation across multiple interventions, then the approach explained in Part D of this thesis could prove useful.

To end this discussion of the micro level on a positive note, it is possible that the roles envisaged for explicit and implicit priority setting are not quite as far apart as some of the literature would suggest. David Mechanic, for example, sees the various explicit tools (i.e. economic evaluation; QALYs; outcomes research; guidelines; etc) as useful aids to decision-making, but not as directives. He wants to maintain clinician judgement as the cornerstone of decision-making at the micro level, but acknowledges the need for a different culture of medical practice. One that is:

> *"[A]ccountable and takes responsibility to use resources wisely and consistent with unfolding knowledge of best practice and cost-benefit outcomes" (Mechanic 1995)(p. 1657).*

Mechanic's position on this is quite close to that of many economists, who see the role of economic evaluation as an aid to decision-making, not as a substitute for decision-making (Sugden and Williams 1978; Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997). He warns, however, that guidelines seen as important educational and practice aids will be incorporated more readily into clinical decision-making than if imposed externally by government bodies as a strategy to control medical decision-making.

2.4 Technical verses due process approaches to explicit priority setting

There is an ongoing debate in the literature between the advocates of explicit priority setting approaches on how "explicitness" should and could be achieved. One school of thought – which might be called the "technical school" – is characterised by a reliance on rational decision rules and the development of technical frameworks in which they are applied. This school has in large part been the preserve of health economists (pursuing the goal of efficiency) and epidemiologists/ clinicians (pursuing the goals of effectiveness and/or needs-based equity). The underlying belief of this school is that it is possible to give definitive answers to priority problems.

The goal of efficiency is based on a maximising concept: the idea that it is possible to maximise the total amount of "benefit" available to the community if both the costs and benefits of an intervention are considered. It thus pursues a consequentialist ethic – usually of a utilitarian nature – of the greatest good for the society as a whole. The exact specification of what constitutes "benefit is strongly debated within the health economics discipline. This debate is discussed in Chapters Four and Five of the thesis. Models based on the goal of efficiency are critically assessed in Part C of the thesis.

The goal of equity is focussed on a just distribution – of what is again a contested issue. Equity as a concept is less precise than efficiency and has more variants. Priority setting approaches ostensibly based on "need," however this is defined, are essentially concerned with equity (eg. equal health care for equal need; equal access for equal need, equal

resources for equal need; etc). The goal of equity is taken-up through out the thesis, particularly in the discussion in Chapters Five and Six. Models based on the goal of equity are also reviewed (albeit briefly) in Part C of the thesis.

In the technical school, decisions made by applying the correct rules (whether efficiency and/or equity focussed) and the associated arithmetic are, ipso facto legitimate, providing one accepts the goal and/or principles on which they are based. Given appropriate information the priority setting algorithm should be able to provide clear guidance to decision-makers on how services should be ranked. Such technical approaches to priority setting often do not acknowledge that there is a need to distinguish between different levels of priority setting. The importance of context and setting is a theme that emerges from the discussion of ethics in Chapter Five and the empirical experience presented in Chapter Six.

In contrast, the second school – what might be termed the "due process" school – questions the assumption that it is possible to devise "rational" decision rules. Its advocates believe that the technical approaches are based on a simplistic view of the health care system and challenge the possibility of definitive answers. Klein, for example, draws attention to the shortcomings of technical approaches and emphasises instead the essentially contested nature of rationing and the role of judgement in making decisions on resource allocation (Klein 1993; Klein, Day et al. 1996; Klein and Williams 2000). For Klein the task is less to refine the technical basis of decision-making than to construct a process that enables proper debate and discussion to occur. Instead of searching for a specific principle upon which to base priorities, a system of bargaining should be used, whereby all stakeholders bring their own objectives to the bargaining table. This does not mean implicit rationing, but instead a system whereby decisions are made explicitly and the reasoning behind specific judgements is clearly explained (Klein 1993; Redmayne, Klein et al. 1993).

The focus on the decision-making process is of course related to the interest in explicit rationing discussed above and to the attempts to involve the public and patients in the process of rationing (see below). Note also that in their recognition of the complexity of the decision-making process, this school is joined by advocates of implicit rationing (Hunter 1997), but they draw very different conclusions as to the appropriate response to this complexity.

Several authors in the literature on priority setting discuss the theme of due process[8]. The work of Daniels, in particular, based on his observations of rationing in managed care organisations in the USA, has been quite influential, certainly influencing the Nordic countries (Holm 2000). Daniels argues that accountability provided by markets is not able to ensure

[8] Refer the works, for example, of David Hunter (Hunter 1993; Hunter 1996; Hunter 1997), Peter Singer (Singer 1997) and Norman Daniels (Daniels and Sabin 1997; Daniels and Sabin 1998; Daniels 2000).

fairness or the legitimacy of priority setting decisions in health care. He argues for "accountability for reasonableness," by which he means that decision-makers have to explain the rationale for their decisions, demonstrating that these are based on reasons and principles (including value-for-money) that are accepted as "relevant by people who are disposed to finding terms of cooperation that are mutually justifiable" (Daniels and Sabin 1997). The frequency with which his ideas are referred to, highlights the importance of the ethical dimension of priority setting and suggests his ideas on process are relevant to a number of different health care systems. Daniel's theme of "accountability for reasonableness" is considered further in Chapter Five.

The "due process" school thus sees decisions made through the "correct" priority setting process as, ipso facto, legitimate. If rule-based systems are not a feasible way to legitimise decisions that may well prove to be both controversial and/or unpopular, then legitimacy must come through due process. The discussion then turns to what constitutes "due process", with notions of transparency, accountability, bargaining, fair treatment, reasonableness and lay participation high on the list of desirable attributes. A number of authors pursue the idea of "procedural rights" as an important aspect of due process, particularly at the micro level. Hunter, for example, argues that a system of procedural rights should be put in place to help balance the "the two poles of collectivism and individualism" (p. 138) (Hunter 1997). Procedural rights are usually defined as rights that help ensure fair treatment of individuals[9] as they come into contact with service providers and/or the government (Coote and Hunter 1996).

There is clear recognition within the "due process" school of the different levels of decision-making and that process criteria may vary between levels. One example is the acknowledged importance at the micro level of allowing opportunities for patients and their families to appeal against decisions that deny their access to health care (Daniels and Sabin 1998). The theme of what constitutes "due process" is picked up in several of the subsequent chapters of this thesis.

The main advantage of the technical school is that, not only are the decisions and their supporting rationale made explicit, but the objectives on which they are based are also

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[9] These ideas are reflected in the introduction by some countries of the Patient's Charter (UK Department of Health 1992) and complaints systems. Procedural rights in health care may be summarised as follows (Bynoe 1996):

- A right to be heard;
- A right for consistency in decision-making;
- A right to relevance in decision-making (a duty on those making decisions to take into account all relevant factors and to disregard irrelevant ones);
- A right to unbiased decisions;
- A right to reasons (openness in decision-making, expressed as a requirement for the decision-maker to give reasons to those affected by decisions concerning them); and
- A right to review.

specified. Use of technical frameworks is more likely to move the health sector closer to specified objectives, such as efficiency or equity, than approaches that lack clear direction. This potential advantage, however, albeit very significant, may not be realised. What looks like sound methodology is sometimes not practicable. A huge quantity of data is often required for technical methods of priority setting. These data may include the costs of interventions (including the costs of current practice); the efficacy/effectiveness of interventions (including current practice); the extent of illness in the population; and possibly information about public preferences. It is claimed that rationing by bargaining, on the other hand, is "ideally suited to situations of extreme uncertainty and complexity where information is poor and incomplete" (Hunter 1996). Unless tractable ways are found to deal with their information needs, technical approaches will be restricted in their application, possibly to choices involving vertical priority setting. Tackling the information problem is therefore a feature of the approach to priority setting proposed in this thesis.

Added to the difficulties in securing adequate data for technical rationing, may be greater difficulties in implementation. Pluralistic bargaining, by its very nature, both exposes potential difficulties and offers a mechanism for the resolution of differences. A solution arrived at through due process, may have a greater chance of implementation than a decision which has been primarily taken in isolation, based on a nominated principle and associated decision rules of the evaluators. This is particularly the case if policy objectives and funding structures of the health care system do not relate closely to any of the "techniques" for priority setting on the basis of efficiency and equity.

The debate between the two schools may be drawn too starkly in the literature however. There seems no inherent conflict between action to provide more and better information on the costs and outcomes of different interventions and work to strengthen the processes for debating that information and arriving at judgements on priorities. The reality is that neither option alone is likely to fulfil the theoretical and practical requirements of an ideal approach to explicit priority setting. Technical methods alone will never be able to deal with the complexity and contested nature of priority setting, but "due process" should ideally utilise the sort of information on effectiveness, efficiency, equity and needs provided by technical approaches. In this thesis it is argued that both elements need to be involved in any approach to priority setting that is seeking strong theoretical foundations and practical relevance.

The key question is the extent to which each approach is used and the respective emphasis on these different alternatives. While the relative importance attached to each element is an issue that continues to divide the technicians focusing on outcome (i.e. health economists / epidemiologists) from the "due process" advocates (i.e. political scientists / behavioural scientists / sociologists), common ground in this debate is starting to emerge. A number of

authors[10] are starting to support this view, but few – if any – have published a clear model with developed theoretical and empirical foundations. This issue is taken-up further in Parts B to D of the thesis.

2.5 Whose judgement: attempts to consult and involve the public

While it is possible to argue from a theoretical perspective that the dictates of economic appraisal should simply be followed automatically[11], virtually all economists agree that economic evaluation is an aid to decision-making, not a replacement for decision-making. This view is certainly reflected in the established critical appraisal guidelines (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997), particularly in those criteria dealing with the specification of the research question and sensible interpretation of the results. It is also reflected in a growing economic literature on the role of ethics in economic analysis[12].

The review of empirical evidence in Chapter Six also highlights the reality that explicit rationing at all levels involves both the use of techniques and the application of judgement. Oregon is perhaps the best known example, but the experience of the Nordic countries, Israel, New Zealand, the UK and Australia, all support this conclusion. At the other level of empirical experience, the notoriety that has surrounded particular cases where patients, particularly children, have been denied treatment, also reinforces this point. Once the role of judgement is accepted, the questions then arise of "whose judgement"; "involvement for what purpose"; and "what is the appropriate process of involvement?"

In relation to the first question of whose judgement, the key issue revolves around medical paternalism verses lay participation (Coast and Donovan 1996). While the views of medical practitioners and other "experts" are drawn on extensively, there is increasing interest in widening the circle to include the representatives of the public and/or of patients. In part, this is due to the general democratic ethic that health authorities in publicly funded health care systems should be answerable to their actual and potential consumers. In part, there is also an ethical concern to utilise the community's values in the difficult choices that deny treatment to individuals. Some authors however, such as Jonathan Lomas (Lomas 1997), see the motivation of governments less as a question of ethics and more as one of pragmatics – i.e. of getting the public to share ownership in the tough choices. Coast (Coast and Donovan 1996) takes a middle course and concludes that the advantages argued for lay participation revolve around the changes in service provision that might result, together with their likely acceptance by the community. By incorporating public preferences into the priority choices

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[10] See, for example, (Coast and Donovan 1996);(Ham and Coulter 2000) and (Singer 1997).
[11] As argued by Alan Williams in an early presentation of the decision-making school (Sugden and Williams 1978).
[12] Recent examples include (Sheill 1997; Blaug 1998; Culyer 1998; Menzel, Gold et al. 1999; Nord, Pinto Prades et al. 1999; Richardson 2000a)).

the resulting services may be better suited to local needs. Priorities set in this way, she contends, will reflect what people want, including their preferences, concerns and values.

The renewed interest in public participation is reflected in government actions around the developed world, particularly in the UK and Canada, that stress individuals' rights as patients and as consumers. The NHS Management Executive in the UK, for example, has released a "Patients' Charter" (UK Department of Health 1992) and attempted to make things easier for those planning public participation by providing a set of documents describing the range of methodologies that could be used to obtain public views (Sykes, Collins et al. 1992).

The "due process" school mentioned earlier certainly acknowledges that there are fundamental questions about who should be involved in the bargaining process and how this decision should be made. Klein warns, for example, that where the groups involved are limited, there is a danger that such bargaining will slip back to implicit priority setting without anybody really noticing[13].

One of the important issues to clarify is the purpose of any community participation/ consultation. The empirical evidence suggests a variety of purposes. In some cases the purpose has been to educate and inform citizens about the need for rationing; in others the task has been to agree values and principles that should guide rationing; and in others it has been to contribute a user perspective to specific problems and choices. In Edgar's account of the experience in New Zealand during the 1990's, for example, she explains that the objectives ranged from information sharing and awareness raising in the first instance, through opinion gathering, to input on specific questions or identification of service priorities (Edgar 2000).

A range of methods and approaches has been employed to seek this participation. Health care reformers have been experimenting with diverse principles and methods for involving "community values" in resource allocation decisions, eg. survey research, town hall public consultations, citizen juries, ad hoc committees with diverse stakeholder representation (Klein 1993; Both 1996; Lomas 1997; Mullen 2000). This experimentation is related to the question of what the "lay viewpoint" actually consists of. There is debate about whether lay views properly come from random surveys, from focus groups or whether interested individuals and/or community representatives are the appropriate course to follow. Much depends, of course, on clear specification of the research question, the purpose of the involvement, together with the budget and time available.

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[13] One of the strengths of the Program Budgeting and Marginal Analysis (PBMA) approach in this regard, is its explicit recognition of the question of who should be involved, together with a process (i.e. the Working Group) for resolving it.

While most commentators on public participation do so from a position of wanting to encourage the greater involvement of both patients and the general public, others are more cautious. Mullen, for example, points out that:

> *" Concerns about the legitimacy of public involvement relate to the 'representativeness' of those participating, the perceived lack of knowledge of lay people in an area populated by professionals, the risk of populism and even public resistance to being involved in 'rationing'. There is also concern that public participation is being used to compensate for the lack of democracy.... " (p. 163) (Mullen 2000)*

In a similar vain, the Parliamentary Health Select Committee in the UK stated that there is a need both for more research and to be more realistic about what can be achieved with public involvement (Committee 1995). Major issues here concern the real willingness of purchasers to incorporate the views and opinions of the public, and, if this is achieved, how far they are prepared to go in changing existing services to meet the priorities expressed by the public – or that flow rationally from their expressed values. Related problems concern the conflicting pressures on purchasing bodies when local preferences conflict with national policies. There is also the willingness of members of the public to participate in difficult decisions about priority setting in health care (Lomas and Veenstra 1995; Abelson 1999).

A number of authors, including Mullen and Lomas, note the need for methodological rigour in deciding how to involve the public. Exhortations to involve "the public" conceal a plethora of issues concerning what issues the public can reasonably be asked to contribute to; who should or should not be consulted and what mechanisms should be used.

Lomas warns from his evaluation of the literature that if the objective of lay participation is shared ownership of priority choices, then there are only limited areas where public input should be sought. More specifically, he argues that:

> *"[T]he general public should be asked to give input to, but not to determine, priorities across the broad service categories that could potentially be publicly funded. Members of the public have neither the interest nor the skills to do this at the level of specific services. The role expected of such members of the public should be made explicit and should focus on collective views of the community good rather than self-interested views of individual benefit." (p. 103) (Lomas 1997)*

> *"[T]he willingness and self-perceived ability of average citizens to contribute to resource allocation decisions is quite limited. Citizens appear implicitly to divide the task of resource allocation into two phases – elicitation of the underlying principles and values and then incorporation of these into more explicit expert calculations of collective (political and fiscal) costs and benefits. Regardless of whether rationing is proposed based on limiting funds, services, or the eligibility of patients, they largely see their role restricted to providing principles and values. They appear to recognise the need for the addition of political, professional or technical experts as the final decision-makers." (p. 107) (Lomas 1997)*

Richardson makes a similar point in his review of a South Australian initiative to involve the community in a prioritisation exercise for metropolitan health care services, viz:

> *"Decisions which involve purely subjective judgements (i.e. the criteria of value, the meaning and importance of equity) are the appropriate subject for community judgements; issues such as the construction of surveys; program costs and the use of Decision Analysis are technical matters. Reliance upon community judgement here is as inappropriate as voting on the techniques for car construction; that is, the task involves technical skills which panel members cannot be expected to have." (p. 10) (Richardson 1997)*

There are no available theories, to my knowledge, that prescribe the answer to which groups should or should not be involved in the process of setting priorities for health care. A concern raised by Klein, for example, is an apparent inverse law of participation, where those in greatest need to further their own interests have the least capacity to do so (Klein 1984). Value judgements must be made about who should, or should not, be included. The available empirical evidence on this issue is also limited, but overwhelmingly supports the notion of a combined decision-making body of some sort that includes public participation (Richardson, Charny et al. 1992; Ham 1993; Abelson, Lomas et al. 1995; Lenaghan, New et al. 1996; Obermann and Tolley 1997).

Turning to the mechanism for participation, Lomas argues for a group process characterised by collective consensus rather than the simple aggregation of individual views, viz:

> *"Thus, consultation on broad service priorities is perhaps best done with the general public in conjunction with providers, managers, and others with expertise able to temper the public's tendency to orient more to the dramatic than the effective. ... collective consensus recommendations from a group are better able to incorporate whatever evidence is available than is the aggregation of the individual views of each member of the group." (p. 108) (Lomas 1997)*

> *"Finally, there appears to be no best method for obtaining public input that overcomes the common problems of poor information upon which to base priorities, difficulty in arriving at consensus, poor representativeness of participants, and lack of opportunity for informed discussion prior to declaring priorities. There is some suggestion, however, that panels of citizens or patients, convened on an ongoing basis and provided with the opportunity to acquire relevant information and discuss its implications prior to making consensus recommendations, offer the most promising way forward." (p. 103) (Lomas 1997)*

Finally, a number of authors have noted that if public participation is to be taken seriously, then participants have to be adequately supported. David Hunter states, for example, that:

> *"[E]ffective public involvement in rationing decisions ought to be encouraged where, and in ways that are, appropriate but it needs to be buttressed and supported.." (Hunter 1993)*

In this regard it is interesting to note that the New Zealand work is being taken forward through a consumer training program in guidelines development which in Edgar's view should "should raise public engagement by several notches" (p. 189) (Edgar 2000).

The question of consumer participation is clearly a complex issue and it is not my intention in this thesis to cover it in any detail. Consumer participation will be covered, only in so far as it relates specifically to key aspects of priority setting.

2.6 Summary of the key points

Issues that provide the setting and context in which priority setting takes place are an important touchstone to reality. Four key issues emerge from the international literature on priority setting, viz:

1. Understanding the choice between implicit and explicit approaches to priority setting;
2. Recognising the importance of the different levels at which priority setting takes place in health care;
3. Understanding the debate between technical and process oriented approaches to explicit priority setting; and
4. Resolving the question of whose judgement should be included in the priority setting process – particularly attempts to consult and involve the public.

It is concluded that:

- Explicit priority setting is likely to be more beneficial to society in most circumstances than setting priorities implicitly, particularly at the macro and meso levels of decision-making. The approach to priority setting at the micro level remains a strongly contested issue.
- There seems no inherent conflict between action to provide more and better information on the costs and outcomes of different interventions (the "technical" approach) and work to strengthen the processes for debating that information and arriving at judgements on priorities (the "due process" approach). Both elements need to be involved in any approach to priority setting that is seeking strong theoretical foundations and practical relevance.
- Once the role of judgement in priority setting is recognised, the questions then become "whose judgement"; "involvement for what purpose"; and "what is the appropriate process of involvement'? There is guidance in the literature on these issues, but they remain contested issues. There is nonetheless, growing recognition of the need for improvements in methodological rigour, for a realistic recognition of what can be achieved and for clarity in the value judgements made in implementing public participation.

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Chapter Three: Thesis Structure and Scope

3.1 Thesis organisation: a guide to the chapters:

The thesis is presented in five parts. Part A addresses the origins, setting and context for the topic of priority setting in health care. Part A not only considered the question of whether there is a need for priority setting, but examined the key issues that set the context in which this debate takes place, viz:

- the choice between implicit and explicit approaches to priority setting;
- the different levels at which priority setting occurs in the health sector and the implications of setting and context;
- the tension between technical rule-based frameworks and due process approaches to explicit priority setting; and
- the role of judgement in priority setting, together with the associated issue of public participation.

These issues are important because they reflect the context and problems that decision-makers face. They are kept in focus throughout the thesis because its fundamental purpose is to develop a framework for priority setting that will be adopted by decision-makers – a framework which is broader than one which focuses exclusively on the issues considered by narrowly defined economic theory or economic orthodoxy. While the literature reviewed in Part A suggests that the importance and need for priority setting is clearly established, the central question of how priority setting is to be achieved is strongly contested. The remainder of the thesis focuses on this question of what constitutes an appropriate approach to priority setting. Two separate but related tasks were undertaken to contribute to its resolution.

First, in Part B, a checklist is developed to help identify the features of an ideal approach to priority setting. Ten criteria are developed based on four key considerations, viz: economic theory; ethics and social justice; lessons from empirical experience; and user considerations. The contributions of economic theory, ethics and empirical evidence are presented in Chapters Four to Six respectively. Criteria with a user rationale stem from an effort to ensure that models of priority setting respond to the particular needs of decision-makers. This rationale reflects the issues presented in Chapter Two, together with implications for decision-makers coming from Chapters Four to Six. In Chapter Seven the four considerations are brought together and linked to the ten criteria. The checklist presented in Chapter Seven represents a significant contribution of the thesis, particularly given the current level of disagreement about the appropriate approach to priority setting. While there are existing checklists to guide the conduct of traditional micro economic evaluation (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997), there are no established checklists that reflect the

particular decision context of priority setting involving the assessment of multiple options for change. This thesis is therefore the first time that criteria from such a broad range of considerations have been brought together to develop a framework for priority setting that is both realistic and theoretically sound.

In Part C of the thesis existing models of priority setting are assessed against the checklist, particularly those from the technical school. This school has in large part been the preserve of health economists (pursuing the goal of efficiency) and epidemiologists/clinicians (pursuing the goals of effectiveness and/or needs-based equity). Models proposed by non-economists are reviewed in Chapter Eight, while models proposed by economists are assessed in Chapter Nine. It is concluded from the assessment in Part C, that while there are current approaches with considerable merit in relation to some of the criteria, none of the current models of priority setting perform well against all the criteria.

The assessment in Part C gives added weight to the second task undertaken for this thesis; namely, to develop and trial a model of priority setting that attempts to meet all the criteria in the checklist. Part D of the thesis focuses on this undertaking. Chapter Ten provides a description of the Macro Economic Evaluation Model (MEEM), together with an overview of its development, potential uses and early case studies. Chapter Eleven focuses on how the information needs of MEEM were met through the creation of a database on health expenditure and the selection of the DALY as the best available summary measure of population health. A chapter is dedicated to the information needs of MEEM, because problems associated with data needs (particularly for technical approaches) are the dominant theme that emerges from the empirical evidence in Chapter Six. In Chapter Twelve the major case study undertaken to test the feasibility of the MEEM approach is presented. The case study reflected a real-life priority setting context and was subject to genuine time and policy constraints. It involved the economic evaluation undertaken to assist the development of the national strategy for cancer control in Australia. Finally, in Chapter Thirteen, MEEM is assessed against the checklist developed in Part B, drawing particularly on the major case study. Chapter Thirteen concludes with a brief comment on the potential role, generalisability and significance of the MEEM approach. It is noted that further major case studies in mental health and cardiovascular disease have been commissioned on the strength of the cancer study, and that this represents an important external endorsement of the practical value and acceptability of MEEM.

Part E of the thesis contains supporting documentation on the MEEM approach. Appendix One provides a list of publications released during my candidature that are based on research undertaken in developing MEEM. Appendix Two provides further detail on aspects of the major case study, particularly in relation to the macro evaluation of the options for change.

3.2 Scope and limitations

Priority setting is a subject that generates vigorous debate across a range of disciplines. It is simply not possible to give consideration to all of the issues involved, and at the same time give due weight to the topic from an economic perspective. The thesis is registered in the economics faculty and an economic orientation is clearly essential. Issues or arguments central to other disciplines, however, such as epidemiology, behavioural science, philosophy, political science or ethics, inevitably arise. Discussion of these issues is necessarily selective and their inclusion largely reflects the extent of their interaction with an economics approach. Thus while issues such as the process of decision-making and policy development, pluralistic bargaining, community participation, preference elicitation methods, evidence of intervention efficacy and political acceptability are raised, there is no attempt to provide a comprehensive coverage of these large subjects. Other issues, such as the role of ethics and social justice, are assessed at greater depth, because of their fundamental significance in normative economic analysis. In short, the thesis attempts to be inclusive, but only comprehensive in relation to key issues from an economic perspective.

Similar issues of scope arose with respect to the coverage of economic theory in Chapter Four, in order that the word limit was not exceeded. A range of sub-disciplines such as public finance; public choice theory; game theory; decision theory; management theory, and systems design, all contribute to an understanding of issues associated with government intervention. While acknowledging the impact of these broader issues, the focus in this thesis is on improving the capacity of economic evaluation to guide government decisions on the allocation of resources in the health sector. More specifically, it is a macro approach to economic evaluation that addresses the applied issues arising from the decision context of priority setting. Accordingly, there is no attempt to provide a detailed coverage of all the various micro evaluation and modeling techniques available, but rather to highlight the key techniques and issues central to the task of priority setting. Further, while it is recognised that there are new evaluation techniques emerging in traditional micro economic evaluation, such as conjoint analysis (CA) and cost-value analysis (CVA), these newer developments are discussed only when they are relevant to the specific choice context of priority setting[14].

In Chapter Six, which outlines the lessons from empirical experience, similar difficult choices of scope and coverage had to be made. Emphasis was given to countries that have adopted explicit approaches to priority setting and which provide useful guidance for the Australian context. The resource allocation experiment in the US State of Oregon was reviewed at some

[14] Thus CVA is raised in several contexts because cost utility analysis (CUA) is assessed as the most appropriate technique for macro evaluation in the health sector, and CVA represents a natural evolution of the QALY to incorporate wider issues of concern to the community. On the other hand, CA is not addressed, except in passing, because its credentials within traditional micro evaluation are not yet established, and its adoption within a priority setting context would be premature.

length because it has generated an extensive literature and because it remains the only large-scale attempt to implement explicit priority setting using a QALY League Table approach. The New Zealand experience is also emphasised because its incrementalist approach to explicit priority setting offers an important alternative to the Oregon approach. Insights were also obtained from the experiences of The Netherlands, the Nordic countries and the UK, but had to be covered at less depth due to the word limit.

Two other important issues of scope arise in relation to Chapter Six. First, it is important to acknowledge the large literature on priority setting/rationing that flourishes in the UK, with an active debate between academics of different disciplines across a range of journals. It was simply not possible to review all this material in depth or to cover issues comprehensively in a brief overview of the UK experience and of the key issues that emerge from it. The experience of the UK was afforded less weight because it has not adopted an explicit approach to priority setting like Oregon or New Zealand, but rather adopted an approach characterised by "pragmatic incrementalism" (Klein, Day et al. 1996).

Second, it is important to acknowledge that no attempt has been made to provide a comprehensive assessment in Chapter Six of whether the priority setting endevours of these various countries were "successful". Success could be judged in a number of ways from a number of different perspectives; including whether they achieved their policy goals; whether decisions enjoyed stakeholder support; or whether their approaches were adopted elsewhere. Such an assessment, even if the data existed and was accessible, would be beyond the scope of this thesis. Rather, a more modest objective was adopted – namely, that of drawing out the key lessons from the experiences of these countries that might inform future attempts at explicit priority setting.

Chapter Six also includes a review of selected Australian experience with priority setting in the health sector. There have been no systematic national attempts in Australia to set health care priorities analogous to the initiatives of Oregon, New Zealand, The Netherlands or the Nordic countries. Nonetheless, there are relevant experiences to report, and in Chapter Six several key initiatives are reviewed. In selecting relevant experiences, reliance was placed on those studies that have been published, either as reports/working papers or in the refereed literature.

In Part C of the thesis existing models of priority setting are reviewed against the checklist. As Parts B and D present the primary contributions of the thesis (i.e. a checklist to assess models of priority setting, together with MEEM, my proposed approach to priority setting); less weight was given to Part C. Accordingly, it was not possible in a brief review to cover all the potential approaches to priority setting and their various permutations. Instead, the focus in Chapter Eight is on two distinctive approaches to priority setting proposed by non-economists,

viz: models that adopt equity as the primary objective (i.e. needs-based models and age-based models); and models that adopt the achievement of consensus as the primary objective. In Chapter Nine a similar approach was taken, with key contributions selected for review (i.e. League Tables; PBMA; the Health Benefit Group/Health Resource Group approach; and the Disease-Based Framework). It should be noted, however, that the detailed review of empirical evidence in Chapter Six does overview a number of other approaches to priority setting (such as the Irrawarregon).

In Part D the development and trialing of MEEM is presented. As the full report on the major case study has been published separately and runs to well over 200 pages, it is summarised in Chapter Twelve with supporting detail provided in Appendix Two. Similarly, most of the minor case studies reported in Chapter Ten have been published, with selected extracts included in the thesis to illustrate the development and applications for MEEM. A full list of the publications based on MEEM is set out in Appendix One. Chapter Eleven focuses on how the information needs of MEEM were made tractable through the development of a database on health expenditure and the utilisation of DALYs as the preferred summary measure of population health. The Acknowledgements contain a brief history of this research in order to document my contribution. As the focus of the thesis is on priority setting rather than cost-of-illness (COI) analysis, no attempt is made to present the COI methodology in detail or to trace its development. References are provided, however, where this detail is available. A similar approach is taken with the Burden of Disease (BOD) database. Emphasis is given to explaining the choice of outcome measure (i.e. the DALY), rather than to detailed explanations of the various summary measures of population health, which involves a large literature in its own right.

In sum, the topic of this thesis involves an exceedingly broad range of disciplines and issues. These have been drawn on selectively in accordance with their relevance to the theme of developing a realistic and theoretically sound approach to macro economic evaluation to guide decision-makers in their resource allocation decisions.

3.3 References

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PART B: DEVELOPING THE CHECKLIST – WHAT ARE THE FEATURES OF AN IDEAL PRIORITY SETTING MODEL?

Chapter Four: The Contribution from Economic Theory

"... whereas the normal way of testing a theory in positive economics is to test its conclusions, the normal of testing a welfare proposition is to test its assumptions... the interest attaching to a theory of welfare depends almost entirely upon the realism and relevance of its assumptions, factual and ethical, in a particular historical context." (de Graaff 1967)(p. 3)

"Why do (public utility) regulators or even the public generally, find it so hard to accept and apply the principles of economic efficiency – principles that are so obvious to trained economists... My continual immersion in public utility regulation has gradually led me away from the 'public is illiterate' view and more towards the 'economists are deaf' view. (Zajac 1985)(p. 119)

4.1 Introduction:

Economics generally distinguishes three concepts of efficiency. The first two address the supply side and are sometimes rolled into one in introductory textbooks. "Technical efficiency" is achieved when production is organised so that maximum output is produced with the resource inputs available. It is an engineering-based notion of efficiency that depends on the physical production function. In theoretical terms, technical efficiency coincides with being on an "isoquant" and there are many technically efficient input combinations for a given production function. "Productive efficiency" (sometimes called "cost-effectiveness efficiency") is achieved when production is organised to minimise the cost of producing a given output. It thus takes into account both the production function and prevailing factor input prices. Productive efficiency coincides with the intersection of the isoquant and isocost lines and under standard convexity assumptions there is normally only one cost-effective input mix in a given setting. The third and arguably[14] most important concept of efficiency, particularly for strategic planning and priority setting, is "allocative efficiency". Allocative efficiency incorporates the demand side and is achieved when resources are allocated so as to produce the "optimal" level of each output in line with the "value" consumers place on them.

It is important to appreciate three aspects of these efficiency concepts. First, that efficiency is a purely instrumental concept – it has meaning only if an explicit objective has been articulated against which efficiency can be assessed. Second, there exists a hierarchical relationship between these concepts – technical efficiency is required to achieve productive efficiency and productive efficiency is in turn required to achieve allocative efficiency. Third, and arguably the most important, there exist alternative ways to define "optimal" and to define

[14] While many economists would support the primacy of the allocative efficiency concept, it is often the neglected concept. Technical efficiency within hospitals, for example, has been a priority concern for many years.

"value" within the key concept of allocative efficiency. The assessment of these alternative ways to define and measure allocative efficiency is at the heart of this chapter.
One type of assessment is to examine the congruence between the economic evaluation methods employed to measure efficiency and their conceptual framework in economic theory – this is provided in Section 4.3. A second type of assessment focuses on the validity of the conceptual frameworks themselves – this is provided in Section 4.2. A primary focus of Section 4.2 is the paradigm clash that has emerged in the normative economics of health, a clash between the orthodox tradition of "welfare economics" and the newer theoretical framework of "extra-welfarism". The rejection of welfarism by many health economists has also led to the "Decision-Making Approach" (Williams 1972; Sugden and Williams 1978) where prominence is afforded the objectives of decision-makers commissioning the analysis. De Graaff's observation in the title quote above captures the central features of this ongoing theoretical debate – a debate rooted in different views about the "relevance and realism" of the factual and ethical assumptions underlying the competing theories.

4.2 Theoretical foundations: from welfarism to extra-welfarism and the decision-making approach:

4.2.1 Overview:

The term "welfarism" or "welfare economics", refers to the theoretical framework for normative economic analysis that has developed within the neo-classical economic tradition[15]. The welfare economic framework, which is familiar to most economists, rests squarely on notions of individual utility or preference as the foundation of analysis. This tradition is very much in accord with liberal political opinion, as individual autonomy is paramount. Social welfare (an increase in which is at the heart of economics) is a function[16] only of individual welfare (or utility) and judgements about the superiority of one policy option over another are made by reference to the sum of these individual utilities (irrespective of the non utility aspects of each policy). Moreover, the individual utilities are a function only of goods and services consumed[17]. It is assumed that individuals are usually the best judges of their own welfare (the "consumer sovereignty" assumption) – a view that with a few added conditions gives substance to the neoclassical faith in free markets.

"Extra-welfarism" refers to frameworks for normative economic analysis that reject the exclusive focus of neoclassical welfarism on utilities of individuals. This approach relaxes this

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[15] See for example the writings of (Kaldor 1939; Arrow 1963; de Graaff 1967; Baumol 1969; Ng 1979; Boadway and Bruce 1984); or the commentaries of (Sen 1977) and (Culyer 1971).
[16] Note that this function may take various forms. Utilitarianism is a simple additive function where utility is maximised irrespective of distribution. Egalitarianism is consistent with a welfarist position in combination with the view that utilities ought to be equal. If the function is not additive, however, the question arises concerning the ethical basis by which we judge the function. While redistribution is possible under welfarism, the focus under normal circumstances is to redistribute wealth and not final consumption (Personal Communication, Richardson [2001]).

assumption to enable other aspects of policy change to be included in the assessment of efficiency. Since in the welfarist approach the focus of social welfare is utility received from the consumption of goods and services, an important theme of extra-welfarism are characteristics that may have value in of and of themselves, and not simply as a means of obtaining utility. The appropriate characteristics involved are subject to debate and ongoing research, but obvious candidates include individual health status and notions of social justice (Scanlon 1975; Sen 1985; Sagoff 1994; Barer, Getzen et al. 1998).

Extra-welfarist approaches represent an important break with the welfare economic tradition, but that break should not be over-played and its historical roots should be recognised. Extra-welfarism is best thought of as supplementing and "transcending" (to use Culyer's term (Culyer 1989)), rather than replacing traditional welfarism, in that it does not necessarily exclude individual-based welfare from the judgement, but it does supplement individual utility with other aspects relevant to societal welfare.

The historical roots of extra-welfarism in economics can be traced back a fair way. Culyer (Culyer 1989), for example, cites Bergson's (Bergson 1938) "classic theoretical article" of 1938 in which the specified social welfare function included terms that could be interpreted as extra-welfarist. Bergson did not pursue these terms, however, dropping them in favour of an explicit partial analysis. The most important extra-welfarist strand from a historical perspective was undoubtedly the notion of "merit goods". Musgrave (Musgrave 1959) raised this term in his "Theory of Public Finance" in 1959, describing them as goods whose consumption is considered so meritorious (by government) that they are made available on terms that are more generous than in the market place. Attempts were made to bring merit goods within the welfarist framework (eg by Culyer in 1971 (Culyer 1971)), but these were generally regarded as unsuccessful (Culyer 1989). These attempts nonetheless stimulated the search for a better framework, rather than leaving the concept of merit goods as a kind of ad hoc "escape clause" (to use the expression coined by Margolis (Margolis 1982)). It became increasingly unacceptable to a growing band of economists, that a notion, which explained an important observed phenomena of clear normative significance, could not be accommodated by traditional theory. The concept of merit goods was thus a watershed[18], because it plainly involved the possibility of governments overruling the judgements of individuals about what was of value to them. It raised the issue of what weights should be attached to individual utilities in the social welfare function and who should be assigning those weights.

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[17] There are caveats made to this generalisation in the literature, but the focus on goods and services remains.

[18] The work of Pigou and Marshall in the "material welfare" tradition (Robinson 1986) consolidated the importance of external criteria and challenged the extreme libertarian view that any interference with consumer sovereignty by governments must reduce utility.

Then in 1972 an explicit departure from welfarism was advocated by Williams (Williams 1972) and discussed further by Sugden and Williams (Sugden and Williams 1978) in the context of cost-benefit analysis. Called the "Decision-Making Approach" (DMA), this framework advocated the use of directly obtained or carefully inferred values of "policy-makers" or "decision-makers". The answer to the question "who decides what entities with what weights go into the social welfare function?" under this framework is "decision-makers". While this framework does not theoretically preclude either a welfarist or extra-welfarist approach – as the arguments in the objective function are specified by the decision-maker – it is best classified as a variant of non-welfarism[19]. The rationale for the DMA framework is important because it offers a theoretical foundation for those economists who recognise that the role of economic evaluation within the decision-making process is contingent upon its perceived relevance to policy-makers.

During the 1970's and 1980's, Amartya Sen[20] became a strong advocate for extra-welfarist approaches to evaluation in economics and for the importance of achieving social justice in resource allocation decisions. Sen argued that a particularly important class of non-utility information about individuals was their "basic capabilities" – by which he meant a person being able to perform important basic functions. If a quadriplegic, for example, is unable to perform particular basic activities, then he or she is seen as having special "needs" that are independent of his or her total or marginal utility.

Culyer, who coined the term "extra-welfarist" (Culyer 1989), developed Sen's ideas by advocating the more general notion of "characteristics of people". These characteristics may include, for example, their genetic endowment of health; their socioeconomic status; their moral worth and "deservingness"; or their severity of pain. Only some of the characteristics of people (which will include some of their capabilities) will be deemed relevant for inclusion in the social welfare function and the list of such relevant characteristics is likely to vary between cultures and countries. For Culyer, relevant characteristics are contingent, related to the concept of need and will vary with context. Whereas the concept of "need" received little support amongst traditional welfarists, extra-welfarists – to quote Culyer – "*have been able to use the term with some precision and confidence*" (Culyer 1989). In a series of articles[21] published through the 1980's and 1990's, Culyer developed an extra-welfarist framework centred on health as the proximate maximand.

Culyer's work, in the words of Jeremiah Hurley (Hurley 1998):

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[19] It is clear from the literature that "extra-welfarism" is not a precise term, with Culyer himself defining it in different ways in different articles (i.e. as both subsuming and replacing utility). I have adopted the term "non welfarist" as a general category that includes Culyer's extra-welfarism, together with anything else that is not welfarism.

[20] See (Sen 1977; Sen 1979; Sen 1980; Sen and Williams 1982; Sen 1985; Sen 1987)

[21] See (Culyer 1980; Culyer 1984; Culyer 1989; Culyer 1990; Culyer 1992; Culyer 1995; Culyer and Evans 1996).

> *"... represents one of the more sustained, and more successful, efforts in the health sector to develop from first principles an alternative to the welfare economic framework." (p. 375)*

For applied analysis, Culyer advocated cost utility analysis with the use of Quality Adjusted Life Years (QALYs) as the measure of health, albeit QALYs in which the quality weights are not necessarily derived from utility values. In contrast, the empirical approach derived from the welfare economic framework is cost benefit analysis; a market-like appraisal technique based on the "Potential Pareto Improvement" criterion discussed below.

4.2.2 Orthodox welfarism: a satisfactory theoretical foundation for the allocation of health sector resources?

Orthodox welfare economics is built on four central and related concepts (Bator 1957; Hurley 1998; Richardson 2000a): utility maximisation; consumer sovereignty and the associated notion of revealed preference; consequentialism; and welfarism. The first concept, utility maximisation, is essentially a behavioural assumption. The latter three are normative assumptions regarding who is in the best position to judge welfare and the types of information necessary to facilitate that judgement (Hurley 2000).

"Utility maximisation" embodies the proposition that individuals choose rationally according to defined notions of consistency – the so-called axioms of choice (Varian 1978). "Consumer sovereignty" is the proposition that consumers are the best judges of their own welfare (i.e. of their own utility) and reveal their preferences through their choices of goods and services in the market. Consumer sovereignty is thus contrary to the notion of paternalism – that a third party may know better than the person may what is best for them. "Consequentialism" holds that consumer preferences are in turn based on outcomes, not process[22] – that any action, choice or policy should be judged on its effects or consequences. "Welfarism" is the assumption that social welfare should be judged entirely as a function of its impact on individual utilities. Completing the process requires a method for summing the individual utilities in order to determine social welfare and efficiency (i.e. policy changes that improve social welfare). The adequacy of these assumptions to provide an appropriate foundation for priority setting in the health sector are now examined, starting with the key issue of how improvements in social welfare are determined.

Orthodox welfarism has had two approaches to determining whether policies lead to improvements in social welfare. In early neo-classical welfare economics utility was assumed to be cardinally measurable and interpersonally comparable (Marshall 1961). The best policy was simply the one that maximised the sum of utilities in the population (i.e. utilitarianism).

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[22] The possibility that the orthodox utilitarian approach could be re-constructed to attach utility to "process" is discussed below. It is not normally done in practice and risks an all-embracive and vacuous definition of utility.

With the development of ordinal utility theory (the so-called "second theory of welfare economics")[23] the assumptions of cardinal measurement and inter-personal comparison were dropped. The retreat from interpersonal comparisons reflected the view that economists have no special professional competence in making such judgements. The intrusion of subjective values into economic analysis ran the risk of bringing positive and empirical analysis into disrepute by giving a false "scientific" authority to values having no such authority, or worse, may turn into special pleading (Culyer 1984). Further, welfarists saw no clear agreement among members of any social group as to the relative deservingness of its members. As recorded by Harberger (Harberger 1971) their conclusion was that *"Costs and benefits....should normally be added without regard to the individuals to whom they accrue"*. [The irony of this conclusion for extra-welfarists, is that having correctly concluded that economists have no professional qualifications to make interpersonal comparisons, welfarists then did exactly that by giving each person the same weight.]

As these ideas took hold, the problems associated with summing utilities were circumvented by recourse to the criterion of "Pareto Optimality". A policy change is judged to be Pareto Optimal if and only if it is impossible to increase one person's utility without simultaneously decreasing another's. The Pareto Criterion (PC) embodied Keynes' plea for economists to act like *"humble, competent people, on a level with dentists"* (Keynes 1972). The value judgement that a change that harmed no one and made at least one person better off seemed innocuous enough. For applied welfare analysis, however, this shift came with a heavy price. First, nearly all policy changes in the real world hurt someone, and strict application would lead to policy paralysis. Second, for a given set of resources, each of many possible allocations of those resources can be Pareto Optimal – the PC does not lead to a single best allocation, but to a utility possibility frontier. As Culyer and Evans explain (Culyer and Evans 1996):

> *"The fundamental theorems of welfare economics refer to the linkage between the initial resource endowments of transactors in an economy, with given tastes and technology, and the potential outcomes – through transformation, exchange and consumption – in a multi-dimensional utility space. If utility maximising consumers and profit-maximising firms interact in a perfectly competitive environment, with all the stringent structural and behavioural assumptions that underlie price theory of the textbooks, then the economy will reach its utility-possibility frontier... At this frontier – the potentially infinite set of Pareto-optimal points – no transactor's utility can be increased through reallocation without reducing that of another... None of this tells us anything about the goodness or badness of different points on that frontier relative to each other or even points off it... Hence one can draw no conclusions from these theorems about more or less desirable ways of ordering social arrangements, only about what might, under certain conditions, be possible. Terms like 'efficiency' or 'optimality', however, sound normative, whether or not modified by 'Pareto'... This is at best confusing and at worst deliberately misleading."(p. 246)*

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[23] The second theory focuses on the relationship between initial resources and a Pareto efficient equilibrium. The theory is not so much about cardinal or ordinal theory per se, as it is about providing a lifeline to save welfare theory from the accusation of non-comparable utilities (Personal Communication [Richardson, 2001]).

This is why Pareto's concept of efficiency and optimality, while endowed with an impeccably precise technical meaning, has very little practical usefulness for economists who wish to inform the decision-making process in the real world. Further, as Baumol states (Baumol 1969), the PC simply side-steps equity issues associated with the income distribution, which further diminishes its role:

> *"Pareto optimality analysis sidesteps the issue of income distribution... [Optimality rules resting on a Paretian foundation] remain either silent or prejudiced in favour of the status quo on the issue of income distribution and are, therefore, necessarily incomplete or unsatisfactory even on matters for which distribution is not a primary issue. Ultimately, the Paretian criterion can be considered the welfare economists' instrument par excellence for the circumvention of this issue." (Cited in Reinhardt 1998, p. 26)*

Two theorems of welfare economics justify their near exclusive focus on efficiency over distributive equity (Hurley 2000). The first theorem states that the allocation of resources generated by a perfectly competitive market process is Pareto Optimal (i.e. achieves all three levels of efficiency). The second theorem states that any Pareto Optimal allocation can be achieved through a perfectly competitive market. The theorems provide the justification in welfare economics for taking a market allocation as the reference standard. Because any Pareto optimal allocation can be reached through a competitive market process given the right initial distribution of resources (income), welfare economists feel free to analyse only questions of efficiency, leaving questions of the right distribution of resources to the political process[24]. The only efficiency rationale for non-market arrangements is market failure caused by violation of the model's assumptions (refer discussion Chapter One). In the absence of costless, lump-sum transfers (i.e. in the real world), however, efficiency and distributive concerns cannot be separated (Reinhardt 1992).

In an effort to overcome these limitations, the attention of welfarists shifted to the "Potential Pareto Improvement" (PPI) – also called the "Kaldor-Hicks criterion" (Hicks 1939; Kaldor 1939; Hicks 1941). A policy is said to produce a PPI if benefits that accrue to the gainers are sufficiently large that they could compensate the losers, making the losers no worse off than they were before the policy, while still retaining some net benefit for the gainers. The PPI is an attempt to derive policy relevant recommendations within a Paretian value framework without explicit interpersonal comparisons. While much policy work that claims economic authenticity (particularly under the mantle of cost benefit analysis) has been undertaken on the basis of PPI, exactly why the possibility of compensation that does not necessarily take place should influence the ranking of alternative policies has never been made clear – despite the theoretical and ethical debate it has attracted.

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[24] Ng makes the assumption, for example, that it is the role of governments to re-distribute income (Ng 1979). As Richardson comments, this is akin to the economist (like Pontius Pilate) "washing his hands" of distributive concerns. It seems a little odd that welfarists are prepared to place such faith in government, when everywhere else in welfare economics the government role is denigrated. [Personal Communication, Richardson (2001)]

Criticism of the theoretical basis of the PPI has focused on its ability to produce unambiguous rankings (Hurley 1998) and whether it can serve as a conceptual foundation for using the net benefit criterion in cost-benefit analysis (Blackorby and Donaldson 1990). The major debate, however, has centred on the ethical issues involved, particularly whether PPI provides an acceptable basis for societal decision-making. While many economists have discussed the ethical problems associated with hypothetical compensation, Reinhardt's contribution has been the most entertaining, dismissing PPI as the "Unrequited-Punch-In-The-Nose-Test" (Reinhardt 1992). Richardson (Richardson 2000a) rightly argues that at best the PPI encourages the application of "*potentially better*" policies and at worst, bases policy advice on the dubious ethical proposition that "*potentially better*" means "*better*" – a misleading use of our language.

A more benign interpretation of the PPI is that economists pass back the issue of whether or not the compensation should take place to decision-makers. This rationale, while plausible, is weakened by the common disregard of distributive issues in most economic evaluation work, which leaves the decision-maker with minimal information to make such judgements. In the health sector this is even more problematic, because when decisions regarding life and death are made, compensation is not possible, even in principle. As Richardson (Richardson 2000a) concludes:

> *"As compensation for health and health services not received has never occurred nor even been contemplated in any country, the Kaldor-Hicks criterion is simply irrelevant and the concept of 'pure economic efficiency' – value free improvement is misleading." (p. 5)*

Without the PPI principle and the PC forerunner, it is impossible in practice, as argued by Williams (Williams 1998), to separate the analysis of efficiency and the analysis of equity. Further still, Richardson argues persuasively in a series of recent papers, that the failings of welfarism re-establishes the importance of the ethical debate ignored by neoclassical orthodoxy (Richardson 1999; Richardson 2000a; Richardson 2000c). While touched on in this chapter, the important role of ethics in resource allocation is taken up further in Chapter Five.

An alternative defence for PPI discussed by Hurley (Hurley 1998) and other commentators[25], is that economists may believe that, over time, everyone will be better off when policies are based on PPI. The essence of this defence is that individual cases of injustice will cancel themselves out. At best this is an ad hoc defence of PPI and cannot claim the authority of welfare theory and its associated rigorous proofs. It is an untested (and possibly untestable) hope. As Hurley points out, however, it is quite possible that the competitive market-based solutions favoured by the welfarist approach will systematically favour one group of society

[25] See commentators such as (Buchanon and Tullock 1962; Pauly 1995; Reinhardt 1998; Richardson 2000a).

over others. The systematic skewing in the distribution of income associated with market-based policies and globalization provides empirical support for this concern. It is quite unlikely, as Richardson argues, that most of the nation will remain neutral or pleased by the observation of a growing disparity in income, health status or access to health care services, as long as no one is disadvantaged in absolute terms. To the contrary, there is nothing that will breed disharmony as quickly as the granting of advantage to some members of society while others are ignored (Richardson 2000c).

This defence also leaves another fundamental problem. The starting point for a judgement about the relevance of a normative theory – about how to assess when society is better or worse off – is the proposition that a framework for normative analysis ought to be congruent with the fundamental values that prevail in that society (Culyer 1989; Hurley 1998; Richardson 2000a). This does not mean the unthinking adoption of every societal whim or preference, but rather that deeply held values in society are an important reference standard that need to be established through empirical research – what Richardson calls "empirical ethics" (Richardson 2000a). Further, such a reference standard is arguably a more important reference standard for normative assessment than an abstract theoretical standard lacking empirical validation, regardless of how rigorous, refined, and elegant it is. Unlike positive theory, which may be tested empirically, normative or ethical theory can only be judged using agreed normative criteria. These ethical criteria are resolved in practice by their airing and debate in the "intellectual market", together with the role of government as "circuit breaker" (Richardson, 2000)[26].

Culyer (Culyer and Evans 1996) makes the related point that the personal values of economists have no more normative weight than the personal values of any other member of the community. Culyer argues that even if every economist agreed that PPI was a valid basis for social decision-making, however unlikely that event may be, it would carry little weight unless it were shared by the general community – or their representatives via the democratic process. Buchanan (Buchanan 1987) takes a similar position:

> *"...propositions in political economy find empirical support or refutation in the observed behaviour of individuals in their capacities as collective decision-makers – in other words, in politics." (p. 7)*

Summarising the discussion of neoclassical welfarism to this point, the key Pareto concepts for efficiency and for a social welfare improvement have been found to be highly problematical, particularly to serve as the theoretical basis for practical advice to policy-makers on priority setting. While individual utility is a relevant argument for inclusion in the social welfare function, it needs to be supplemented by other issues of concern to society – such as need, health status, equity and social justice. Before moving to discuss extra-

welfarism as the theoretical foundation in lieu of welfarism, it is important to flag, albeit briefly, problems with the associated welfarist assumptions of utility maximisation, consumer sovereignty and consequentialism, on which the Pareto concepts depend.

Starting with utility maximisation, there are serious doubts as to the applicability of this concept as the sole or even primary objective in all contexts, due to the likelihood of preference failures and the fact that preferences are commonly endogenous. There is a discussion in the literature (Bowles 1998; Rabin 1998; Goodin 2000; Richardson 2000a), for example, of different concepts of preferences from the complete, well-ordered preferences of the axioms of choice (Varian 1978) that underlie neoclassical orthodoxy. These authors raise the possibility of "preference failures" due to poor information or poor understanding; the impact of context; and failures due to lack of will or motivation – all issues very real in the health sector. As Richardson (2000a) summarises:

> *"... the determinants of preferences and even their existence may be unclear and, consequently, the relationship between their expression (or lack of expression), well-being, and what we should seek to achieve is, at best, variable and uncertain." (p. 9)*

Extra-welfarists argue that welfarism is inherently limited because utility focuses too much on mental and emotional responses to commodities and characteristics of commodities and not enough on what they enable you to do (Culyer 1990). A problem with focussing on such mental states, for example, is adaptation (Elster 1982; Sen 1987b; Kahneman and Varey 1991)). Those born in poverty often adjust their expectations, for example, to what is realistically achievable[27]. Similarly, the disabled are often able to adapt to their disabilities and live fulfilling lives. That such individuals may have high levels of "utility" does not detract from their claims for special assistance. An extra-welfarist approach can accommodate such concerns in a way that welfarism cannot (Culyer 1990).

Perhaps the more important problem for consumer sovereignty, however, is that social institutions influence peoples' capacities and their values. If market forces – or other self-interested parties – can engineer preferences, then there is less weight to the welfarist ethic that gives pre-eminence to individual preferences. For example, if cigarette companies can increase the preference for cigarettes, then such endogenous preferences make consumer sovereignty less appealing as the cornerstone of "liberal" values. Further, even with fixed preferences, society may also choose to override individual preferences. In the health sector, this issue often takes the form of the merit goods argument[28], where individuals acting as

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[26] The issue of ethical values is taken up at some length in Chapter Five.
[27] Sen's evocative and rhetorical question is whether we should redistribute from the Indian peasant to the dissatisfied New Yorker if the former is highly adapted and contented and the latter is not (because the marginal transfers may increase total utility).
[28] Note that in this second context, we override not because preferences have been induced, but because we believe their harm outweighs the importance of consumer sovereignty as a principle in these cases.

citizens support policies that overrule the consumption preferences of individual members of their society (eg alcoholism; tobacco control and other forms of drug addiction).

Another type of problem with the welfarist concept of utility maximisation relates to the meaning of the word "utility" itself. Richardson (Richardson 1994), for example, refers to at least four types of utility: (i) pleasure/pain in the hedonism tradition; (ii) psychological strength of preference as manifest in feelings of anger or satisfaction; (iii) an ordinal ranking of preferences serving as an organisational framework in positive analyses; and (iv) behaviour corresponding with the von Neuman-Morgenstein axioms of expected utility. There is certainly room for debate – possibly confusion – as to what exactly is the form of utility that ought to be maximised. The defence that utility, by definition, is revealed by what a person does, irrespective of what reasons and/or feelings are involved is hardly convincing, particularly for normative analysis. Some commentators (Harsany 1997) argue that welfare economics should be reconstructed and based on "informed" rather than actual preferences – that is, that surveys of individuals undertaken to inform policy decisions should be based on procedures that encourage deliberation. While the concept of deliberative judgements has appeal for strategic planning and priority setting contexts, it sits more comfortably in the extra-welfarist approach than with orthodox neoclassicalism (as it conflicts with the usual welfarist assumptions of perfect information and that consumers know, with certainty, the results of their consumption decisions (Rice 1998).

A different challenge to the primacy of individual utilities comes from those economists who have observed that a communitarian philosophy and the inclusion of community benefits – as distinct from benefits captured through individual utility – is shared by many in the community. Mooney, for example, seeks a mechanism whereby communitarian values, expressed by individuals acting as community members and ultimately as citizens, may be used to specify the objectives of the health care system (Mooney 1996; Mooney 1998). Shiell and Hawe (Sheill and Hawe 1996) argue, particularly in the context of public health, that many programs have the community, not individuals, as the basis of program theory and as the unit of analysis. The notion of community is very different to that typically employed in economic analysis, particularly analysis based on welfarism (Hawe 1994). In community development programs, community is seen ecologically. In welfare economics, it is seen as nothing more than the aggregate of individuals. Sense of community and community competencies are properties of the community, and it is questionable whether aggregating the effects on individuals (Sheill and Carter 1998) can capture the full benefits of community action.

Combining with the assumption of utility maximisation is the concept of consumer sovereignty and revealed preference – often referred to as the Neoclassical Theory of Demand. Specification and criticism of the various restrictive assumptions underlying this behavioural model have been well rehearsed in the economic literature, including most health economics

textbooks, and recently brought together very cogently by Rice (Rice 1998). The key issues are information asymmetry, supplier-induced demand, externalities and uncertainty (together with moral hazard and adverse selection for the insurance solution to uncertainty), that were reviewed briefly in Chapter One. The implications for policy hinge on judgements about the empirical significance of these various forms of market failure. The reluctance of governments around the world to leave the consumption of health care to unregulated and unsubsidised markets suggests that concerns about the competence of consumers to make rational health care choices are very real to policy-makers and the communities they serve.

Finally, the assumption of consequentialism means that any policy being evaluated can only have instrumental value for achieving a pre-determined outcome of concern. An emphasis on outcomes in evaluation is not unreasonable, as most policy-making is undertaken with a purpose in mind. The danger with consequentialism is twofold: (i) an over-emphasis on outcome per se at the expense of issues associated with process; and (ii) a focus on one aspect of outcome – efficiency – at the expense of other important outcomes – such as equity or saving those in most need. Within the welfarist framework this danger receives impetus from the assumptions that engender a false dichotomy between efficiency and equity (Zajac 1985; Reinhardt 1992; Hurley 1998).

Consequentialist thinking is often contrasted with approaches that emphasise due process and context over outcome – and indeed this contrast was highlighted in Chapter Two as a key debate in the priority setting literature. The importance of process and context also emerges in Chapter Six as a lesson from international experience. In the UK, for example, Draper and Tunna (Draper and Tunna 1996) in reviewing the notorious case of Child B (Jaymee Bowen) comment:

> *"Health authorities have an obligation to ensure procedural justice in the allocation of resources, as well as respect the rights of individuals... In adjudicating a special claim on resources, by an individual, who is likely to die quickly if resources are not forthcoming, commissioners may feel compelled to assist, even if they would not consider the small possibility of benefit worth the cost under other circumstances, perhaps where death is not imminent." (p. 44)*

In the context of Oregon, for example, Hadorn (Hadorn 1991) argued that rationing which may be acceptable in abstract, or at least in some contexts, would not be acceptable in the case of an emergency. Imperatives such as the "rule of rescue" are well known, but the importance given to context in such cases may conflict with the assumption of consequentialism (Richardson and McKie 2000e).

Approaches that emphasise a fair and reasonable process as legitimising decisions, often accord individual rights prime status – as illustrated by the priority setting principles agreed by Sweden (refer Chapter Six). In principle, procedural justice might be conceptualised as

consequences because utility functions can include nearly anything as arguments (McGuire, Henderson et al. 1988; Culyer 1998). The Bergson-Samuelson-type social welfare functions, for example, have utility arguments that incorporate distributional concerns through their functional specification (Boadway and Bruce 1984). But this seldom occurs in welfarist analysis and would be difficult to do in practice. Richardson (Richardson 2000c) sums up the problem neatly in the following passage:

> *"Defining processes as part of the consequences of an action would imply that all of the considerations of procedural justice would be reconceptualised as consequences. Thus, for example, the processes by which outcomes were achieved would be redefined as outcomes and the same consequences derived by two different processes would be seen as two different outcomes. This is clearly not intended by orthodox statements of theory in which the arguments of a utility function are conceived as goods, services and in some more general statements, utilities – outcomes – for other members of society." (p. 4, footnote 4).*

Yet without the assumption of consequentialism, the welfarist concept of efficiency is undermined, as an outcome might be considered unacceptable because of the process by which it was derived, not because of the outcome per se. This is a very real possibility in the health sector, where empirical evidence suggests purely technical approaches to priority setting are rarely accepted; where due process is regarded as an important component of legitimising decisions; and where "access" to health services, rather than health outcomes, might be considered to meet social obligations (Mooney, Hall et al. 1991).

In the end, however, it is difficult to disagree with the assessment that neither an exclusively consequentialist framework, nor an exclusively process-oriented framework, does justice to the range of concerns that deserve inclusion in an appropriate evaluative framework for priority setting. Concepts such as "duty", "respect" or "fair" have value outside their utility effects for individuals. Outcomes also clearly matter and often are of prime importance. The challenge is to develop frameworks that can incorporate the full range of considerations in ways that reflect how they are valued by society. The ability of extra-welfarism to meet this challenge is now considered.

4.2.3 Extra-welfarism as the theoretical foundation:

The starting point for this discussion is Culyer's work on extra-welfarism, as he is so closely identified with this theoretical framework. In contrast to the welfare economic theory and its focus on individual utility, the extra-welfarist approach concentrates on the characteristics of people, particularly non-utility characteristics. Two pivotal concepts that emerge from Culyer's work are deprivation and need. Culyer (Culyer 1990) argues that:

> *"If the characteristics of people are a way of describing deprivation, desired states, or significant changes in people's characteristics, then commodities and their characteristics are what is often needed to remove their deprivation." (p. 12)*

Though never stated unequivocally[29], Culyer's writings (Culyer 1989; Culyer 1990) strongly imply that health should be the outcome of prime concern, preferably measured with QALYs. Ill health creates a need for health care, which restores a person's health (or controls the worsening of health). If the relationship between health interventions and health status can be determined through evaluation, than health researchers can use the concept of "need" with more precision than in most other sectors. With its emphasis on need, extra-welfarism has affinity with the earlier material welfarist tradition of Pigou and Marshall (Marshall 1890). It is important to note, however, that in Culyer's framework ill health per se does not create a need for health care. For Culyer, there must be an effective intervention available, before ill health becomes a need.

In Culyer's extra-welfarism health maximisation thus replaces utility maximisation as the "proximate maximand" (Culyer, 1989, p51). For rationing the decision rule becomes "equalising marginal products in terms of health per unit resource" (Culyer, 1989, p51) and "optimal resource use is determined by equality of marginal health output per unit in various activities and across various groups (Culyer, 1989, p55). In adopting a health maximising stance, however, Culyer does not ignore equity. He proposes a set of distributive weights based on the characteristics of people (note also the work of (Wagstaff 1991)). While the concept of such equity weights is by no means new – see for example the earlier work of Weisbrod on cost benefit analysis (Weisbrod 1968) – such weights sit far more comfortably with an extra-welfarist framework than with welfarism, because they constitute non-utility information.

To summarise, extra-welfarism integrates three key concepts that do not fit easily into the welfarist framework: the concept of need (as opposed to demand); the concept of health as the key outcome (as opposed to utility) and the inclusion of equity in relation to each. The extra-welfare analytic framework can be described thus:

> *"From the set of characteristics of people, define the set of characteristics that are normatively relevant for evaluation in the health sector, measure the level of deprivation in these characteristics (health care in particular) to address these deprivations, and determine alternative allocations of resources to reduce the deprivations." (Hurley, 1998, p379)*

The health sector has been particularly receptive to Culyer's extra-welfarist ideas, in part because of features of health care markets that render questionable major elements of the welfare framework and in part because the role of health care in the health production

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[29] Note, that as mentioned previously, Culyer is not consistent in his writings on extra-welfarism, with extra-welfarism defined as both complementing and replacing utility in the social welfare function (Culyer 1989). A typology based on either utility maximisation (welfarism) or health maximisation (Culyer's extra-welfarism) would leave many gaps, such as when duty or the rule of rescue result in neither utility nor health maximisation. The approach I have chosen, therefore, is to conceive of two broad approaches to the social welfare function, viz: welfarism or non-welfarism, with non-welfarism as extra-welfarism plus anything else that violates the welfarist assumptions.

function provides greater scope for third-party judgement than for many other goods (Evans 1984). The single most important break from welfarism is rejection of the principle that social welfare can be judged purely in terms of utilities achieved by individuals. The question then arises, however, as to whether the substitution of "healthism" for "welfarism" satisfactorily reflects societal values. Hurley (Hurley 1998; Hurley 2000) raises three concerns with Culyer's extra-welfarism that relate to the type of information that enters the evaluation and the way that information is used. He questions the overwhelming primacy afforded consequentialism, the need for monism (uni-dimensionality in the outcome measure) and the restricted range of justice concepts that can be accommodated. Consideration of these criticisms leads naturally to the role of the Decision-Making Approach (DMA).

Hurley argues that both welfarism and extra-welfarism are strongly consequentialist, and questions the ability of "healthism" to capture process considerations (Hurley, 1998). Culyer rejects this criticism (Culyer, 1998) employing the welfarist argument that processes can be considered a component of the consequences. He endorses the inclusion of the public in the processes through which decisions are taken, together with the processes for change by which outcomes are achieved. While the inclusion of process issues is in principle consistent with the extra-welfarist framework, Culyer's focus on health gain in practice lends credence to Hurley's position. In addition, as previously argued the clouding over of the outcome/process distinction is unhelpful. A more useful position is to clearly recognise the important distinction between outcome and due process and to accept that the objectives of society in relation to health and health care are multi-dimensional. The focus in the Decision-Making Approach of Williams and Sugden on the objectives of policy-makers provides a sounder and more consistent theoretical framework for this to occur.

Monism, or uni-dimensionality in the specification of outcome, is a related issue. In welfarism that single outcome is utility, in Culyer's extra-welfarism, it is health (i.e. QALYs). Monism is driven by the need to be able to rationally rank alternatives in accordance with a decision rule (i.e. Net Present Value in CBA; cost per QALY in CUA; cost per life year in CEA) and is often considered fundamental to traditional forms of economic appraisal and to the league table approach. Hurley maintains, however, that for both conceptual and practical reasons, monism imposes far greater restrictions than can be justified by the benefits it provides (Hurley, 1998). Hurley makes three points: first; that the inherent diversity and incommensurability of different types of outcomes preclude meaningful transformation into a common metric; second, that the response of providing one piece of information and letting the decision-maker provide the rest detracts from the decision rules argument for monism; and third; that the measurement properties required to achieve complete rankings make its theoretical validity questionable.

The first point is a well-known criticism, but this does not detract from the need for it to be addressed. In applied work derived from the welfare framework all effects are measured in

dollars, whereas for extra-welfarism, health effects are reduced to a single measure, such as QALYs. The acknowledged problem here, is that monism may distort the measurement of benefits, or exclude consideration of important types of benefit altogether – particularly ethical and equity issues. Of course there may be deficiencies due to the defective application of monism, which need to be separated from problems with the principle itself.

The second point on monism relates to the practical significance of achieving complete rankings (and the associated decision rules) through a uni-dimensional outcome. If it is known in advance that decision-makers have multiple objectives, then why should the evaluation be distorted to focus only on one aspect of their objectives? Experienced practitioners (for example: (Drummond, Torrance et al. 1993; Drummond, O'Brien et al. 1997)) recognise this and argue for the results of economic evaluations to be reported at a disaggregated level in order to enhance meaningful comparison across programs. An increasing number of practitioners are questioning whether the entire economic analysis should be structured to produce a single number, which in the end, must be combined with other information to be of real use to decision-makers. This questioning is intensified by the widespread recognition that the contribution of economic evaluation to decision-making has by no means achieved its potential[30].

The third point raised by Hurley on monism involves the measurement properties of the outcome measure. Here Hurley questions whether as much is gained by monism as is commonly believed. The previous discussion of the Pareto Criterion and Potential Pareto Improvement illustrates that when ordinal utility is involved, incomplete rankings result. Within welfarism complete rankings can only be generated under assumptions of cardinally measurable, interpersonally comparable utility, such as in classical utilitarianism (Broadway and Bruce, 1984). Analogous assumptions, argues Hurley, must be made within the extra-welfarist approach regarding the measures of health and the decision rule employed (Hurley, 1998).

It is also important to note that multiple outcomes do not necessarily imply an inability to rank alternatives – although it is clearly more complicated. Nor do multiple outcomes necessarily generate inconsistency in choice (Sen and Williams 1982). In short, as Hurley (1998) concludes:

> *"The links among uni-dimensionally, achieving a complete ranking of alternatives from best to worst, and consistency in choice (rationality) are more complex than often supposed, and this complexity substantially undercuts the ultimate value of monism within evaluative frameworks." (p. 383)*

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[30] See, for example, (Ludbrook and Mooney 1984; Drummond, Stoddart et al. 1987; Drummond, Hailey et al. 1991; Drummond, Brandt et al. 1993; Hall 1993; Ross 1995; Mooney and Wiseman 1999).

Culyer's (1998) response to Hurley's rejection of monism is twofold. In principle he supports Hurley's position. Since the major objection to welfarism is its exclusivity, any replacement must be inclusive of whatever aspects of social welfare are deemed relevant. In practice, however, he believes that the weight attached to monism is an empirical issue. He argues (rightly in my view) that the values which underpin the concept of social welfare to be employed in economic evaluation should be empirically based (for example, on the values of the client; a sample of the general public; or those stated by the Minister of State or his/her representative). It follows, therefore, that deciding whether "healthism" is acceptable is also an empirical matter that is likely to vary with context and issues of practicality. If health gain is judged by decision-makers in the health sector to be the prime outcome of concern, Culyer suggests that setting other considerations to one side (or perhaps bringing them in at a later stage of the decision-making process) may do little damage. There is certainly substance to Culyer's defence, but it does emphasise the importance of deciding whose values are to be used and how these values are to be elicited. Again, this is an issue that is best handled by the Decision-Making Approach (and in my view by the PBMA approach that logically belongs to that theoretical framework).

As an important aside, Culyer (1998) also defends his interest in developing QALYs as the measure of health gain with the comment:

> *"Progress in the measurement and use of one (important) type of outcome should not have to await the outcome of a deeper and more comprehensive theoretical settlement of all issues raised in the emerging research programme... It is important that these potentially enriching departures from Paretianism are not strangled at birth on the grounds that the theory is as yet incomplete or that they entail a loss of discretion by economists as to the choice of value judgements." (p. 369).*

It is difficult to see an alternative to the need for practical judgements of the kind that Culyer has raised. Indeed, the need for judgement as opposed to ritualistic adherence to technical rules, is a major theme to emerge from various chapters within this thesis (see, for example, Chapters Two, Five and Six).

The third, and perhaps most significant of Hurley's concerns in a policy sense, relates to the links between evaluative economics and justice. The opening quote to this chapter taken from Zajac's work has at its foundation the observation that society cares deeply about issues of justice when priority setting decisions are taken. There is a growing literature documenting that justice and equity figure prominently in the resource allocation rules that individuals and societies adopt[31]. The substance of this literature is taken up in Chapter Five and is not

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[31] See, for example: (Yaari and Bar-Hillel 1985; McGuire 1986; Elster 1992; Frolich and Oppenheimer 1992; Miller 1992; Hausman and McPherson 1993; Nord, Richardson et al. 1995a; Nord, Richardson et al. 1995b; Williams 1997; Dowie 1998; Mooney 1998; Olsen and Richardson 1998; Menzel, Gold et al. 1999; Nord, Pinto Prades et al. 1999; Olsen and Richardson 1999; Ubel, Richardson et al. 1999; Ubel, Richardson et al. 2000).

reviewed here. What is clear from this literature, however, is that there is considerable support for Hurley's view (1998) that:

> *"On both empirical and philosophical grounds, there are compelling reasons for economists to take justice and equity more seriously in evaluative economic analysis." (p. 384)*

As discussed previously, the welfare framework, strictly adhered to, is essentially mute with respect to distributive concerns and studiously avoids ethical considerations[32]. The extra-welfare framework of Culyer is able to accommodate distributive equity through weighting the QALYs for relevant characteristics of individuals. It is important, however, that in any such application, the ethical basis for the weights selected be made clear. There is evidence to suggest, for example, that in general society values differently the production of health in relevantly defined sub-groups of the population (Williams 1988). Such values would make QALY weights a feasible proposition. It is also important to note the importance of context. In settings where the relations are impersonal and possibly competitive (such as markets) priority tends to be given to reward based on contribution or desert. In contexts where relations are more personal and/or cooperative, notions of equality and of responding to need are given priority. Even within the health sector, where cooperative values will have primacy, resource allocation principles will still vary by context and research question. The importance of context and the role of judgement are themes that come to the fore in various chapters of this thesis.

The major substance to Hurley's concern, however, is not in the way distributional weights might be operationalised, but rather the exclusion of considerations of justice beyond distributional justice. In both the ethical (Chapter Five) and empirical (Chapter Six) literature on priority setting, concepts of procedural justice play a prominent role. Issues arise relating to how decisions are made; who is involved; what factors are considered and what weight they are given. As reviewed in Chapters Two and Six, process considerations come to the fore in any explicit rationing of health care resources. The empirical evidence suggests that systems that are perceived to work well are heavily influenced by a concern for procedural fairness and do not attempt to maximise health gain through automatic application of decision rules.

Like others[33] before him Hurley concludes his review with the admonition that researchers ought to support the policy-making process by identifying relevant issues and providing information needed for deliberation over those issues. He argues that the research question has to drive the analysis, rather than simply imposing a pre-determined framework. Both the welfarist and extra-welfarist frameworks considered to this point have sought analytical solutions implemented through decision rules (what is referred to as technocratic solutions in

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[32] While necessarily adopting, but not acknowledging, a particular ethical position.

the priority setting literature [refer Chapter Two]). In the face of the complexity posed by differing concepts of equity and justice, economists historically retreated to Pareto. The result was an elegant but stilted framework of little practical use to policy-makers in the real world. The challenge, as Hurley rightly concludes, is to develop an evaluative framework with enough rigour to be theoretically meaningful, but with enough flexibility to accommodate the range of complex elements that are relevant to evaluations of societal welfare. While less developed than either the welfarist or extra-welfarist approaches, most appealing framework presented to date is the Decision-Making Approach.

4.2.4 The decision-making approach

With the Decision-Making Approach (DMA) of Williams and Sugden (Williams 1972; Sugden and Williams 1978), economic appraisal is seen as a process that assesses efficiency in terms of the objectives specified by the decision-maker(s) commissioning the analysis. A range of perspectives (from societal to health provider) is thus consistent with economic evaluation undertaken under this non-welfarist framework. In virtually every advanced economy, however, the majority of health expenditure is financed from the public purse, either explicitly or through tax expenditures (OECD. 1998) and decisions by government will dominate priority setting and strategic planning in the health sector. When the decision-maker is the government or a government authority, the perspective can be considered "societal" in the sense that governments are assumed responsible for making decisions in the public interest. The government decision-maker is entrusted with the task (via the democratic political process) of making choices on behalf of the general public, and this trust implies the formation of objectives on their behalf, and importantly, the reflection of societal ethical values.

Two points stand out from the DMA focus on the decision-maker as the appropriate authority to proscribe the arguments in the social welfare function, as well as their relative importance. First, that it is an important part of the analysts' duty to find out clearly from clients what the relevant objectives and values are; and second, as noted previously, that the DMA does not preclude a welfarist approach, although it is a variant of non-welfarism. This enables economists working under the DMA framework to select from the full range of applied economic techniques (whether they are linked to welfarist or extra-welfarist foundations) restricted only by their relevance to the research question. It also means that analysts can go beyond the limitations shared by welfarism and extra-welfarism (i.e. over-reliance on consequentialism, monism and neglect of procedural justice), provided these issues are endorsed by the decision-makers.

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[33] See, for example (Lindblom and Cohen 1979; Schmid 1989; Mooney and Wiseman 1999)

In relation to the first point, a number of authors have noted that ascertaining decision-maker objectives is not always easy (Sugden and Williams 1978; Culyer 1990; Culyer 1998; Mooney 1998)). These authors also recognise, however, that it is nonetheless a key aspect of the evaluation and priority setting process. For Culyer (1998), the elicitation of objectives is an important aspect of the economist's contribution to the decision-making process. The economist's task is to spell out the full implications of options for change, having regard to the decision-makers' objectives, and to ensure that no reasonable option is excluded from the analysis. At an applied level, some evaluation techniques are more suited to this role than others. The focus in the Program Budgeting and Marginal Analysis (PBMA) approach on clear elicitation of decision-maker objectives, for example, together with techniques to translate objectives into benefits, make it ideally suited to the DMA framework.

At the broad policy level, clarity about objectives requires the analyst to seek authoritative government statements on policy aims. Empirically, there is strong support for equity in health care. Van Doorslaer and colleagues (van Doorslaer, Wagstaff et al. 1993) found, for example, that official policy statements in ten OECD countries all placed great emphasis on equity, both in relation to the financing of health care and in its use. Most government intervention in health care has been to ensure that access to necessary services is not determined by income – as would follow from the orthodox welfarism. It seems unfair to many that those with the same level of medical need (however defined) should receive less treatment simply because they have less income. Thus, while governments may pursue efficiency in the provision of health care services, they balance this with other social objectives such as distributive and procedural justice.

Selection of the DMA as the theoretical foundation for priority setting has important implications for the way in which economic evaluation should be conducted. It impacts on perspective, the choice of comparators, the identification and measurement of relevant costs and benefits, together with issues of "due process" that are commonly ignored in conventional appraisals focused on individual projects. The broader societal values that can be accommodated by the DMA poses important challenges. If in addition to efficiency (regardless of whether the maximand is considered to be utility or health gain), objectives are broadened to include issues of distributive equity and procedural justice, how are they to be incorporated into the economic approach? It is to this issue that we now turn, reviewed in the context of the links between evaluation techniques and the theoretical foundations discussed above.

4.3 Implications for design and conduct of economic evaluation

4.3.1 Introduction and key concepts

This section shifts focus from the validity of the theoretical frameworks for normative analysis, to applied economic evaluation methods, particularly the congruence between evaluation techniques and their conceptual underpinnings. The development and application of evaluation techniques comprises a large part of the health economics literature because of the reliance on non-market allocation methods in the health sector. This section does not attempt a detailed discussion of all the individual evaluation techniques available (refer scope and limitations in Chapter Three), but rather highlights the key techniques and issues central to the task of priority setting. Note also, that the techniques reviewed can be utilised to inform different research questions – from decisions about the design of individual interventions through to broad-based approaches to priority setting involving multiple interventions. While the techniques themselves are reviewed here, their use within economic approaches to priority setting (such as QALY League Tables) is reviewed in Chapter Nine.

The various economic evaluation techniques available either derive from, or can be related to, the three normative frameworks emphasised thus far, viz: welfarism and the two major elements of non-welfarism – extra-welfarism and the DMA. Each normative framework implies important differences in the specification of the economic protocol, including the delineation of the research question and selection of evaluation technique (see below). But there are also important similarities between any evaluation methods that purport to be classified within the economics discipline. Adherents of all three approaches would agree, for example, that the concepts of "opportunity cost" and "marginal analysis" are central to the economic perspective. The concept of costs as forgone opportunities (or benefits forgone) provides the logic for two important characteristics of economic appraisal: first; that it considers both costs and consequences; and second, that it involves a comparison of alternatives. It is possible to distinguish economic appraisal from other forms of evaluation using these two characteristics (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997).

Similarly, economic evaluation stresses the analysis of marginal costs and marginal benefits of a health service or policy as fundamental to the measurement of efficiency. If the objective is to maximise utility (or health gain) for a given budget, then the task is to ensure that the last dollar spent on each program improves utility (health) by the same amount. The rationale is simply that if this criterion were not met, resources could be transferred between programs to improve total utility (total health) with the same resources. As Mooney (Mooney 1993) explains:

> *"If no budget constraint exists, then a programme should be expanded or contracted to the point where marginal benefit equals marginal cost; if there is a budget constraint, then all*

programmes should operate at a level whereby the ratio of marginal benefit to marginal cost is the same for all."

While in theory marginal analysis relates to the last unit of production/consumption or to the last individual in receipt of or denied service, in reality it is operationalised as practical units of change. These units of change (which reflect lumpiness in the production function and/or budget issues) may involve the expansion or contraction of comparator health services or the design and scale of activities within a specified health service, including the sub-populations to which the services could be addressed. In practice, most health care organisations face rigidities in the free movement of resources and relatively fixed budgets. Often decisions relating to health services planning and priority setting are not about whether to introduce or close a health service per se, but rather whether to have a little more or less of existing services.

Advocates of the three normative frameworks would also agree that a "clear concept of benefit" was central to undertaking economic evaluation, although as discussed in Section 4.2, there would be heated debate about what the components of benefit should be and how that benefit should be measured, valued and aggregated. An important element of this debate involves distinguishing the question of how best to allocate resources across quite different programs (i.e. allocative efficiency) from the question of how best to pursue a chosen objective (i.e. technical and/or productive efficiency). While the concepts of efficiency are linked (refer Section 4.1), the focus of priority setting is very much on allocative efficiency and improvements in societal welfare. The choice of evaluation technique is not arbitrary from a priority setting perspective, for some techniques have greater credentials to address the issue of allocative efficiency than others, and their theoretical foundations will reflect quite different concepts of societal welfare.

4.3.2 The evaluation protocol

The natural starting point to examine the congruence between economic evaluation methods employed to measure efficiency and their conceptual framework in economic theory, is the "evaluation protocol" – that is, the document which should clearly specify the methodological design of the evaluation. A useful way of considering issues of protocol is to address key design elements picked-up in accepted critical appraisal guidelines (Drummond, O'Brien et al. 1997).

The research question:

The starting point for any evaluation or exercise in planning and priority setting, should be a clear specification of the research question. This requires a description of three things: i) the study perspective or viewpoint; ii) the choice of comparators; and iii) the context and setting of

the study. All of these aspects are likely to vary depending on the theoretical underpinning that the analyst adopts.

Perspective:

The perspective for analysts who adopt the orthodox welfarist framework, for example, is clearly societal (i.e. all costs and consequences irrespective of to whomsoever they accrue). Allocative efficiency (using the potential Pareto improvement criterion) can theoretically be addressed across different sectors of the economy (although not without problems – see example (Drummond and Stoddart 1995)), but in practice this is rarely attempted. Usually decisions involving the allocation of resources between sectors of the economy are left to the political process without the involvement of analysis based on the welfarist framework. Economic evaluation to assess allocative efficiency usually takes place within sectors of the economy (such as health) and "societal" is interpreted within that narrower context. This intra-sector focus, however, does not exclude the inclusion of inter-sectoral effects in the evaluation of health sector interventions. The extent to which they are addressed is a protocol issue for the analyst. The measurement of inter-sectoral outcomes is facilitated in the welfarist framework by the cost-benefit technique [CBA], which measures both costs and outcomes in monetary units (see below).

In contrast to the welfarist framework, both the extra-welfarist and decision-making frameworks are consistent with a range of perspectives. Study viewpoints can vary from societal, to third-party payer (public and/or private), to provider institutions (such as hospitals or community health centres), through to that of the patient or groups of patients. When the perspective of the extra-welfarist framework is specified as societal, it is important to note that it is restricted, both in theory and practice, to the narrower setting of health sector interventions. The evaluation techniques aligned with extra-welfarism (cost utility analysis [CUA] and cost-effectiveness analysis [CEA] – see below for further details) either only capture health-related outcomes (CUA) or are restricted by uni-dimensional outcome measures (CEA). Debate exists on the related point of whether it is appropriate to include intersectoral effects in CUA/CEA. Mooney (Mooney 1988), for example, recommends their exclusion, arguing for the need for symmetry in the specification of costs and outcomes. Other economists, such as Drummond and colleagues (Drummond, O'Brien et al. 1997) support their inclusion on the more pragmatic principle that analysts should seek to include all costs and consequences that are relevant to the research question.

Within the decision-making framework the perspective is clearly that of the decision-maker commissioning the study (refer 4.2.4). While it certainly can be societal in the sense that governments are assumed responsible for making decisions in the public interest, often evaluations are focused on the third-party payer (public) perspective. While providing greater flexibility and sensitivity to the needs of individual decision-makers, the variety of possible

perspectives in the extra-welfarist and decision-making frameworks emphasises the need for clarity in the specification of the research question.

Choice of comparators:

Arguably, the choice of comparator programs is the most important decision in undertaking economic evaluations, for it impacts dramatically on both the validity and usefulness of the result. Certainly, Drummond and colleagues (Drummond, Torrance et al. 1993) argued so in an article assessing the usefulness of league tables. The guiding concept of "opportunity cost", strictly applied, would mean that the project(s) being evaluated should be compared with the next best option(s) (Birch and Gafni 1992). This theoretical position would apply to both the welfarist and extra-welfarist frameworks, which both give primacy to this concept. In the decision-making framework, on the other hand, primacy would be given to evaluating options that were relevant from a policy perspective. This may or may not focus on the "next best option", assuming this theoretical comparator could be ascertained.

In practice, however, issues of both internal and external validity impact on the choice of comparators in all studies, irrespective of their theoretical base. Internal validity will take into account the availability of quality data on which to base the analysis, particularly evidence to support the efficacy/effectiveness credentials of the options compared. External validity will focus on the usefulness of the study to inform the needs of decision-makers. Here, the options that have most relevance to the policy issues at hand might be included, rather than the theoretical "next best option". The balance between internal and external validity should be guided by the purpose of the study and will, no doubt, be influenced by what role the analyst sees for himself/herself in the decision-making process (and this in turn will reflect the theoretical frameworks).

Irrespective of the interplay between internal and external validity, the evaluation literature (Gold, Siegel et al. 1996; Johannesson 1996; Drummond, O'Brien et al. 1997) provides important guidance on two key aspects of choice of comparators. Firstly, that the most important question for an economic study to address is what difference the chosen option(s) will make compared to current practice (i.e. will its (their) implementation improve societal welfare?). Secondly, emphasis is often placed on the wisdom of being inclusionist in the choice of comparators – that all relevant comparators should be included. This last point has important implications for economic evaluation in terms of its application to priority setting. In the context of one-off studies addressing a single illness or problem, there is usually a reasonably limited set of possibilities to consider. In the context of studies addressing priority setting, however, such as the development of national strategies to address whole ICD-9 disease chapters, there is a very broad range of possibilities. Here, the process by which options are generated and selected for inclusion becomes an important design aspect of the protocol. It is for this reason, together with reasons related to the tractability of information

collection and assessment, that one recommendation of this thesis is that economic protocols be specifically developed for the priority setting context.

Study context and setting:
When assessing the usefulness of economic evaluations (or advice about the allocation of resources based on them) users need to know two things: i) are the results valid from a methodology perspective? and ii) if valid, are they relevant to their setting and decision context? The priority setting decision context not only has important implications for the selection of comparators, as mentioned above, but also for the range of stakeholders involved and for the processes that give legitimacy to the decisions taken. The discussion in Chapter Two, for example, covered the importance of recognising the levels of decision-making in the health sector (macro, meso, and micro), the importance placed on due process (i.e. procedural justice), and the role of judgement in applying analytical data to specific contexts (particularly where life or death is involved). The discussion in Chapter Six on the role of ethics will further endorse the importance of setting and context.

The flexibility within the theoretical frameworks to accommodate these issues was discussed in Section 4.2. The extra-welfarist framework and the decision-making approach (particularly the latter) exhibit the greatest potential to reflect setting and context within the technical process.

Choice of evaluation technique:
The choice of technique is normally guided by the principle of matching evaluation methods to the complexity of the research question. The complexity of the research question is in turn related to whether allocative and/or productive efficiency is being assessed, and to the concept of benefit adopted. The strengths and weaknesses of the key evaluation techniques available in relation to these two issues are assessed below in Section 4.3.3.

The choice of technique, as well as the specification of the protocol more generally, should also recognise that economic evaluation is an aid to decision-making, not a substitute for decision-making (Drummond, O'Brien et al. 1997). There is rarely just one way of carrying out an evaluation, and the merit of different approaches should be considered. While CBA is normally justified under a welfarist foundation, Sugden and Williams (Sugden and Williams 1978) argue, for example, that the potential Pareto improvement criterion could be chosen by government decision-makers working under the decision-making approach[34]. As it is quite possible that different evaluation techniques will give different answers, this raises the important question of whether or not there is a "correct" answer. In my view correctness is a

[34] Sugden and Williams also note that the relevance of the compensation principle is enhanced because the government is in a position to convert potential compensation into actual compensation through their control of the tax system.

function of the study objectives and perspective, and there is therefore, no such thing as "the correct answer".

Description of comparators:

As with the basic concepts discussed in Section 4.3.1(opportunity cost; marginal analysis; clear concept of benefit), there are many characteristics of a good economic study that are common to the genre. A clear description of the comparators is a case in point, and applies irrespective of the technique selected or the underlying theoretical framework.

Time period of the study

Specification of the time period for an economic evaluation involves two components: first, the period over which the intervention itself is run; and ii) the time period over which the costs and benefits that the intervention gives rise to are tracked. The key determinant for the assumptions about time period are not so much the form of appraisal or the theoretical underpinning, but the context and purpose of the study. Where the study is exploratory (rather than definitive) and/or where time or resources are limited, the time period over which the intervention is run may be limited – say to an assumption of one-year in "steady-state" operation. Similarly, where an evaluation of multiple interventions is involved to inform decisions on priority setting, simplifying assumptions may also be made to provide a standardised assessment frame across all the interventions and to reflect data availability. This is the situation with the case study described in Chapter Twelve, for example, where the purpose is to trial a macro approach to evaluation that is attempting to triage interventions.

If on the other hand, a study was addressing a single topic and/or was attempting to be definitive, then it would be important for the time period to reflect more accurately the life cycle of the technology involved. Issues such as the rollout period and learning curve would be factored into the analysis and the intervention may be simulated over say a thirty-year period involving successive cohorts.

Decisions about the time period is a further reflection of the need to fine-tune evaluation protocols to the specific context of the study.

Identification, measurement and valuation of costs and benefits

At the conceptual level, the cost side of economic evaluation has not been a source of great controversy between the different normative approaches and their associated techniques. Issues such as the reporting of input quantities separate from input prices; the use of discounting; the selection of 'top-down' verses 'bottom-up' costing approaches, etc are common to the various techniques available. Where differences have occurred, they largely reflect the differences in inclusion/exclusion criteria emanating from the study perspective. There are, nonetheless, a number of problems and unresolved issues in empirical application

of the accepted notion of opportunity cost. Shadow pricing, for example, which is often necessary because health care markets are heavily regulated and usually non-competitive, is rarely straightforward. There have also been interesting debates about the inclusion of certain cost categories, such as costs incurred in the additional years of life and productivity costs (Klarman 1982; Gold, Siegel et al. 1996; Johannesson and Meltzer 1998). The most substantive issue from a methodological perspective is the productivity costs issue (Olsen and Richardson 1999). It raises interesting problems for extra-welfarists, because by and large, they have sought to separate evaluation of health programs from individuals' economic resources.

Far more contentious has been the outcome side of economic evaluation, where vigorous debate continues regarding the outcomes to be included and how they are to be measured. Indeed, the major differences in the normative frameworks discussed above are manifested in the identification, measurement and valuation of outcomes. Further, the three key techniques of economic evaluation (i.e. cost-benefit analysis [CBA]; cost-utility analysis [CUA]; and cost-effectiveness analysis [CEA]) are distinguished on the basis of how they deal with outcomes. As Hurley (2000) notes in his recent overview article:

> *"A defining element in the historical development of outcome measures is the fact that the primary "outcome" of many health care interventions is life-years, and in particular, life years of varying quality. How should one value the extension of a person's existence, without which nothing is possible and which cannot be traded (intra-personally among individuals)?"(p. 98)*

While health economists have played a major role in developing methods for valuing life-years, they have often worked collaboratively with researchers from other disciplines (eg. psychology, decision science, epidemiology, biostatistics, medical science), particularly when non-monetary measures were involved. Within the welfarist normative framework methods have been developed to value life both in money terms (for CBA) and through Paretian non-monetary measures that reflect individual preferences (in order to establish a welfarist base for CUA). Within the extra-welfarist approach methods have focused on CUA and on developing non-Paretian subjective health measures that reflect the quantity and quality of life years gained. The techniques of economic evaluation are taken-up in greater detail below.

Marginal analysis and sensitivity analysis

The central role of marginal analysis, together with the need for sensitivity analysis to assess the impact of uncertainty, is common to all the evaluation approaches. The rigour in the application of these analytic techniques is a characteristic of a quality study per se, rather than having any connection with the different normative frameworks.

Decision rules and presentation of results

The implicit or explicit objective of economic evaluation is to improve decisions about the allocation of health care resources. This involves an understanding of both the decision rules

inherent in the form of technical analysis undertaken, together with the way in which such technical analysis impacts on the decision-making process. The decision rules associated with the individual techniques certainly vary[35] and are reviewed below. The problems and prospects of using economic evaluation to inform priority setting has been debated in recent years, particularly following attempts in a number of countries to use it to address important policy areas. This empirical experience is reviewed in Chapter Six and a strong message emerges that the application of economic evaluation is not just a technical issue. In general, the actual use of economic evaluation is still quite limited in relation to its potential. The various reasons for this are discussed in Chapter Nine and include the need for analysts to be more sensitive to the needs of decision-makers. The emergence of the decision-making approach offers considerable promise in this regard, together with associated techniques that are specifically developed for the priority setting context.

Before moving to a consideration of the techniques themselves, it is useful to flag one important issue that relates to the technical decision rules. It is raised here because it reflects directly on the philosophies inherent in the normative frameworks. It concerns the often-repeated allegation that CEA, CUA and CBA are, in a practical sense, nearly equivalent (Phelps and Mushlin 1991). The logic is that if, at the end of the day, decision-makers must apply their values in reaching a decision, then the CEA/CUA ratio is virtually equivalent to the CBA net present value, since decision-makers will make their own assessment of the monetary equivalent for the life year or QALY. While this argument has superficial appeal, it ignores important conceptual and ethical differences in the normative frameworks. The welfarist foundation of CBA calls for valuations based on the judgement of individuals and what they are willing-to-pay for health gains. In contrast, to rank programs in CEA/CUA requires a social judgement as to willingness-to-pay for a health outcome. Extra-welfarists do not deny that society must make trade-offs that place a value on health gains, but they argue that such judgements should reflect societal values and what society wants from its health care system. Thus if CUA and CBA result in similar conclusions, then from a theoretical point of view this is coincidental.

4.3.3 The techniques and their theoretical underpinnings

Overview:

The term economic evaluation is usually associated with three key techniques: cost-benefit analysis (CBA); cost-utility analysis (CUA); and cost-effectiveness analysis (CEA). These three techniques are explored in some detail below. Before doing so, however, it is important

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[35] It is also important to recognise that the specification of decision rules can also vary with the decision context (Richardson 1991). The decision rule for a health authority perspective, for example, should be (net benefit) / (budgetary cost); whereas a broader perspective (say societal) would include all resource flows, irrespective of their source.

to acknowledge the recent emergence of cost-value analysis (CVA)[36]. While CVA is not an established technique, those involved in its evolution[37] all argue that CUA is now evolving into CVA. The emergence of CVA is significant because it continues the evolution of the outcome measure in an attempt to take on board other elements of social (ethical) preferences, such as age, severity, rule of rescue, or fair innings. Ethical aspects of this development are taken up further in Chapter Five. The re-emergence of Program Budgeting and Marginal Analysis (PBMA) as a form of economic evaluation is also significant as mentioned at various points in the discussion to date. In many ways PBMA, however, PBMA is not so much an evaluation technique, but rather provides a decision-making process within which various technical approaches to assessing value (such as CBA, CUA, CBA or CVA) can be placed. PBMA will be mainly addressed, therefore, in Chapter Nine as one of the economic models of priority setting, with only brief references in this chapter to provide a balanced overview.

Welfare economic theory provides an important conceptual foundation for CBA, although it should be recognised that there are gaps between the Paretian theory and applied CBA (Boadway and Bruce 1984; Hurley 2000)) and that Sugden and Williams also provide a DMA framework for CBA (Sugden and Williams 1978). Critical elements of CBA drawn from welfare economic theory include: (i) a concept of benefit based on consumer preferences and the associated notion of utility; (ii) the measurement of utility in a money metric; (iii) the aggregation of such monetary measures across individuals to obtain a total net benefit measure (the Potential Pareto Improvement Criterion [PPI]); and (iv) the assumption that PPI represents an improvement in societal welfare.

As discussed in Section 4.2, these assumptions are unlikely to be met in the real world, especially in the health sector. Nonetheless, welfare economic theory provides an important intellectual foundation for evaluating programs and interventions by measuring their costs and benefits in money terms, calculating the net benefit and ranking the allocative efficiency of those interventions on the basis of net benefit. Welfarists see CBA as the gold standard of economic evaluation, because in principle, with both costs and benefits determined in dollar terms, CBA can determine whether a particular project is "worthwhile". A CBA measures worth using PPI, however, which for non-welfarists undermines the credentials of CBA.

A second tradition in economic evaluation, which emanates from the decision sciences and system analysis, focuses on the "technical" and "cost-effectiveness" forms of efficiency (Gold,

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[36] Other new evaluation techniques are also emerging (such as conjoint analysis (Ryan, Scott et al. 1996) but there is no attempt in this thesis to provide a comprehensive assessment of recent methodological advances in applied micro economic evaluation. As noted in Chapter Three, this reflects the focus of this thesis on developing macro evaluation techniques for the specific decision context of priority setting.

[37] Eric Nord's book is the key reference (Nord 1999), but other important contributions include Menzel (Menzel, Gold et al. 1999), Richardson (Richardson 2000d), Olsen (Olsen, Smith et al. 1999), Ubel (Ubel, Richardson et al. 1999; Ubel, Richardson et al. 2000) and Williams (Williams 1997; Williams and Cookson 2000).

Siegel et al. 1996; Hurley 2000). This tradition is exemplified by CEA and CUA. Costs are still measured in dollar terms, but outcomes are measured in either natural units of outcome for the programs being evaluated (for CEA) or quality-adjusted life years (for CUA). The result is summarised in a ratio, which represents additional cost per unit of outcome achieved. Although not initially developed in reaction to CBA, both CEA and CUA were embraced by health economists because of the difficulties (conceptual, ethical and practical) in placing a dollar value on life and because of the emergence of extra-welfarism which emphasised health as the primary outcome for normative analysis in the health sector. Whether CEA and CUA are suitable techniques to assess worth is debatable, and this issue is taken-up further below.

The heritage of the decision sciences – with their focus on seeking the best way to achieve an objective defined by those commissioning the analysis – can also be clearly seen in the development of the DMA framework. Similarly, the PBMA technique (refer Chapter Nine) with its emphasis on decision-maker objectives and practical solutions to data requirements, reflects this heritage and finds a natural home in the DMA framework. Like CBA, however, PBMA also seeks to address allocative efficiency through evaluation of increments and decrements across programs. This characteristic reflects a broader heritage that incorporates management theory and generic economic principles (i.e. opportunity cost and marginal analysis). Although PBMA is still very much an experimental technique in early development (with no acknowledged critical appraisal standards), it does have predecessors in the US Planning-Programming-Budgeting-System (PPBS) and the UK Public Expenditure Survey (Wildavsky 1966; Wildavsky 1969; Bevan 1983). As Deeble (Deeble 1999) describes:

> *"It is in many ways a formalisation of some familiar bureaucratic methods but with additional rigour, a concentration on resource allocation at the margin rather than whole programs and, sometimes, an extension of provider preferences to include those of consumers and the community as well." (p. 17)*

Cost-Benefit Analysis (CBA):

The advantages of CBA in determining worth (i.e. allocative efficiency) come at the expense of difficult measurement issues, such as the assignment of dollar values to life, illness, clean air, and other non-marketed goods and activities. The most common approaches to assigning dollar values to health consequences are an output-based approach (or "human capital" approach as it is usually called) and a preferences-based approach. The human capital approach reflects the pioneer work of welfarists such as Weisbrod (Weisbrod 1961) and Fein (Fein 1958) to develop the CBA approach. The economic value of additional years of life was the value of economic production associated with those years. Because of its relative simplicity it became the most commonly used measure in the CBA literature and was the original method recommended by the US Public Health Service (Hodgson and M.R. 1982).

Two defects of the human capital approach led to its demise, although more recently interest has again focussed on its use in measuring production effects in the economy, as opposed to placing dollar vales on human life[38]. First, it has strong, and to most, unacceptable equity consequences (such as the low value of life it attributes to the elderly, to unemployed people, to people on low incomes, and to "home-makers"). Modifications such as imputing the value of household work partially addresses these concerns, but still run up against the more fundamental ethical objection that it is inappropriate to link the value of life to economic production. Second, the view among most welfarists has been that the appropriate measure of value is the intensity of individual preferences (i.e. a closer alignment with welfare theory) and this is not reflected by future labour costs (Richardson 1991). The work of Schelling (Schelling 1968) and Mishan (Mishan 1971) demonstrated that "willingness-to-pay" is the only measure consistent with Paretian welfare theory.

As Hurley (2000) notes, however, these advances were a "mixed blessing". They affirmed the theoretically correct approach from a welfare perspective, but presented an obstacle to applied CBA due to measurement difficulties that are still to be satisfactorily resolved. CBA generally estimates willingness-to-pay (WTP) by the area under the demand curve, but there are no relevant demand curves in health where individuals trade chances of death. Further, the assumption of consumer sovereignty is often violated in the health sector, so that measurement techniques relying on the demand curve lose their normative relevance (Evans 1984; Rice 1998). Economists attempted to use indirect methods, such as observing labour markets where greater risk of death is compensated for in higher wages (Viscusi 1992; Viscusi 1993), but the validity and relevance of such measures is questionable (Hurley, 2000). Heroic assumptions are required about the competitiveness of labour markets, about the knowledge of workers of the relative risks involved, and about the extent to which wages reflect job characteristics. The relevance of WTP values obtained from work settings to sickness and health interventions is also questionable.

Recent WTP methods have therefore turned to surveys (called contingent valuation) which employ hypothetical scenarios to elicit preferences, rather than rely on revealed preference through actual choices. As with the human capital approach, however, contingent valuation has been criticised on both its equity implications (i.e. WTP is affected by ability-to-pay) and its theoretical foundations (Richardson 1991). Contingent valuation requires that the health effects associated with health care interventions are described to individuals and that they imagine there is a market for these effects. Individuals are then asked what they would be prepared to pay to obtain them. What to ask and how to ask it are the key areas of debate in the contingent valuation literature. As Hurley (2000) notes:

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[38] See (Koopmanschap and Rutten 1993; Olsen 1993; Weinstein and Manning 1997; Olsen and Richardson 1999; Brouwer and Koopmanschap 2000).

> *"Operationalising this (contingent valuation) requires a host of assumptions and decisions regarding the outcome being valued (eg., health only, health and non-health benefits, benefits measured under certainty or uncertainty, etc.), and the specific methods employed to elicit willingness-to-pay. The exact design chosen can have important influences on the values obtained, and much of the current work on contingent valuation is to understand better the effects of alternative designs on the values elicited." (p. 100)*

There remains a vigorous debate amongst economists on the merit of contingency valuation, in both the health economics and environmental health literatures[39]. Typical is the claim by Diamond and Hausman (Diamond and Hausman 1994) and their co-authors in (Hausman 1993) that contingent valuation produces results responsive to theoretically irrelevant considerations (eg. the order of the questions or the payment vehicle) and insensitive to theoretically relevant considerations (eg. the size of the risk or health effect). Hanemann (Hanemann 1994) on the other hand is a spirited defender of the technique.

The continued use of contingent valuation in environmental and transport economics, however, has led to a renewed interest in the application of WTP in health care (Carter and Harris 1998). Despite this, however, and the qualified support by a number of respected economists, many remain skeptical of the technique's potential to offer practical policy guidance. Given the uncertainty over the validity, reliability and sensitivity of the survey methods and associated results, WTP must still be regarded as experimental. This is reflected in the following conclusion of Smith and colleagues after a thorough review of the WTP literature – including empirical applications – at the behest of the Commonwealth Department of Health and Family Services:

> *"1. Individual preferences, reflecting utility, are not necessarily the desired outcome of health care interventions; and*
> *2. WTP is not sufficiently advanced as a measurement technology to be confident that the values provided are valid and reliable estimates of the monetary equivalent of that utility." (Smith et al., 1999, Abstract)*

Neither the CBA technique, nor its welfare theoretical foundations, demonstrates strong credentials as the preferred evaluative framework for priority setting in the health sector. The defining characteristic of CBA is the "market-like" attempt to measure all benefits and costs in dollar terms. As a number of authors have pointed out (Richardson 1991), it might be regarded as paradoxical that as a society we have rejected market valuations of health care by providing public funding, yet are willing to consider surrogate market values in the economic evaluation of social programs. In practical terms the consequences of attempts to derive a dollar equivalent to the value of human life led to a widespread perception, among non-economists and many economists, that CBA was not a very useful technique for the health sector. It reflected a more general view that many program benefits could not be

sensibly converted into dollars. It led to the application of cost-effectiveness analysis (CEA) to health sector interventions (Klarman 1982).

Cost-Effectiveness Analysis (CEA):

From an ethical view CEA provided for systematic analysis and planning while avoiding the need to measure benefits in monetary terms. CEA is based on the idea that decision-makers want to meet a given objective at least cost (i.e. on pursuing technical and productive efficiency) and has support from both the extra-welfarist and decision-making frameworks. The central measure used is the cost-effectiveness ratio, where effectiveness is measured as a uni-dimensional health effect (such as cases treated, functional status, cancers detected, or life years saved). A decision rule based on adopting all interventions with incremental cost-effectiveness ratios less than or equal to a particular value is optimal in the sense that:

- The resulting set of health care services will maximise the aggregate health effects achievable with the resources used; and
- The resulting aggregate health effects will have been achieved at the lowest possible cost. (Gold, Siegel et al. 1996)

Although there is nothing in CEA that addresses issues of social justice, the technique was supported by many analysts for its consistency with the objective of ensuring access to effective health care. At a pragmatic level CEA made economic analysis easier to carry out and measurement in natural units was more intuitively appealing to non-economists (particularly those with medical backgrounds). Although it was recognised early on by economists that CEA could not address questions of allocative efficiency[40] (as the output of interventions is not valued) the frequency with which CEA is undertaken in the health sector suggests this has not been seen as a major limitation. Either the normative implications of CEA have been over-played by economists or decision-makers in the health sector were happy to accept that health gain was the primary objective. In reality, both explanations probably apply. Certainly, CEA can be quite powerful where the treatment or prevention objective is not being questioned directly and where the outcome measure is accepted as a reasonable proxy for the benefits of the interventions being assessed.

But the limitations of CEA also need to be recognised, both in regard to its ability to satisfactorily capture health effects, and as conventionally applied, for its neglect of social justice. Measuring programs in natural units limits the capacity to compare across different

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[39] See (Cummings, Brookshire et al. 1986; Jones-Lee 1989; Gafni 1991; Kahneman and Knetsch 1992; Johannesson 1996; Johansson 1996; O'Brien and Gafni 1996; Drummond, O'Brien et al. 1997; Olsen, Smith et al. 1999; Smith, Olsen et al. 1999; Smith, Olsen et al. 1999).

[40] Allocative efficiency has been used in two senses in the literature, corresponding with welfarist and extra-welfarist perspectives discussed earlier. For welfarists, allocative efficiency means placing resources where the greatest utility is gained. For extra-welfarists, allocative efficiency is where the greatest health gain may be obtained.

interventions. Only programs that generate identical types of outcome can be compared. It is not possible to compare the efficiency of allocating resources to interventions that target mortality (such as heart surgery or cancer treatments) with those that target morbidity (such as musculo-skeletal conditions, chronic pain or palliative care). In principle, CBA could include both mortality and morbidity issues, but with its decline a suitable measurement technique for capturing both mortality and morbidity was lacking until the development of the quality adjusted life year (QALY) and cost-utility analysis (CUA).

Cost-Utility Analysis (CUA):

The QALY is a general health measure that seeks to capture changes in both the quality of life (morbidity) and the quantity of life (mortality). The QALY represents the number of years in full health that is equivalent to an actual profile that includes periods of less than full health. Accordingly, it can serve as the outcome measure for a wide range of health interventions and has no direct dependence on a person's economic resources. CUA thus has a strong natural home in extra-welfarism, together with the DMA, when decision-makers adopt health status as the main objective of the health sector.

According to Hurley (Hurley 2000) the concept of the QALY appears to have started with Klarman and colleagues (Klarman, Francis et al. 1968) in their study of renal disease, but its formal development occurred independently in the US ((Fanshel and Bush 1970; Weinstein and Stason 1977)), Canada (Torrance, Thomsa et al. 1972) and the UK (Rosser and Kind 1978). It was first used in Australian studies in the early 1990s[41], but since then important developments have occurred under the leadership of Richardson and Hawthorne (particularly in the application of psychometric procedures to utility-based QALYs (Hawthorne, Richardson et al. 1997; Richardson 1997; Richardson, Olsen et al. 1998; Hawthorne and Richardson 1999)). Dolan (Dolan 2000) provides a recent and insightful discussion of the QALY methodology.

Cost utility analysis (CUA) lies somewhere between CEA and CBA, in terms of the problems it can address, but exactly where, is an issue of some debate (Butler 1992; Gold, Siegel et al. 1996). It can be seen as either a form of CEA which can cope with more than one form of output (i.e. combining quantity of life and quality of life); or as a form of CBA where QALYs are the criteria of value (rather than dollars) and where rankings can be made for setting priorities within a fixed health sector budget. CUA can certainly address problems of technical and productive efficiency, and is clearly important to use when quality of life is either the most important or one of several important outcomes.

[41] By Hall, Gerard and colleagues in the economic evaluation of breast cancer screening (Gerard, Hall et al. 1991; Hall, Gerard et al. 1992).

Whether CUA is also a suitable technique to assess whether a health service is 'worthwhile' (i.e. allocative efficiency) is debated by economists and is closely related to the view taken as to CUA's appropriate theoretical foundations – that is, to the view taken on how societal value should be measured[42]. Although CUA is easily placed within the extra-welfarist framework (and its use to assess allocative efficiency is clearly acceptable within that framework), advocates of welfarism have also sought to establish its credentials within the orthodox framework (where the allocative efficiency role is unclear).

Mooney (Mooney 1988) makes the related and important point that CUA can address allocative efficiency, but within a constrained environment – that is, for allocative decisions within the health sector. All else being equal, the most desirable options are taken to be those which result in the cheapest QALYs (or the most QALYs if the budget is fixed). CUA does not, however, tell us what a QALY is 'worth' and therefore defines no threshold value of cost per QALY beyond which a given intervention is not worthwhile. Whether or not this is a serious limitation depends, among other things, on one's view about the method of determining the size of the health care budget. If it is accepted that the size of the health budget is politically determined, then the main task for economic appraisal is to advise on how the assigned budget can be spent efficiently. If, on the other hand, the task for economic appraisal is to help determine the allocation of funds to health care, then CUA has serious limitations.

Assuming the former position (which is certainly closer to the extra-welfarist and decision-making approach frameworks), then the question that remains is how good a measure of benefit QALYs are? In this regard, there are a number of issues, some of which re-visit the discussion in Section 4.2, and will only be briefly mentioned here. Mooney (Mooney 1988; Mooney 1996), for example, has introduced the point that if there are relevant dimensions of benefit other than those that are related to health status (as measured by the various versions of QALY), then CUA has limitations in this health sector allocative efficiency role. What he has in mind relates to process utility (i.e. the process of care rather than just the outcomes), as well as outputs unrelated to health status, such as better information. An example is screening programs such as breast cancer screening or genetic screening, where one of the objectives may actually be to give attendees better information, rather than simply to detect illness. Similarly, limitations arise in relation to the ability of CUA to adequately capture society's concern for distributional and procedural justice. Technical analysis, such as CUA, has an important place in generating evidence to support decision-making, but it may need to be placed within a broader approach to priority setting that reflects the values of society.

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[42] Allocative efficiency has been used in two senses in the literature, corresponding with welfarist and extra-welfarist perspectives discussed earlier. For welfarists, allocative efficiency means placing resources where the greatest utility is gained. For extra-welfarists, allocative efficiency is where the greatest health gain may be obtained.

A second, although obvious point about CUA, is the importance of understanding the basis on which the various QALYs have been developed, particularly the methods used to establish the quality of life weights. It is important to distinguish, for example, between QALYs based on psychometric rating scales (Rosser and Kind 1978) and utility-based approaches that use choice-based exercises (EuroQol. 1990). Because they are preference-based and derived under uncertainty involving trade-offs, economists tend to prefer QALYs constructed using utility weights. It is important to note, however, that utility-based QALYs are used as both extra-welfarist measures of subjective health and as utility measures within the welfarist tradition.

As noted by Torrance (Torrance 1986), the basic assumption in CUA is essentially extra-welfarist, viz:

> *"the difference in utility between being dead and being healthy is set equal across people. In this way the method is egalitarian .... each individual's health is counted equally!"*

The subjective value assigned QALYs allows them to be simply summed, but means the maximand is not total utility (i.e. is not welfarist), but a weighted average of individual's utilities *'where the weights are designed to treat individuals equally irrespective of the absolute intensity of their preferences'* (Richardson 1991).

Welfarists have attempted to develop non-monetary Paretian outcome measures that are intended to represent more accurately patient preferences over health states. The most prominent example is the Healthy Year Equivalent (Mehrez and Gafni 1989) and the large debate it has generated about the merits of the HYE verses the QALY. Recent overviews of this somewhat tortuous and prolonged debate are provided by Drummond et al., (Drummond, O'Brien et al. 1997) and Dolan (Dolan 2000).

It sometimes seems lost in this debate, however, that the QALY and the HYE are not necessarily intended to measure the same construct and that they have different theoretical foundations. The QALY is intended by many as a subjective measure of the value of health and the rationale for its use in normative economic appraisal comes directly from the extra-welfarist framework. As Culyer argued, although the QALY uses utility theory (which he sees as a strength), it is not meant to be a utility score in the welfarist mould (Culyer 1989). As Hurley (Hurley 2000) concludes, "*the fact that it does not map perfectly with preferences is not necessarily a flaw.*" In CUA based on extra-welfarism, the marginal social utility of one year of quality-adjusted life expectancy is assumed equal for all individuals, irrespective of their present health status or social standing. In contrast, the HYE emanates directly from a Paretian framework and attempts to keep the centrality of individual preferences and the welfarist assumptions intact.

For Richardson (Richardson 2000a) the protracted debate on HYEs verses QALYs illustrates the danger that health economics may be usurped by formalists at the expense of robust empiricism, viz:

> *"Scholastic debate over the extent of the correspondence, of each of these with the underlying axioms of economic orthodoxy is surely the economic equivalent of the medieval debate over the number of angels which could balance on the head of a pin. The purity of this debate is never sullied by reference to the fact that the axioms are entirely discredited as general descriptions of human behaviour and that, almost certainly, a more pressing issue to resolve is the psychometric validity and reliability of the two methods of preference elicitation, and the threat to these arising from the magnitude of the cognitive tasks demanded by the two techniques." (p. 3)*

There has been a considerable effort in recent times to establish whether CUA can be given a welfarist base. Garber & Phelps (Garber and Phelps 1995; Garber and Phelps 1997), for example, demonstrate that with various restrictive assumptions it is possible to build a welfarist foundation for CUA such that basing decisions on individual-level CUA ratios is equivalent to a Potential Pareto Improvement. They note, however, the difficulty this entails for public policy:

> *"The variability of the optimal cost effectiveness ratio across persons leads to a fundamental tension in using it to guide the allocation of health care resources: insurers, and policy-makers may wish to equate cost effectiveness across interventions and across populations, yet members of the population have very different optimal cost effectiveness ratios. Cost effectiveness applied at the population level may give the most efficient egalitarian distribution of resources, but it is not likely to be Pareto optimal." (p. 29)*

Some authors oppose QALYs on ethical grounds – for example, on the argument that the only priority in health care should be the preservation of life and that all have an equal right to life no matter what its length or quality (Harris 1985). As Williams ((Williams 1987) and Richardson (Richardson 1991)) argue, however, there are a variety of ethical bases that could underpin the way our health system works, and at the end of the day, we simply have to stand up and be counted as to which view we take. The recognition of the importance of ethical issues has led to various suggestions that QALYs could be weighted, but the problem is to justify a weighting scale in a principled or morally acceptable way. These issues are taken-up in Chapter Five on the role of ethics and social justice in priority setting.

While there are certainly important conceptual and practical questions associated with CUA, the technique can no longer be considered as being in an experimental stage and warrants selection as the preferred evaluation technique for the health sector. While serious attempts have been made to place CUA in a welfarist framework, the result is not appealing for those who seek a practical measure of health gain to inform policy planning and priority setting. In contrast, the extra-welfarist framework, together with the decision-making framework to the extent that decision-makers rate health gain as the prime objective, provide a sound

theoretical foundation for CUA with substantial practical and policy advantages. The recent emergence of CVA is a positive development because it continues the evolution of the outcome measure in CUA to take on board ethical issues of concern to society.

Concluding comment on techniques:

While economists can become rather evangelical at times, the power of these evaluation techniques should not be over-stated. None provide a formula for the removal of judgement, responsibility, or risk from decision-making activities. They are, in essence, methods of critical thinking, of approaching choices, of pursuing consistency and quality in decision-making. While they generate quantitative statements about the costs and consequences, they can also provide a framework for comprehensive identification of relevant costs and benefits.

Some researchers have distinguished between technical evaluation (i.e. CBA, CEA, & CUA) and implementation evaluation. Others refer to techniques such as Social Audit, (BTCE. 1984), or Cost Consequences Analysis (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997) which facilitate a broader reporting of consequences and context. The essence of these approaches is to complement the arithmetic with a qualitative description of the parties affected by health service options, the way in which their interests are affected by the options, together with a description of arrangements for public participation. Such techniques, which often focus on issues associated with implementation, can be an important complement to the cost-benefit arithmetic (Carter and Harris 1998). Further, the broader notion of benefit raised in this chapter, including the importance of social justice, can also be accommodated by the emerging techniques of PBMA (Mooney, Gerard et al. 1992; Pearcock, Richardson et al. 1997b), which links the measurement of benefit to the objectives decision-makers. Attention to issues of context, due process and implementation, in addition to technical analysis, is something that analysts need to give greater consideration. This theme will be picked-up in Chapter Six that examines the lessons from empirical experience.

4.4 Summary of key points for inclusion in the theoretical rationale (T) for the checklist

The key points made in this chapter were:

- Welfarism and extra-welfarism represent the two prominent approaches to normative economic analysis in the health sector and have been the focus of sustained debate and intellectual development. They derive from two distinct conceptual foundations: extra-welfarism is focused on health gain, with need often assessed by a third party; while welfarism is utility-based and gives primacy to individual preferences and consumer sovereignty. A third approach, the Decision-Making Approach (DMA) is less developed, but offers sufficient rigour to be theoretically meaningful. Primacy in this approach is given to the objectives of the decision-maker.

- The building blocks of welfare economics (i.e. utility maximisation, consumer sovereignty/revealed preference and consequentialism) do not provide a satisfactory theoretical basis for normative analysis in the health care sector. While individual utility is a relevant argument for inclusion in the social welfare function, it needs to be supplemented by information on other issues of concern to society – such as need, health status, equity and procedural justice.
- Non-welfarist approaches provide a theoretical framework to broaden the arguments in the social welfare function beyond individual utility. Both extra-welfarism and the DMA provide a satisfactory theoretical home for society's view of health as a "merit good" and for government intervention for reasons that extend beyond market failure.
- The health sector has been receptive to Culyer's extra-welfarist ideas, in part because of features of health care markets that render questionable major elements of the welfare framework and in part because the role of health care in the health production function provides greater scope for third-party judgement than for many other goods. Culyer's "healthism" has been accepted and widely applied by health economists through CUA.
- As both Culyer (extra-welfarism) and Williams & Sugden (DMA) acknowledge, the ethical values that underpin a non-welfarist concept of societal welfare should be empirically based; but this in turn raises the key issues of whose values and how are they are to be ascertained[43].
- If health gain is judged by decision-makers in the health sector to be the prime outcome of concern, then healthism is also a major component of the DMA. Unlike neoclassical welfarism, there is also a capacity in healthism (consistent with its conceptual building blocks) to accommodate distributive equity through weights based on the characteristics of people (such as socio-economic status; aboriginality; remoteness; or ethnicity). Healthism can be criticised, however, for its continuing pre-occupation with consequentialism and monism (uni-dimensionality in the outcome measure) and for its neglect of society's concern for procedural justice.
- Rejection of the welfarist approach, limitations of the extra-welfarist approach, together with increasing interest in communitarian values, focuses attention on the DMA. The DMA is an important development because it offers the flexibility to accommodate the range of complex elements that are relevant to judging improvements in societal welfare. The DMA is assessed as providing the most appealing theoretical foundation for resource allocation

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[43] This issue is taken up in Chapter Five where it is argued that Richardson's concept of "empirical ethics" has much to commend it (Richardson 2000a; Richardson 2000c). Richardson sees social decisions as the outcome of a social process that involves, inter alia, the government as "circuit breaker", but preferably informed by empirical evidence on values from the community. This issue was also discussed in Chapter Two as one of four central issues that provide the context and setting of priority setting in health care. It is no coincidence that those countries that have adopted an explicit approach to priority setting have also embarked on an explicit process of community consultation (refer Chapter Six).

models that seek practical relevance in the eyes of decision-makers and real world practitioners.

- For Williams and Sugden (Williams 1972; Sugden and Williams 1978) the role of the economist in the DMA becomes one of clearly eliciting the objectives of the decision-maker and matching the form of analysis to the decision context (rather than forcing the problem to match the technique). For Richardson, the role would also include ensuring decision-makers were appraised of community values (Richardson 2000c).
- Economists working under the DMA framework are able to select from the full range of applied economic techniques (whether they are linked to welfarist or extra-welfarist foundations) guided by the relevance of the techniques to the research question. The DMA framework also allows analysts to go beyond the limitations shared by welfarism and extra-welfarism, provided the values involved are endorsed by the decision-makers.
- The choice of evaluation technique is not arbitrary from a priority setting perspective, for some techniques have greater credentials to address the issue of allocative efficiency than others, and their theoretical foundations will reflect quite different concepts of societal welfare. Each normative framework implies important differences in the specification of the economic protocol, including the delineation of the study perspective, the choice of comparators, selection of evaluation technique and measurement of benefits.
- There are also important similarities between any evaluation method that purports to be classified within the economics discipline. The concepts of "opportunity cost", "marginal analysis" and a "clear concept of benefit" are central to an economic approach to evaluation and priority setting. Similarly, at a more applied level, rigour in the measurement of costs and benefits, together with the use of methods such as sensitivity analysis, are characteristics of a quality study, rather than reflections of the underlying normative frameworks.
- Welfarists see CBA as the gold standard of economic evaluation, because in principle, with both costs and benefits determined in dollar terms, CBA can determine whether a particular project is "worthwhile". A CBA measures worth using the potential Pareto improvement criterion, however, which for non-welfarists undermines its credentials. Further, individual preferences, reflecting utility, are not necessarily the desired outcome of health care interventions; and "willingness-to-pay" is not sufficiently advanced as a measurement technology for analysts to be confident that the values provided are valid and reliable estimates of the monetary equivalent of that utility. In summary, neither the CBA technique, nor its orthodox welfare foundations, demonstrate strong credentials as the preferred evaluative framework for priority setting in the health sector.
- Both CEA and CUA were embraced by health economists because of the difficulties (conceptual, ethical and practical) in placing a dollar value on life and because of the

emergence of extra-welfarism which emphasised health as the primary outcome for normative analysis in the health sector.

- CEA can be quite powerful where the treatment or prevention objective is not being questioned directly (i.e. to assess productive efficiency) and where the uni-dimensional outcome measure is accepted as a reasonable proxy for the benefits of the interventions being assessed. But the limitations of CEA also need to be recognised, both in regard to its ability to address allocative efficiency, and as conventionally applied, for its neglect of social justice issues.
- CUA lies somewhere between CEA and CBA in terms of the problems it can address, but exactly where, is an issue of some debate. CUA can certainly address problems of technical and productive efficiency, and is clearly important to use when quality of life is a significant outcome. Whether CUA is also a suitable technique to assess whether a health service is 'worthwhile' (i.e. allocative efficiency) is closely related to the view taken as to CUA's appropriate theoretical foundations – that is, to the view taken on how societal value should be measured. Although CUA is easily placed within the extra-welfarist and decision-making frameworks (and its use to assess allocative efficiency is clearly acceptable within those frameworks), advocates of welfarism have also sought to establish its credentials within the orthodox framework where the allocative efficiency role is unclear.
- While there remain conceptual and practical questions associated with CUA, the technique is assessed as the preferred evaluation technique for the health sector, for use both within evaluations of single interventions and the macro evaluation of multiple interventions. The continued development of the outcome measure in CUA offered by the recent emergence of CVA is viewed as a positive development. The re-emergence of PBMA provides a valuable framework in which CUA can be applied to the priority setting decision context.

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Chapter Five: The Role of Ethics and Social Justice

"Lastly, and perhaps most importantly, economists and others who conduct evaluative economic analyses must appreciate more deeply that such analyses are inherently exercises in social ethics." (p.392) (Hurley 2000)

"Arguably, amongst the greatest practical challenges facing those interested in health policy and priority setting is the need to encourage health practitioners, policy-makers and the electorate at large to analyse and reflect upon the ethical, social and historical origins of their beliefs and practices." (p.89) (Harvey 1996)

"The important conclusion, however, is that there are numerous bases for rejecting the 'league table' approach in which priority is assigned in direct proportion to a cost benefit ratio where the constituent costs and benefits do not include all the factors relevant to social welfare." (p. 8) (Richardson 2000d)

5.1 Introduction

The role of ethics in allocative efficiency has an important theoretical dimension that was taken up in Chapter Four. It involves the debate that is developing on the place accorded neoclassical orthodoxy (i.e. welfare economics) as the appropriate theoretical foundation for resource allocation decisions. As Richardson argues, economic theory as embodied in neoclassical orthodoxy, has adopted a set of assumptions which sanitise economic analysis of virtually all ethical content (Richardson 1999; Richardson 2000a). Yet given the basic task of economics is to maximise social welfare – that is, addresses the issue of what society values – this creates a fundamental dilemma, viz:

"Economics purports to examine the relationship between scarce resources and limitless wants. Its objective is to maximise social welfare in the face of scarcity. But to do this requires an analysis of wants and welfare. Especially in a social context with interdependent individual welfare this is an unavoidable ethical enterprise. Yet economic orthodoxy seeks no empirical evidence on the nature of society's wants nor subjects its core concepts to ongoing ethical debate. Rather, individual and social objectives are assumed."(Richardson 2000a)

Increasingly economists are starting to challenge the relevance of the neoclassical position, both in economics in general (Solow 1997; Blaug 1998) and in health economics in particular. Many senior health economists argue that the starting point for a judgement about the relevance of a normative theory – about how to assess when society is better or worse off – is the proposition that a framework for normative analysis ought to be congruent with the fundamental values that prevail in that society (Williams 1988; Culyer 1989; Mooney 1994; Evans 1998; Hurley 1998; Reinhardt 1998; Richardson 2000a). This does not mean the unthinking adoption of every societal whim or preference, but rather that deeply held values in society are an important reference standard that need to be established through empirical research – what Richardson calls "empirical ethics"(Richardson 2000a). Further, such a reference standard is arguably a more important reference standard for normative

assessment than an abstract theoretical standard lacking empirical validation, regardless of how rigorous it is. Unlike positive theory, which may be tested empirically, normative or ethical theory can only be judged using agreed normative criteria. These ethical criteria are resolved in practice by the acceptance in the "intellectual market" (Richardson 2000a) of rules of justice. For many economists, this not only re-establishes the importance of ethics in resource allocation issues, but also of alternative theoretical and ethical foundations. Chapter Four focussed on the theoretical implications, particularly the relative merits of the extra-welfarist and decision-making approaches as the theoretical foundation for priority setting. This Chapter focuses on the different ethical bases from which the priority setting debate can be conducted. Two central themes are presented, with most weight given to the second.

First, in Section 5.2, the characteristic ideologies behind the "free market" and "pure public" health care systems are identified (albeit briefly), together with the broad approach to priority setting that flows from each. The "libertarian" and "egalitarian" viewpoints involved are an important ideological dimension of the need for an explicit approach to priority setting presented in Chapter One. Second, in Section 5.3, the principal ethical approaches that might underlie an explicit approach to priority setting are identified. Two ethical approaches – "deontology" and "consequentialism" – together with distributive justice[44], stand out amongst the ethical issues of relevance to priority setting in health services. The importance of procedural justice is also discussed in this section. Next the implications of these ethical models are teased out, both for the normative basis of ethical criteria that could be used to guide explicit priority setting (Section 5.4), and for the conduct of economic evaluation (Section 5.5). Finally, in Section 5.6, the key implications of this chapter for the ethical rationale of the Checklist are brought together.

5.2 Ideologies behind the "free market" and "pure public" health care systems and implications for priority setting

Two ideological viewpoints in the provision of health care are dominant in the literature, which can be loosely termed – the "libertarian" view and the "egalitarian" view[45] (Donabedian 1971; Culyer, Maynard et al. 1981; Sugden 1983; Maynard and Williams 1984; Gillon 1986; Williams 1988; Wagstaff and Van Doorslaer 2000). In the libertarian view, access to health care is part of society's reward system and, at the margin at least, people should be able to use their income and wealth to get more or better health care than their fellow citizens should they so wish. The egalitarian view takes a very different position – i.e. that access to health

[44] Distributive justice is not a separate ethical approach vis-à-vis deontology or consequentialism. Distributive justice could be justified on deontological grounds (i.e. it is just "right" that citizens have access to health care); likewise distributive justice focuses on outcomes and therefore implies consequentialsim. The line of least resistance is to recognise this, but for practical purposes, view distributive justice as a particular form of consequentialism. In this thesis I focus in particular on equity aspects of distributive justice – what I term "distributive equity".

care is every citizen's right ("like access to the ballot box or to the courts of justice" (Williams 1988)) and should not be influenced by income or wealth. Each of these broad viewpoints is associated with views on related issues such as personal responsibility, social concern, freedom and autonomy (refer Table 5.1), which point to the type of health care system they generate.

The egalitarian viewpoint suggests that a publicly financed system should predominate, with health care being prioritised and distributed according to "need" and financed according to "ability-to-pay". This can best be accomplished by government, provided such a public system avoids government failure (refer Chapter One) and is kept responsive to social values. In this system, the government must undertake rationing and priority setting preferably based on a socially approved system of rules. The libertarian viewpoint, on the other hand, points towards a health care system dependent primarily on private finance, with access determined according to willingness (and ability) to pay. This can best be accomplished in a market-oriented system (providing it can be kept competitive). Priority setting is achieved through the "invisible hand" of the competitive market, with well-informed consumers able to maximise their own utility, producers kept responsive to consumers' demands by the profit motive, with an effective price mechanism keeping things in balance. Under this system, government involvement should be kept to a minimum and limited to providing a safety net for the poor.

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[45] Sometimes called the "Marxist approach" (Donabedian 1971), but as Gillon (Gillon 1986) notes, the underlying principle in the context of health care (i.e. "distribution according to need") is not exclusively Marxist and is an important component of 20th century egalitarianism (Sugden 1983).

Table 5.1: Attitudes typically associated with libertarianism and egalitarianism

Attitude	Libertarian	Egalitarian
Personal Responsibility	Personal responsibility for achievement is very important and this is weakened if people are offered unearned rewards. Moreover, such unearned rewards weaken the motive force that assures economic well-being and in so doing they also undermine moral well-being because of the intimate connection between moral well-being and the personal effort to achieve.	Personal incentives to achieve are desirable, but economic failure is not equated with moral depravity or social worthlessness.
Social Concern	Social Darwinism dictates a seemingly cruel indifference to the fate of those who cannot make the grade. A less extreme position is that charity, expressed and effected preferably under private auspices, is the proper vehicle but it needs to be exercised under carefully prescribed conditions (eg the recipients must first mobilise all their own resources, and when helped, must not be better off than those who are self-supporting).	Private charitable action is not rejected but is seen as potentially dangerous morally (because it is often demeaning to the recipient and corrupting to the donor) and usually inequitable. It is preferable to establish social mechanisms that create and sustain self-sufficiency and that are accessible according to precise rules concerning entitlement that are applied equitably and explicitly sanctioned by society at large.
Freedom	Freedom is to be sought as a supreme good in itself. Compulsion attenuates both personal responsibility and individualistic and voluntary expressions of social concern. Centralised health planning and a large government role in health care financing are seen as an unwarranted abridgement of the freedom of clients as well as of the health professionals and private medicine is thereby viewed as a bulwark against totalitarianism.	Freedom is seen as the presence of real opportunities of choice; although economic constraints are less openly coercive than political constraints, they are nonetheless real and often the effective limits on choice. Freedom is not indivisible but may be sacrificed in one respect in order to obtain greater freedom in some other. Government is not an external threat to individuals in society but is the means by which individuals achieve greater scope for action (i.e. greater real freedom).
Equality	Equality before the law is the key concept, with clear precedence being given to freedom over equality wherever the two conflict.	The main emphasis is on equality of opportunity. Where this cannot be assured the moral worth of achievement is thereby undermined.

Source: (Williams 1988)

In practice, however, most countries adopt a health care system that is financed and delivered by a mixture of the two approaches, with traces of both ideologies reflected in policy-making. The widespread existence of mixed systems could be viewed as an acknowledgement that the dominant ideology is not held by everyone in that society and that the views of the minority should be respected. Often, as Australia has experienced, the emphasis changes with the government of the day (with the Liberal Party being closer to the libertarian viewpoint and the Labor Party closer to the egalitarian viewpoint). Policy-makers in Europe give the impression of being more inclined to the egalitarian end of the spectrum (OECD 1992; OECD 1994), while countries like the United States tend towards the libertarian end. Wagstaff and Van Doorslaer conclude in their recent paper that: "The empirical work to date on equity in health care reflects the apparently pro-egalitarian bias amongst policy-makers" (Wagstaff and Van Doorslaer 2000).

Wherever the balance lies, it is not the aim of this thesis to address the relative merits of "public" verses "private" or "mixed" approaches to the provision and financing of health care. The topic has been raised briefly, as the underlying ideologies of egalitarianism and

libertarianism flow over into the ethical values raised by priority setting, both in relation to the role of the government and the way priority setting is approached. Libertarian theories, for example, place far less weight on notions of distributive justice than egalitarian approaches. The libertarian theory of Robert Nozick, for example, ignores distributive issues altogether (Nozick 1989). For Nozick, as Elster explains, "If liberties and duties are respected, whatever distribution emerges will ipso facto be just" (Elster 1992). Egalitarian theories, on the other hand, vary from "strong egalitarianism" where everybody must get an identical share of the "distribuendum", to Rawl's-type egalitarianism of "maxi-min", in which inequalities are accepted as long as policies benefit the worst-off (Rawls 1971; Olsen 1997).

5.3 Deontology, consequentialism and the role of justice

5.3.1 Background: ethical enquiry and the impossibility of 'truth'

Many of those involved in the debate about priority setting – a mixture of academics, health care practitioners, policy advisors, and administrators – support an explicit approach to decision-making, of opening to public scrutiny the informal rules that operate unacknowledged. To this extent their position and that of medical ethicists coincides (Gillon 1986; Harvey 1996). Both groups are concerned to clarify the process of reasoning that underpins decisions. Moral reasoning has been defined (ten Have 1988) to involve four steps, viz:

1. clarification of exactly what the moral problem is;
2. identification of the moral principles and rules that pertain to the situation;
3. statement of the arguments for and against the various rules; and
4. provision of clear guidance for practice and behaviour.

While moral reasoning, expressed in these terms, certainly involves a structured approach to problem analysis, there is an important limitation that must be recognised. Moral reasoning can illuminate the issues, but it can provide no decision rule to choose between the alternative ethical approaches. It is for this reason that those approaches to priority setting that adopt decision rules (such as the utilitarian approach of economists) need to state clearly what their ethical assumptions are. As ten Have states:

> *"[M]oral reasoning provides no rational way, no indisputable algorithm, by which to choose between conflicting moral theories or principles." ((ten Have 1988) cited on (p. 86) (Harvey 1996))*

Richardson explains the point more clearly and his explanation is worth quoting at some length, viz:

> *"[U]nlike a positive theory which may be tested against objective observations, normative or ethical theory can only be tested against normative criteria. For example, we may ask whether*

principles adopted are those which would be selected from behind a veil of ignorance; whether they are those which accord with moral intuition; whether they are those which accord with a particular religious view, etc. However, to demonstrate that a particular set of criteria is 'correct' in some sense requires the application of 'meta criteria' which themselves need justification. As the meta criteria also need justification any attempt at ultimate justification leads to infinite regress. Ultimate justification or the demonstration of 'truth' is, therefore, impossible....
The dilemma exists whether or not it is explicitly recognised. Nor does the difficulty in determining ethically acceptable behaviour imply that the problem may be circumvented by relying upon 'economic theory'. At best, 'normative economic theory' embodies ethical principles which have been sanctioned through time, contemplation and use. At worse, and as suggested here, it may have been sanctioned by nothing more than history and authority." (p.16) (Richardson 2000a)

The choice of one ethical system above another remains a largely[46] subjective, value-laden judgement. There is no logical way of resolving differences of ethical perspective except in so far as discussion or structured debate may encourage a convergence of thinking through identification of inconsistencies and/or the appreciation of the viewpoint of others. This recognition in turn creates an important place for structured debate as part of the process of priority setting in order to clarify ethical values pertaining to the decision context involved.

Richardson also makes the valid point that society needs a "circuit breaker" for it to function on the ethical level, and that this circuit breaker is of course the government of the day and ultimately the Parliament. This recognition of the government as "circuit breaker" adds weight to the credentials of the Decision-Making Approach as the theoretical foundation of priority setting (proposed in Chapter Four on the basis of economic theory).

Three ethical concerns – usually expressed as deontology, consequentialism and social justice – stand out amongst the ethical issues of relevance to priority setting in health services. These issues provide the focus for the remainder of this chapter.

5.3.2 Deontology and consequentialism in health care

The word "deontology" derives from the Greek word for duty ("deon"). In this ethical model the merit of an action is judged principally by whether the person acted according to a perceived duty and intended some good to occur, not according to the actual outcomes of the action. Under this model there may be certain duties that need to be performed regardless of the consequences. In Immanuel Kant's[47] supreme moral law, no person should be treated only as a means but always as an end – that is, it is wrong to ignore one's duty to an individual for the sake of the greater good of other individuals. For Kant, "right" action should be judged on the basis of the old maxim "do unto others what you would have them do unto you".

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[46] The term "largely" rather than "wholly" is used, as it is evident from the literature that most ethicists would accept certain rules of consistency in ethical reasoning.
[47] Immanuel Kant (1724-1804) was probably the best known exponent of the deontological approach (Harvey 1996).

Flowing logically from this Kantian perspective comes a respect for autonomy and the wishes of individuals. In health policy this often finds expression in a respect for patient wishes and autonomy in their medical care, together with various commitments to community consultation. Interestingly, it also finds expression in the special characteristics of the doctor-patient relationship (as well as the paternalistic tendency of some doctors to override patient preferences). Rutten, for example, has noted the common perception that:

> *"[M]edical ethics is very much concerned with the individualistic considerations of virtue and duty and that it tends to emphasise the need for the individual doctor to do his utmost for the individual patient." (Introduction) (Rutten 1988).*

Further, an elaboration of rules of conduct based on deontology has accompanied the professionalisation and rising social standing of various health care practitioners, particularly doctors (Weale 1988). Harvey has suggested that many professions have arrived at a similar perception; viz, that society expects its "professions" to display more concern for their clients than simply a desire to produce measurable benefit. Mooney adds a further dimension, discussing ethical codes of conduct in terms of the well-known asymmetry of information between patient and doctor, and the resulting agency relationship (Mooney and McGuire 1988). Lacking the technical knowledge to make sound judgements, the patient is forced to hand over property rights in his or her health to the doctor. A deontological ethical code, Mooney argues, helps to reassure the patient that the health professional will act as an agent in the patient's best interests. For others, the dominance of individualistic ethical codes in medical ethics needs to be balanced by a concern for the common good, which clearly relates ethics to a social level (Jonsen and Hellegers 1974; McGuire 1986).

There are thus strong deontological elements, characterised by the individual as the focal point, in the practice and policy of health care. It is also evident in the writings of several economists, with Gavin Mooney's ideas on process utility and communitarian claims having strong deontological overtones, for example (Mooney 1996; Mooney 1998).

"Consequentialism" on the other hand, is a classification used to describe a group of moral theories that judge merit primarily on the basis of outcomes, with the community rather than the individual, as the focal point. There are different theories under the heading of consequentialism, involving discussion across a range of disciplines – including various sub-disciplines of economics, such as health economics (Sen 1987; Hausman and McPherson 1993; Wagstaff and Van Doorslaer 2000; Williams and Cookson 2000), game theory (Clark 1995) and economic philosophy (Feldman 1994). Key issues that emerge include:

- whether *maximisation* of some value is a desirable principle or whether mere *satisficing* is acceptable;

- whether the normative status of actions should depend on the *intrinsic value* of the consequences or whether only preference satisfaction or happiness counts; and
- whether *moral* normative status should be taken into account in problem solving (rightness, wrongness, obligatoriness, desert, virtue, rationality, justice).

Not surprisingly, there are a number of approaches within the broad consequentialist classification, distinguished essentially on the basis of the relevant outcomes taken into consideration, together with the emphasis that is placed on maximisation. "Utilitarianism", for example, is an important subcategory of consequentialism developed by philosophers and economists. It is distinguished by i) its focus on happiness, welfare or "utility" as the relevant outcome[48]; and ii) by the judgement that the morally right course is to *maximise* utility, irrespective of its distribution.

Classical utilitarianism is usually associated with the works of Jeremy Bentham (Bentham 1789) and John Stuart Mill (Mill 1861). While Bentham took a "hedonistic" view of what yields utility (i.e. value is based on avoiding pain and promoting pleasure); Mill gave more weight to "higher pleasures" than to "lower pleasures" when estimating total utility (Olsen 1997). Mill argued, for example, that:

> *"It is quite compatible with the principle of utility to recognise the fact that some kinds of pleasure are more desirable and valuable than others. It would be absurd that, while in estimating all other things quality is considered as well as quantity, the estimation of pleasure should be supposed to depend on quantity alone. It is better to be a human being satisfied than a pig satisfied; better to be Socrates dissatisfied than a fool satisfied." ((Mill 1861) quoted in Olsen, 1997, p3.)*

Extending Mill's ideas, Feldman proposes a utilitarianism of "desert" such that:

> *"[W]hen persons deserve a certain good....then it is extra good for them to receive it....when persons do not deserve a certain good but get it anyway, then it is not very good to receive it. ((Feldman 1997) quoted in Mooney, 1998, p.1176).*

The maximisation aspect of utilitarianism is based on what Mill called "the greatest happiness principle", i.e. the moral principle is that "actions are right in proportion as they tend to promote happiness". While Mill's principle is sometimes mistakenly put as "the greatest happiness of the greatest number", the correct version is "greatest total happiness" (Mackie

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[48] While these terms are often substituted for each other, it is not at all self-evident that they are, in fact, interchangeable (Harvey 1996). Further, as mentioned in Chapter Four (4.2.2), Richardson (Richardson 1994) has defined four different possible meanings for the term "utility"; viz: i) pleasure/pain in the hedonism tradition; ii) psychological strength of preference; iii) an ordinal ranking of preferences serving as an organisational framework for positive analyses; and iv) behavior corresponding with the Neuman-Morgenstein axioms of expected utility.

1977; Hamlyn 1987; Olsen 1997). A more contemporary formulation that emphasises utility[49] rather than happiness is put by Gillon; viz: maximising the "satisfaction of individual' autonomous preferences" ((Gillon 1986) reported by Harvey, 1996, p. 88).

In health care policy, there are also important variations on the happiness/ welfare/utility outcome, that keep maximisation as the underlying moral principle (Winslow 1982; Kilner 1990). These variations on the consequence of interest come from a range of disciplines and stakeholders. Certainly in the health economics discipline, the arguments to be included in the social welfare function have been an area of sustained and continuing theoretical debate, including their application to evaluation techniques (refer Chapter Four). Important consequences include: the "number of lives saved" and associated notions of severity; "life years saved" and "quality adjusted life years saved" (QALYs); "accumulated earnings"; and "social value" (a judgement regarding the usefulness of individuals to society). The ethical basis for the various outcomes chosen, however, often receives insufficient attention.

Researchers from various disciplines have commented on the primacy often afforded saving human life. The need to do whatever possible in dramatic circumstances – particularly life or death situations – has been labelled "the rule of rescue" (Hadorn 1991; Richardson and McKie 2000e). Similarly, there is substantive evidence of the importance placed on the severity levels of patients in assigning priority (Olsen 1997; Richardson 2000d). A concern for severity is often associated with John Rawls theory of maximin mentioned earlier (Olsen 1997). Consequences of a pecuniary nature have also been given prominence. Accumulated earnings, for example, has been used to estimate production losses in a range of economic evaluation techniques, as well as the cost of premature death in early applications[50] of cost benefit analysis (CBA) in the health sector. With the rise of cost effectiveness analysis (CEA) and cost utility analysis (CUA), however, "accumulated earnings" was less favoured, giving way to "life years saved" and "QALYs" as the consequence of prime importance. While consequences based on notions of "social value" are likely to be contentious[51] today (instance, for example, the primacy in the Swedish values given to human dignity and solidarity [refer Chapter Six]), they have certainly been used in the past. Interestingly, social worth was a consequence explicitly considered by the Swedish Hospital in Seattle in selecting

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[49] This is similar to the position of some economists, who take the view that failure to maximise health outcomes with available resources is simply unethical (Maynard 1987; Williams 1988). While not strictly a utilitarian view (as health gain rather than utility is the maximand), it is certainly a strong consequentialist position.

[50] As discussed in Chapter Four, early versions of CBA based on the human capital approach to valuing mortality and morbidity effects gave way to the willingness-to-pay technique, an approach more acceptable to classical welfarists as it reflects individual utility functions. When the research question is production losses, however, as opposed to the value of human life, reliance is still placed on the human capital approach or variants thereof (i.e. the frictional cost method).

[51] In my own experience with eliciting values from students on exercises involving life or death situations (such as Cave rescue), "social value" always emerges as an important consideration in judgements on who should be saved. Young mothers with children, for example, are never left behind.

patients in the early days of renal dialysis. Relevant criteria included patients' involvement in such things as church and community activities (Winslow 1982).

Although many ethicists have not been receptive to some of these alternative formulations of "consequences" (such as QALYs) they have nonetheless been utilised as the basis for rationing decisions (Harvey 1996). Clearly, there are important differences between the deontological and consequentialist (particularly utilitarian) ethical approaches, together with important issues within each approach. Many of the conflicting views expressed about priority setting have their (usually unacknowledged) roots in these differing ethical approaches. This realisation led Harvey to the view that:

> *"Arguably, amongst the greatest practical challenges facing those interested in health policy and priority setting is the need to encourage health practitioners, policy-makers and the electorate at large to analyse and reflect upon the ethical, social and historical origins of their beliefs and practices." (p.89) (Harvey 1996)*

At the risk of over-simplification[52], the most likely groups to promote explicit priority setting are those holding consequentialist views, with health economists being the most active in this regard. Groups with consequentialist principles (particularly utilitarian principles) are not only likely to promote explicit approaches to priority setting, but also a reliance on technical methodologies to guide the decision process. Groups holding deontological principles on the other hand, are less likely to accept that rationing is necessary (preferring the 'more money' or 'science to the rescue' solutions discussed in Chapter One) and are less likely to accept a heavy reliance on technical methodologies. The majority of stakeholders, however, are likely to hold a combination of deontological and consequentialist principles, with the weight given to competing principles dependent on the decision process and context. Elster argues, for example, that it is somewhere between the utilitarian and Rawlsian solutions, rather than strict egalitarianism, that the commonsense perception of justice lies (Elster 1992). Frohlich and colleagues provide empirical evidence that utilitarianism, coupled with a safety net, is the preferred solution for many (Frohlich, Oppenhemer et al. 1987). The intuitive problem with the Rawlsian maximin solution, is that the exclusive focus on those worst-off in society, ignores the forgone utility gains of other members of society. Recognition of the range of plausible answers, of this ethical complexity, highlights the importance of the process by which decisions are made, particularly the role of discussion to clarify the concept of benefit and the associated ethical values.

While doctors and health economists are sometimes presented as representing the polar extremes of the deontological/utilitarian divide, this characterisation is too simplistic and often

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[52] These are simple charactertures that should not be over-interpreted. A deontologist, for example, may well argue for equal access and promote explicit measurement and explicit priority setting in order to achieve it.

overplayed. The Hippocratic Oath, for example, carries consequentialist overtones[53] and there are many instances where doctors choose between patients using consequentialist logic. The simplest examples are triage in wartime, patient selection for scarce life-saving interventions (eg organ transplants) and the routine work practices of many hospital accident and emergency departments. Gillon offers numerous examples from primary care of doctors acknowledging that potentially beneficial interventions cannot always be offered to their own patients due to the opportunity cost involved (Gillon 1988). It is simply not possible to sustain the generalisation that doctors' moral choices always reflect a preference for the presenting patient over the concerns of a wider population of patients (known or unknown). Whilst health care practitioners are undoubtedly concerned about the consequences of their actions, most would be unsympathetic, however, towards the strict utilitarianism of the neoclassical welfare school. Both the narrow definition of benefit and the utility-maximisation requirement of neoclassical economics would compromise deontological concerns about integrity, duty and the process of care.

Similarly, it is quite incorrect to classify all economists as strict utilitarians[54]. While economists certainly prefer a societal perspective in their analysis of policy and options for change (and hence are less likely to be swayed by deontological concerns for the individual); there have been attempts within health economics to integrate elements of deontology into the utilitarian (welfarist) framework. One version has accepted the importance of the process of care (i.e. the special relationship between practitioner and patient) by including "process utility" within the social welfare function (Gillon 1988; Mooney and McGuire 1988). Total utility thus becomes the sum of utility that arises from the consequences of actions (outcome utility) and utility that arises from the way in which those outcomes were achieved (process utility). Certainly, in principle utility functions can be conceptualised to include almost anything (McGuire, Henderson et al. 1988; Culyer 1998).

The incorporation of deontological concerns as a special type of utility is not universally accepted, however, either by deontologists or utilitarians. Some deontologists, for example, focus on the moral rightness of actions, and are uncomfortable with the whole utilitarian calculus as a way of making such decisions (Veatch 1993). Concepts such as duty, respect,

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[53] The doctor is required to "follow that system or regimen which, according to my ability and judgement I consider for the *benefit* of my patients". The widely commended principles of beneficence and non-maleficence (doing good and not doing harm) are also intrinsically consequentialist. Levinsky adopts a strongly consequentialist position (but not utilitarian) in his statement: "Physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations" (Levinsky 1984).

[54] Strictly speaking, economists generally classify themselves as "welfarists", which is not utilitarian per se. Welfarism allows social welfare to be a function of utility. Where the function involves the simple addition of utility we have utilitarianism. Where the function includes other elements (such as human characteristics, distributive equity etc) we have utilitarianism moderated by other influences (Culyer's extra-welfarism for example).

fairness or the sanctity of life per se, are thought to have value outside their utility effects for individuals. Similarly, many welfare utilitarians would also have problems, as their utility function is conceived of as goods, services, and in some more general statements, outcomes for other members of society. Inclusion of process utility (or broader notions of justice) does not sit well with orthodox statements of theory (refer Chapter Four).

For extra welfarists, there is far greater scope to include additional elements in the social welfare function, but thinking along these lines has focused on distributive equity, rather than procedural justice (Hurley 1998). Some economists of this school who are sympathetic to the importance of ethics and social justice, are nonetheless uncomfortable with the notion that the same consequences achieved through two different processes would be seen as two different outcomes (Richardson 2000c); or more importantly, of the need to combine all effects into a single measure (i.e. Hurley's rejection of "monism" (Hurley 1998)). Alternative approaches that clearly differentiate the steps involved in broadening the concept of value should allow views based on deontology and consequentialism to be applied in an explicit and coordinated way. Promising initiatives include Nord's Cost-Value Analysis (Nord 1999) and newer approaches to PBMA (Peacock, Richardson et al. 1997b; Carter, Stone et al. 2000).

5.3.3 Distributive justice in health care

Distributional justice has been the dominant reason why governments intervene in the health sector (van Doorslaer, Wagstaff et al. 1993). The rationale is based on the following general line of reasoning. Health is a critical component of human well being and individual functioning. Ill health and the consequent need for health care has large random components beyond the control of individuals. Justice therefore dictates that those in ill health should receive treatment on the basis of their need for care, not on the basis of their ability-to-pay (as is the case for most commodities) or other non health related attributes (Hurley 2000).

The notion of distributive justice thus concerns principles of fairness, with a particular focus on the just distribution of a chosen characteristic. Many deontological critics of utilitarianism have expressed concern at the potential impact of this approach on the distribution of health care and the lack of explicit interest in equity issues (Winslow 1982; Menzel 1990). For Winslow, for example, utilitarian considerations should be paced second to equity, by which he means equal access for equal need.

For most writers in this field[55] distributive justice involves the idea of balancing the competing claims of individuals in society in a way that is seen as *impartial or disinterested*. Many philosophers and ethicists draw on the "veil of ignorance" (social contracts made by people

[55] Gavin Mooney, for example, questions the need for impartiality in his writings on equity on the basis that explicit community values are required that are context specific (Mooney 1994).

who do not know in advance how any of their decisions will effect them personally) as a useful analytical device (Rawls 1971). In this regard, it is important to distinguish arguments for redistribution of resources based an equity rationale, from arguments based on caring externalities (involving efficiency concerns and the nature of interdependent utility functions). If utility functions are interdependent then efficiency dictates that these interdependencies are taken into account in assessing the optimal distribution of resources. In the absence of such interdependencies there is no orthodox efficiency rationale for distributive concerns. In contrast, the equity rationale for intervention, because it is based on notions of justice and fairness, appeals explicitly to impartial arguments of what is right and just. Equity concerns may underlie utility interdependencies, but they may not (Culyer 1989; van Doorslaer, Wagstaff et al. 1993; Dolan 2000; Hurley 2000; Williams and Cookson 2000).

A growing experimental and survey literature[56] documents the extent to which individuals and the community care about distributive justice (particularly "distributive equity") in the health sector. Individuals display a consistent preparedness, for example, to sacrifice total benefit to achieve more equity in its distribution, even when they are in the group hurt by the redistribution (Yaari and Bar-Hillel 1985; Kahneman and Varey 1991). Agreement about the importance of the equity objective, however, does not translate easily into agreement about what the relevant concept of equity should be. Distributive equity certainly concerns the just distribution of some good, service or characteristic of interest – what Sen (Sen 1992) calls the "focal variable" and others the "distribuendum" (Olsen 1997) – but theories differ on what that focal variable ought to be. The choice of focal variable is critical, because achieving equality in respect of the focal variable usually means accepting inequality in regard to other dimensions. Many different focal variables have been proposed for the health sector – expenditure, resources, access, utilisation, need, health status – together with various combinations (i.e. equal resources for equal need; equal access for equal need) and permutations thereof. Those that have received the most sustained attention, and which are the most relevant for priority setting, fall within three broad equity principles, viz: i) allocation according to need; ii) allocation according to health status; and iii) allocation to ensure equality of access (Hurley 2000).

5.3.3.1 Allocation according to need:

The principle that health care resources should be prioritised according to need has a strong intuitive appeal and draws support from various theories of social justice. For the principle to be operationalised, however, the concept of "need" must be clearly defined. There are (at least) three very different conceptions of the need for health care in the literature, viz:

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[56] See, for example, (Yaari and Bar-Hillel 1985; McGuire 1986; Elster 1992; Frolich and Oppenheimer 1992; Miller 1992; Hausman and McPherson 1993; Nord, Richardson et al. 1995a; Nord, Richardson et al. 1995b; Williams 1997; Dowie 1998; Mooney 1998; Olsen and Richardson 1998; Menzel, Gold et al. 1999; Nord, Pinto Prades et al. 1999; Olsen and Richardson 1999; Ubel, Richardson et al. 1999; Ubel, Richardson et al. 2000)).

- First, there is ***need as defined by the extent of illness***[57], usually based on epidemiological assessments of disease incidence/prevalence and distribution (i.e. "need as a reflection of the size of the problem" (p. 76) (Mooney 1994)). One way of using this concept of need is to measure health losses using summary measures of population health, such as QALYs/DALYs or health adjusted life expectancies (Mathers 1997; Murray and Acharya 1997; Richardson 2001). This definition has an egalitarian flavour of concern for an equitable distribution of health profiles (Olsen 1997).

- Second, is ***need as defined by disease severity,*** rather than simply the extent of illness (i.e. "those severely ill have the most need" (p. 91) (Olsen 1997; Hurley 2000)). This definition has a strong Rawlsian flavour of concern for the least well off and the fate of patients if left untreated. Under this definition the needs of a few patients with severe illness would be given priority over the needs of many patients with minor ailments. Survey results in Norway, Australia, Spain and USA have uniformly attested to the importance of severity as a criterion for judging need (Richardson 2000d; Richardson and McKie 2000e).

- Third, is ***need as defined by the existence of an effective intervention*** (i.e. "a need only exists when Y has been demonstrated to achieve X" (p. 91) (Culyer and Wagstaff 1993; Hurley 2000)). This definition is promoted by both extra-welfarists (refer Chapter Four) and advocates of evidence-based medicine, and has a strong consequentialist flavour. This definition is very similar to need as defined by the "capacity-to-benefit", which potentially takes into account both the existence of an effective intervention and the heterogeneity of patient responses. This third definition of need focuses on health gain[58] as opposed to the pre-treatment or post-treatment profiles of the population (Olsen 1997). An important variant extends the definition to focus on the worthwhileness of the intervention in order to distinguish needs from wants, particularly in public systems of funding (eg to exclude interventions such as cosmetic surgery from public funding). Some would go still further and add that Y must not only be effective and a worthwhile use of public funds, but also cost-effective.

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[57] A variant is need as defined by the level of community concern, where size of the problem is based on community surveys rather than epidemiological data.

[58] If those most in need are also those who can gain the most benefit from health care, then equity and efficiency are not in conflict; the same allocation of resources advances both efficiency and equity. Note that it is only health gain that is taken into account in conventional cost-utility analysis, not information on equality of health status or disease severity. There is also an issue under this definition as to whether capacity-to-benefit is judged by the individual or by an expert third party, with the latter the more likely to occur in utilisation of this definition.

While there are some potential connections between these various formulations of "need" (eg using data gained under definition one to compute three, such as DALYs recovered), there are also important differences. Need conceptualised as size of the problem, is very different to need conceptualised as severity or as potential health gain. Unfortunately, there is no scientific basis for choosing between them as normative principles. Judgment is required having regard to policy objectives, decision context and the theories of social justice held to be the most appropriate[59].

It is also important to acknowledge that "need" – however defined – is often combined with two additional concepts, viz: "horizontal equity" and "vertical equity". The term horizontal equity is normally used to refer to needs that are the same in some relevant dimension (such as severity or capacity to benefit); while vertical equity refers to needs that are different in some specified dimension. Under the principle of allocating resources according to need, horizontal and vertical equity call for equal treatment for equal need, and unequal treatment in proportion to unequal need[60]. To cite a common example, although access to accident and emergency departments is available to all on an equal basis, treatment is prioritised according to severity, not on a first-come first-serve basis.

One final point requires recognition on these concepts of need. While they are all useful to establish *when* a need exists, they are less helpful to establish *how much* health care is required[61]. This provides for a natural coalition between needs-based concepts of equity, and the efficiency principle of applying marginal analysis, in assisting policy decisions. It is also the reason that the definition of need is sometimes linked to expenditure. Culyer and Wagstaff, for example, defined need as "the expenditure required to effect the maximum possible health improvement, or equivalently, the expenditure required to reduce the individual's capacity-to-benefit to zero" (Culyer and Wagstaff 1993). For ethicists, such definitions pose the difficulty of combining the extent of need with the resources necessary to meet that need. This approach to defining need creates the dilemma experienced in Oregon (see Chapter Six), where large numbers of people suffering minor ailments (but nonetheless involving substantial expenditures), might receive a higher ranking than a few people suffering life-threatening conditions.

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[59] Jan Olsen, for example, provides an interesting exploration of the impact on priority setting of adopting a strict egalitarian, Rawlsian maximin or utilitarian position, that picks up the first, second and fourth definitions of need given above (Olsen 1997). Olsen notes a study by Frohlich (Frohlich, Oppenhemer et al. 1987) which showed that when choosing between maximin; utilitarianism; utilitarianism with a floor; and utilitarianism with a floor and ceiling; 25 out of 29 respondent groups unanimously choose utilitarianism with a floor.

[60] Various economists have pointed out that a variant of this is the principle of equalisation of marginal met need (Mooney 1986; Culyer 1995a). Coupled with need defined as capacity-to-benefit, this allows the diminishing marginal benefit effect to be integrated. As noted previously, however, this specification is really an efficiency criterion (i.e. a necessary condition for maximising health in the population) and had been criticised on that basis as an equity principle.

[61] With the exception of definition three, when it is used as part of a cost effectiveness evaluation.

Many ethicists find the inclusion of cost, resources or expenditures in statements of moral principle to be highly problematic (except to the extent that the wording of the principle excludes their relevance). Nonetheless a distribution principle linking need and expenditure is widely used at the population level by central and/or state governments to distribute resources to their regions based on each region's relative need (DHSS 1976; Birch, Eyles et al. 1993; Wagstaff and Van Doorslaer 2000). The average expenditure on residents in each region is designed to correspond to the need for care in each region, compared to other regions.[62]. The widespread use of such resource allocation formulae illustrates the close relation at the population level between the principle of allocation according to need and the principle of allocation to achieve equal access.

5.3.3.2 Allocation to achieve equality of health status:

Given that health care is basically consumed to produce health (i.e. for instrumental reasons), there is a strong argument that an equitable allocation of health care resources is one that encourages an equal distribution of health. Culyer, a major advocate of this approach to equity, makes two qualifications: first, that equalising health status should not be achieved by intentionally reducing the health of some members of society; and second, in recognition of the multiple determinants of health, it is not expected that health care alone can lead to an equalisation of health status (Culyer and Wagstaff 1993). This definition of equality often finds practical expression as "minimising inequalities of health status".

For Culyer, the extra-welfarist social welfare function can certainly include arguments that capture an aversion to inequality and allow for different weights to be attached to the health of different groups of society (refer Chapter Four). Wagstaff (Wagstaff 1991) has developed a specification for such a social welfare function, which accommodates both a range of concerns for inequality per se (from libertarian indifference to Rawlsian concern for the least well-off), together with differential concern for the health of various groups in society.

The question of differential aggregation weights has received considerable conceptual and empirical attention in the literature, particularly by extra-welfarists, and particularly in an economic evaluation context (Weisbrod 1968; Harberger 1971; Williams 1988; Culyer 1989; Murray and Lopez 1996; Williams 1997; Nord 1999; Nord, Pinto Prades et al. 1999; Richardson 2000b). The standard methods for aggregating health effects across individuals (eg. summing QALYs) use equal weights for each individual, which ignores any distributional concerns. There is ample evidence, however, that society cares about who is affected by decisions to introduce, withdraw or modify health care programs. To the extent that these

[62] Heterogeneity may still exist, however, as no individual is forced to consume care (except in exceptional circumstances). Whether small area variation in utilisation rates is deemed to be a problem depends largely on whether the cause is assessed as demand-side (i.e. consumer choice) or supply-side (i.e. poor system design, poor performance, supply-induced demand, etc).

distributional concerns can be linked to the observable characteristics of people (such as age, income, ethnicity/aboriginality, or rurality/remoteness), a system of differential aggregation weights may be able to reflect these concerns (Weisbrod 1968; Culyer 1989; Culyer 1990). If the concept of weights is acceptable then the key questions become: on what basis such weights can be justified; and how they can be estimated? A number of approaches are evident in the literature, which reflect either i) an attempt to elicit community preferences as the ethical basis for weights; or ii) involve the selection of an equity principle by researchers on moral reasoning (Hurley 2000).

Early research on community preferences focused on the value individuals place on health by age group and occupational status (see, for example (Williams 1988; Charney 1989) (Nord, Richardson et al. 1995b)); while more recent work has examined societal concerns for severity and potentials for health (Menzel, Gold et al. 1999; Nord 1999; Nord, Pinto Prades et al. 1999; Ubel, Richardson et al. 1999; Ubel, Richardson et al. 2000). Nord and colleagues have developed the concept of "societal value" and "Cost Value Analysis" (CVA), whereby the person trade-off technique is used to develop community weights to adjust QALYs based on patient values elicited through the time trade-off method. While such community weights are still in an early stage of development, they provide a promising vehicle for the explicit inclusion of ethical values in economic analysis. Hurley provides a note of caution[63], however, that "this approach runs up against the well established problem of building a social welfare function from individual preferences in the face of heterogeneity of preferences and preferences that might be judged to be repugnant" (p. 94) (Hurley 2000).

The second approach to weights is based on the selection of an ethical principle by researchers (or decision-makers) on behalf of society, rather than eliciting community preferences. A well-known example is the "fair innings" approach of Alan Williams (Williams 1997; Williams 1998). The "fair innings" is based on the premise that everyone in society is entitled to some "normal" life span of health (i.e. a quality adjusted life expectancy). This ethical principle can be used to derive weights for health benefits (i.e. QALYs) accruing to individuals at different stages of their life.

Combinations of the two broad approaches are also possible, of course, where decision-makers take into account empirical evidence (such as the results of community consultations), but do not necessarily adopt them or adopt them in modified form. The 'combined' approach is reflected in a number of the empirical examples of priority setting

[63] While Hurley's concern is well taken, in reality, most approaches to developing weights are likely to work with means or other statistical measures of central tendency that will average out heterogeneity and balance morally repugnant views (such as racism).

discussed in Chapter Six. The controversial[64] age weights developed by Murray and Lopez in the GBD study, for example, (Murray and Lopez 1996; Murray and Acharya 1997) fall into this category. Murray and Lopez weighted their disability adjusted life years (DALYs) by age weights to reflect the expected productivity of members of society. Hence age groups associated with workforce participation were weighted up, while the elderly and children were weighted down. In developing his age weights, Murray used an empirically based function, which he then extrapolated based on his own assumptions. Total DALYs were left unchanged, but the distribution between age groups was modified by the weighting process. Under Alan Williams' "fair innings" approach, on the other hand, both total QALYs and their distribution would change.

An important issue in designing weights is thus to ascertain the appropriate source and rationale for the ethical principle(s) involved. Unequal weights are usually motivated by a concern for equality in a particular dimension. As with the concept of need discussed previously, there is no scientific basis for choosing between normative principles. Judgment is required having regard to policy objectives, decision context and the theories of social justice held to be the most appropriate. In settings where relations are impersonal and possibly competitive (such as markets) priority tends to be given to reward based on contribution or desert. In contexts where relations are more personal and/or cooperative, notions of equality and of responding to need are given priority. Even within the health sector, where cooperative values will have primacy, resource allocation principles will still vary by context and research question.

5.3.3.3 Allocation to achieve equality of health care access:

The third major approach to distributional equity is allocation to achieve equality of access. Equality of access implies that everyone in society is able to obtain or make use of health care services. As Hurley points out, it pertains to the ability or capacity to do something and not whether it is actually done (Hurley 2000). It thus has more affinity with deontology and process notions of equity, then with consequentialism. Hence, as a number of authors note, it cannot be assessed by examining health care demand or utilisation patterns (Mooney, Hall et al. 1991; Olsen and Rogers 1991). The ethical basis is one of ensuring a "fair chance", rather than the ultimate effects on the distribution of health status.

There is certainly empirical evidence to support this principle. Nord and colleagues, for example, found that Australians want their health care system to provide the same opportunity as others for treatment, irrespective of cost (Nord, Richardson et al. 1995a; Nord,

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[64] Many commentators, both ethicists and economists, object to weights that link societal value to economic productivity. To many they appear more related to efficiency concerns than to equity principles (Hurley 2000).

Richardson et al. 1995b). While there are certainly issues in defining access[65], this principle is the most commonly found definition of equity in policy statements (Donaldson and Gerard 1993; van Doorslaer, Wagstaff et al. 1993; Wagstaff and Van Doorslaer 2000). The particular nature of health and ill health is such that a fair chance of care carries strong egalitarian feelings (Mooney 1994). The principle of equal access is often coupled with the need principle as mentioned previously (i.e. equal access for equal need). Here the associated notions of vertical and horizontal equity become important. The equal access principle specified in this form does not literally mean equal access to all health care – rather it means equal access to certain care (eg primary care), but unequal access to other forms of care (eg specialist care filtered through the GP on the basis of severity).

In introducing this section on distributive justice, the importance of the choice of focal variable (or distribuendum) was raised, because many equity principles are inherently incompatible. Striving for equality on one dimension usually means tolerating inequality in other dimensions. Nowhere is this more apparent than in the "fair chances/best outcomes" trade-off (Daniels 1994). At both the micro and macro level, choices arise in health care where the concept of ensuring equal opportunity or a fair chance will yield different answers to decisions based on achieving best health gains. With transplant operations, for example, if two patients are equal in all respects except one will live ten years and the other twenty, which principle should apply? Though most would reject the extreme positions of giving full priority to fair chances or best outcomes, finding an acceptable balance leads naturally to the role of procedural justice in priority setting.

5.3.4 The role of procedural justice in health care

When general principles of distributive justice fail to give clear-cut answers, either because of the plurality of moral values and/or because of the difficulty of the choices faced[66], then the focus of social justice shifts to fair procedures and to the legitimacy provided by a just process. While distributive justice focuses on the outcome of a distribution, procedural justice focuses on the extent to which the procedures that lead to an outcome are just. Strong advocates of "due process" see decisions made through the "correct" priority setting process as, ipso facto, legitimate. The discussion then turns to what constitutes "due process", with notions of transparency, accountability, bargaining, fair treatment, reasonableness and lay participation high on the list of desirable attributes.

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[65] Mooney, for example discusses opportunity cost verses welfare loss definitions of access (Mooney 1994), while LeGrand and Olsen focus on feasible choice sets, involving both monetary and non monetary factors (LeGrand 1982; LeGrand 1987; Olsen and Rogers 1991).

[66] Norman Daniels, for example, has posed four rationing problems that he believes to be unresolved, viz: i) the fair chances verses best outcomes problem; ii) the priority to be afforded severity when potential health gain is equal; iii) the priority to be afforded the aggregation of modest benefit to large numbers verses significant benefits to fewer people; and iv) the weight to be given to public preferences verses analytically reasoned moral principles (Daniels 1994).

As Norman Daniels has stated:

> *"There is good reason to believe, however, that general principles of distributive justice and general characterisations of the goals of medicine cannot really address the problems of setting priorities in ways that satisfy our moral concerns in particular cases. Rather, we must seek agreement on how to make the practical decisions about limits that arise at various levels within purely public and mixed public and private delivery systems. This point has been recognised in a new wave of commissions, for example in Denmark, that has focussed on assuring a fair, transparent process of decision making rather than the articulation of general principles." (p.94) (Daniels 2000)*

Several authors in the literature on priority setting discuss the theme of due process (refer the works, for example, of David Hunter (Hunter 1993; Hunter 1996; Hunter 1997), Peter Singer (Singer 1997) and Norman Daniels (Daniels and Sabin 1997; Daniels and Sabin 1998; Daniels 2000)). The work of Daniels, in particular, based on his observations of rationing in managed care organisations in the USA, has been quite influential, certainly influencing the Nordic countries (Holm 2000). Daniels argues that the accountability provided by markets is not able to ensure fairness or the legitimacy of priority setting decisions in health care. Similarly, he sees his ideas as particularly relevant for public systems, "where rationing often is carried out covertly and hidden in budget setting practices" and for mixed systems, where the grounds for decision-making "may even be viewed as trade secrets" (Daniels 1996). Daniels (Daniels and Sabin 1997) puts forward four conditions, which he regards as "necessary but probably not sufficient conditions", viz:

i) publicity (the need for decisions and their rationales to be publicly accessible);
ii) reasonableness (the rationales for decisions should appeal to reasons and decisions that are accepted as relevant by people who are disposed to finding terms of cooperation that are mutually justifiable;
iii) appeals (there is a mechanism for challenge and dispute, including the opportunity for revising decisions in the light of further evidence or arguments);and
iv) enforcement (voluntary or regulatory to ensure i) to iii) are met.

Condition i) provides for transparency in decision-making and would enable a kind of case law to be established, analogous to the legal system. Condition ii) is central to Daniels whole approach of "accountability for reasonableness", by which he means that decision-makers have to explain how 'value-for-money' will be achieved in meeting varied health needs of a defined population under reasonable resource constraints. Daniels sees valid reasons as limited to those that "fair-minded" stakeholders can agree in a spirit of cooperation. There will still be disagreement about how to apply the agreed rationale, "but seeking mutually acceptable rules, as fair-minded people do, narrows the scope of disagreement and the

grounds on which disagreement can be adjudicated" (p. 93) (Daniels 2000). Conditions iii) and iv) are more context specific, reflecting the origin of Daniels ideas in the US managed care arrangements.

Daniels believes that his "accountability for reasonableness" approach offers a solution to the controversy between implicit and explicit approaches to priority setting discussed in Chapter Two. Advocates of implicit approaches see the complexity of real life decision-making invalidating a rigid rules-based approach, preferring to "muddle through", not tying the hands of experienced experts (Hunter 1993). Advocates of explicit approaches argue the importance of providing a publicly acceptable rational framework for decisions that encourage consistency and accountability. Daniels acknowledges the difficulty in achieving prior public consensus on principles and decision rules, which explicit approaches seem to require. With "accountability for reasonableness" he suggests consensus about "acceptable, reason-governed practices" can be developed over time in the process of making actual decisions. A form of case law can emerge on reasons and values that are considered acceptable (Daniels 2000). To quote Daniels:

> *"In effect we may have to 'muddle through' on some of our decision-making. But, unlike the requirements of implicitness, we are held to a standard of public accountability that is more in the spirit of explicitness. Our reasoning while we 'muddle through' must be held up for scrutiny and public discussion, and we must be accountable for revising it in the light of that discussion. We must seek decisions all can agree rest on reasonable considerations." (p. 105) (Daniels 2000)*

The debate between explicit and implicit approaches to priority setting may be drawn too starkly in the literature however. There is no inherent conflict between action to provide more and better information on costs, outcomes and ethical values, and work to strengthen the processes for debating that information and arriving at judgements on priorities.

On a related theme, a number of authors pursue the idea of "procedural rights" as an important aspect of due process, particularly at the micro level. Hunter, for example, argues that a system of procedural rights should be put in place to help balance the "the two poles of collectivism and individualism". (p. 138) (Hunter 1997). Procedural rights are usually defined as rights that help ensure fair treatment of individuals as they come into contact with service providers and/or the government (Coote and Hunter 1996). These ideas are reflected in the introduction by some countries of the Patient's Charter (UK Department of Health 1992) and complaints systems. Procedural rights in health care may be summarised as follows (Bynoe 1996):

ii) A right to be heard;
iii) A right for consistency in decision-making;

iiii) A right to relevance in decision-making (a duty on those making decisions to take into account all relevant factors and to disregard irrelevant ones);

ivi) A right to unbiased decisions;

vi) A right to reasons (openness in decision-making, expressed as a requirement for the decision-maker to give reasons to those affected by decisions concerning them; and

vii) A right to review.

All health care systems must make morally controversial decisions that limit access to potentially beneficial medical services. By careful attention to issues of procedural justice the legitimacy and moral authority of decision-makers can be enhanced. The "accountability for reasonableness" approach of Daniels, together with the notion of "procedural rights" summarised above, provide useful guidance to address this challenge. As Daniels concludes, "good reasons for decisions matter and deliberation about them is the key" (Daniels 1996).

5.4 Which ethical criteria should guide priority setting?

Given that striving for justice on one distributional dimension usually means tolerating inequality in others, the question arises whether it is feasible to choose one overarching principle. Each of the ethical principles discussed above are possible candidates as an overarching principle to guide resource allocation throughout a health care system. The inherent difficulty, however, is that resources are allocated through a myriad of decisions taken at macro, meso and micro levels of the health care system. The priority setting debate takes place somewhere between the main ethical concerns of deontology, consequentialism and justice, and their respective merits are not neutral in respect to the context and setting of the choice problem. As Hurley notes:

"One of the strongest and most consistent messages from the empirical research on moral and ethical reasoning of people is the context-specific nature of such judgements (Walzer 1982; Yaari and Bar-Hillel 1984; Elster 1992; Miller 1992; Mannix, Neale et al. 1995). As one changes decision contexts, factors beyond distribution emerge such as notions of procedural fairness, duty, obligation, due process, informed consent, non coercion, or rule of rescue. An equitable or just allocation is one that conforms to the relevant principle." (p. 95) (Hurley 2000)

In settings where the relations are impersonal and possibly competitive (such as markets) priority tends to be given to reward based on the contribution people make. In contexts where relations are more personal and/or cooperative, notions of equality and of responding to need are given priority. Even within the health sector, where cooperative values will have primacy, resource allocation principles will still vary by context and research question. It bears repeating that there is no scientific basis for choosing between normative principles.

Judgment is required having regard to policy objectives, decision context and the theories of social justice held to be the most appropriate.

Utilitarians might argue that deontological concerns and notions of justice could be incorporated into an overarching utilitarian system as discussed above. There are dangers, however, in the endless extension of utilitarianism to incorporate deontological and distributive considerations. First, utilitarians who support efforts to mirror the preferences of the public will come into conflict with others who focus on what they regard as "morally correct" attitudes, or "politically acceptable" solutions, regardless of their popularity. Second, is the practical danger that extended utilitarianism will run ahead of our ability to measure the complex outcomes. As Harvey argues:

"We may be falsely reassured by knowing that we could in principle, and with sufficient time and effort, incorporate these elements into process utility, whilst continuing in practice to make decisions without them." (p. 102) (Harvey 1996)

While Harvey's concern is not misplaced, recent efforts to broaden the concept of benefit in applied economic evaluation (eg Cost-Value Analysis and newer approaches to PBMA using decision theory) offer hope that suitable measurement techniques are being developed. Irrespective of these developments, however, Hurley's concerns about monism (i.e. an over-emphasis on capturing all issues of concern within a single measure should not be neglected (refer Chapter Four). Ethical imperatives may be integrated into economic analysis through the development of appropriate weights, as discussed above, but they may also enter in the form of constraints (or second stage filters) in the choice problem. What is required is recognition of ethical complexity, combined with the importance of both due process and deliberative judgements based on relevant information.

Although the work of economists analysing equity at a conceptual level carries no special weight in terms of what the equity principle(s) should be in any given context, they can certainly play an important role in explaining the implications of adopting alternative principles. Nor does ethics, as a discipline, provide any decision rules for the resolution of this issue (refer 5.3.1). Something outside the ethics discipline must be introduced, and this returns us to Richardson's ideas[67] on empirical ethics and government as the "circuit breaker" (Richardson 2000a). Other economists have also argued the importance of empirical evidence in resolving ethical issues. Culyer, for example, emphasised that the values that underpin the concept of social welfare to be employed in economic evaluation should be empirically based (on values of the decision-maker, the government, or a sample of the

[67] Richardson's position is very close to that of the Decision-Making Approach, but he would provide the ethical information to the decision-maker (based on community consultation et. al.) and not just the results of CEA reflecting the decision-makers' values. [Personal communication, March 2001].

general public) (Culyer 1998). Similarly, Olsen[68] argued that the relevance of introducing information on differences in disease severity and health status (in addition to health gains) is "basically an empirical issue" (Olsen 1997). Richardson, however, puts the case cogently in the following extract from one of his recent papers, viz:

> *"While endorsement by government – and even the Australian government – does not ensure that a policy is morally 'right', there is no known process – including the armchair theorising of ethicists or neoclassical economists – which ensures the achievement of this ephemeral objective. The fundamental tenet of empirical ethics must, therefore, be that the political process, viz, open enquiry and the intertwining of empirical evidence and ethical debate is more likely to present government with socially acceptable and morally justified policy options than any other process. As a minimum, it may achieve a near consensus that procedural fairness has been exercised and those that disagree with either the outcome or the process can, as a minimum, express these arguments." (p. 16) (Richardson 2000a).*

5.5 Ethical considerations in the conduct of economic evaluation

Although the methods of economic evaluation have historically been intended to assess efficiency of comparative health care interventions, it is inevitable that they embody a number of assumptions and procedures that have important equity implications (intended or unintended). In this section those implications are briefly outlined, together with evaluation techniques designed to incorporate selected notions of distributional equity into the evaluation process.

Most attention in the literature has focused on three aspects of economic evaluation, viz: i) methods for measuring and valuing outcomes; ii) the methods of aggregation; and iii) the associated health gain maximisation criterion (Harvey 1996; Olsen 1997; Hurley 2000).

One clear example of the influence of equity is the reluctance of many researchers to link access or societal value to a person's economic resources. This is reflected in the early rejection of cost-benefit analysis (CBA) in the health sector, together with the associated technique of willingness-to-pay to value health gains (except of course by economists receptive to classical welfarism). But non-monetary measures designed to avoid monetary valuations (such as QALYs), also embody important ethical assumptions. As noted by Torrance, the basic assumption of QALYs is egalitarian in the sense that "the difference in utility between being dead and being healthy is set equal across people... that is, each person's health is counted equally." (p. 17) (Torrance 1986). The intent is to treat individuals equally in the health domain, irrespective of their intensity of preferences (Richardson 1991). In reality, QALYs – not people – are treated equally, irrespective of to whom they accrue (i.e. a QALY is a QALY irrespective of age, sex, religion, skin colour, etc). Equalisation on the

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[68] Olsen also provides an important reminder, that "before embarking on surveys which aim 'to tap the intuition of justice among people' (Elster 1992), we should acknowledge that information on the

QALY domain, however, means that recognition of the differing moral claims of individuals may be compromised. An unintended consequence of QALYs, is their inherent ageism – the young have an intrinsically greater chance of accumulating QALYs than the elderly. As discussed in this chapter, distributive equity may call for differential weights attached to health benefits on the basis of their identifiable characteristics (ethnicity/aboriginality; rurality/remoteness; age; disease severity; etc).

Some utilitarian philosophers have been critical of QALY-type measures in two respects (Harvey 1996). First, some utilitarians prefer the source of health state valuations to be the individuals suffering the illness or intervention, not a random sample of the community. While there are sound reasons for both approaches[69], utilitarians following Gillon's approach (i.e. maximising the "satisfaction of individual's autonomous preferences" (Gillon 1986) reject the vicarious preferences of unaffected individuals as a substitute for affected individuals (Harris 1985). Other utilitarians following the Benthamite principle that everyone counts for one and not more than one, object to the ageism implications of QALYs mentioned above. This follows inevitably from the procedure of combining the health state valuation with the years of life over which the health state is experienced.

Aggregation methods inevitably contain distributional equity principles. The economist's penchant for discounting (Drummond, Stoddart et al. 1987), for example, embodies intergenerational equity principles. The discount rate chosen implies a value to be placed on costs and benefits that accrue to future generations, compared to those living presently (Hurley 2000). Contemporary economists tend to the philosophical justification based on the social rate of time preference, rather than the market rate of interest, although the question continues to be debated at some length (Robinson 1990; Gold, Siegel et al. 1996; Hurley 1998; Richardson 2001).

Similarly the addition of unweighted QALYs has strong equity consequences. On the one hand, as mentioned above, QALYs are egalitarian as each person's valuation has equal weight (Williams 1985), but on the other hand, the maximisation of unweighted QALYs focuses only on the amount of health gain, not on its distribution or associated health profiles.

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distribution of other streams of health than the health gains profiles could be crucial." (p. 14) (Olsen 1997)

[69] Arguments favouring measuring utility from members of the general public include: i) society at large should determine values for economic appraisal (given that scarce societal resources are being allocated) not patients with their own special interests; ii) patients may overstate their quality of life because of cognitive dissonance (i.e. it is difficult to acknowledge poor quality health (Festinger and Carlsmith 1959) or adaptation (i.e. they lower their expectations (Sen 1979; Loewenstein and Schkade 1999); iii) impartial value judgements are better made behind a veil of ignorance (Rawls 1971; Daniels 1994); and iv) those who fund government public health services through taxation are entitled to influence the pattern of expenditure (a libertarian view of taxation). Arguments favouring the use of patient values include: i) their first hand knowledge of the health states provides more realistic valuations; ii) providing health state descriptors to the general public to enable valuations, may introduce bias; and iii) the general public may be biased against people with disabilities (Ubel, Richardson et al. 1999).

Further, economic appraisal focuses on maximising health gain, whereas equity principles often have regard to pre and post intervention health levels. A less effective or efficient program that improves the health of those groups in poor health may be preferred to more effective or efficient programs that benefit groups already relatively healthy.

As mentioned previously, the concept of "societal valuation" and "Cost-Value Analysis" is being developed by an informal collaboration of researchers as a means of integrating societal concerns for distributional justice into economic appraisal (Menzel, Gold et al. 1999; Nord 1999; Nord, Pinto Prades et al. 1999; Ubel, Richardson et al. 1999; Ubel, Richardson et al. 2000). This approach utilises a two-stage process whereby first, patient valuations are used to estimate health gains as per standard CUA (using time trade-off); and second, these QALY gains are weighted using public values (based on person trade-off) that reflect societal concerns for severity and health potentials (Nord, Pinto Prades et al. 1999). As Hurley comments, such multi-attribute utility approaches, which focus on both health gain and equity concerns, are one important way forward (Hurley 2000). The use of this emerging technique within a priority setting context will pose new challenges for its advocates, including the consistency of societal values across multiple interventions.

An older but still useful approach (particularly as a default option) is to utilise a profile approach, rather than trying to summarise all outcomes of consequence in one index score. Techniques such as the 'social planning balance sheet', 'cost consequences analysis' or 'social audit' have all been available for some time, and include the broader issues of distributional justice in the presentation of results (Bureau of Transport and Communication Economics 1984; Gold, Siegel et al. 1996). The disadvantage of these profile approaches, however, for those who prefer clear and precise decision rules, is that they inevitably involve a level of judgement in combining the various consequences, that would have to handled on a case by case basis. For others, judgement is an inevitable part of priority setting, and so long as explicit rationales were provided on the judgement process, a case law would build-up as decisions were made.

Still another approach is PBMA, which has particular usefulness in choice problems involving multiple interventions. The focus in PBMA on broader notions of benefit and pluralistic bargaining allow a concern for the decision process to be incorporated, in addition to distributional justice (see further discussion in Chapter Nine).

5.6 Summary of key points for inclusion in the ethical rationale (E) of the Checklist

Set out below is a brief summary of the key points drawn from the discussion in this chapter. In Chapter Seven these points are drawn together under the ethical rationale (E) for the

Checklist. The equity rationale informs the development of criteria to assess the features of an ideal approach to priority setting for the health sector. The key summary points are:

- The starting point for judgements about whether society is better of worse off is a framework of normative analysis that is congruent with the fundamental values that prevail in that society. These values need to be established through what Richardson calls "empirical ethics" – i.e. the intermingling of empirical evidence on what the community values and ethical debate – together with what Daniels calls "case law", whereby acceptable reason-governed practices are developed over time in the process of making actual decisions.
- Ethical debate involves a range of ideological perspectives on what constitutes social justice. The libertarian and egalitarian ideologies, for example, are reflected in the free market verses government-control approaches to the financing and provision of health care. These ideologies flow over into the role of government in priority setting and the way priority setting is approached.
- Two ethical approaches – deontology and consequentialism – together with a concern for distributive equity, stand out amongst the ethical issues of relevance to priority setting in the health care sector. Most stakeholders will hold views that reflect a combination of these ideologies, with the particular combination likely to vary with the choice problem and setting.
- It is important to recognise that while ethical reasoning involves a structured approach to problem analysis, it offers no decision rules to choose between these alternative ethical approaches. Despite their importance to the content and acceptability of decisions, the choice of one ethical system over another, or as is more likely, the particular blend of ethical values, remains a matter of judgement.
- There is no logical way of resolving these differences other than a convergence of thinking through structured discussion and recognition of the legitimacy of alternative viewpoints. This recognition reinforces the importance of due process in priority setting exercises, whereby values are clarified and deliberative judgements are taken after meaningful discussion. Further, it underscores the importance of gathering empirical evidence on the values that are held to be important by the community, particularly in relation to concepts of distributive and procedural justice. Finally it emphasises the role of government (and ultimately the Parliament) as "circuit breaker" to decide ethical values, which in turn reinforces the credentials of the Decision-Making Approach as the theoretical foundation for priority setting.
- At a more detailed level, there are a number of issues in relation to these ethical approaches that are worth highlighting.

- First, the term "consequentialism" describes a group of moral theories where widely divergent views are held about i) the need for outcome maximisation, particularly having regard to the significance of distributive equity; and ii) whether only individual preferences count or whether the intrinsic/moral value of consequences also matter. Utilitarianism is an important subgroup of consequentialism developed by both economists and philosophers. The choice of outcome measure usually has important ethical implications that should be acknowledged.

- Second, there is widespread agreement about the importance of distributive equity, but this does not translate easily into agreement about what the relevant concept of equity should be. The choice of focal variable (or distribuendum) is critical, because achieving equality in respect of one equity dimension usually means accepting inequality in regard to other dimensions. There is no scientific basis for choosing between rival notions of equity as normative principles. Judgement is required having regard to policy objectives, decision context, community values and the theories of social justice held to be the most appropriate. Concepts of equity that have received the most sustained attention are: i) allocation according to need; ii) allocation according to health status; and iii) allocation to ensure equality of health access.

- It is important to note that the three approaches to distributive justice will generally lead to different answers for the allocation of resources. Nowhere is this more apparent, for example, than in the "fair chances verses best outcomes" trade-off. When general principles of distributive justice fail to give clear-cut answers, either because of the plurality of moral values and/or because of the difficulty of the choices faced, then the focus of social justice shifts to fair procedures and to the legitimacy provided by a just process for making decisions. The work of Daniels on "accountability for reasonableness", together with notions of procedural rights offered by Bynoe, Hunter and others, offers useful guidance in this regard.

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Chapter Six: Lessons from Empirical Experience

"Proponents of cost/QALY analysis need not despair; Oregon's experience merely demonstrated that cost-effectiveness should not be accepted as the sole criteria for decision-making, not that it should be ruled out altogether." (p. 340) (Buist 1992).

"Nevertheless, it is clear that techniques drawn from economics and other disciplines have been used alongside debate if priority setting is to be seen as legitimate by citizens and other stakeholders." (p. 64) (Ham 1997)

6.1 Introduction

The combination of constrained resources and increasing demands has led government policy-makers in a number of countries to address the issue of priority setting more directly than in the past, to search for new policy instruments to complement the continuing use of waiting lists and clinical discretion. Important empirical evidence now exists on explicit attempts at priority setting, on the role afforded the objective of efficiency in those attempts, together with the assessment of efficiency through economic evaluation. The emergence of explicit priority setting is exemplified by the experiences of the State of Oregon in the USA, of The Netherlands, New Zealand, the Nordic countries and the UK. This experience is reviewed in Section 6.2 of this chapter, with a focus on lessons that are relevant to any attempts to apply explicit approaches to priority setting in Australia. While approaches obviously cannot be simply transposed from one country to another, given the different cultures and health care systems involved, there are nonetheless important themes emerging from this international experience that provide useful guidance. Emphasis is given to the experiences of Oregon and New Zealand. Oregon is important as it remains the only large-scale attempt to implement an explicit priority setting process and because its initial method was based on the QALY League Table approach. New Zealand is emphasised because its incrementalist approach offers an important alternative to Oregon and because increasing emphasis is being given to economic analysis.

In Section 6.3 selected Australian experiences of explicit priority setting of health services are briefly reviewed. While these do not reflect any broad-based national initiative equivalent to the international experiences reviewed in Section 6.1; there are nonetheless important issues to note. In Section 6.4 the focus moves from the population level to lessons that can be learned from notorious individual cases that epitomise the difficult choices involved in priority setting. Such cases demonstrate the tension between a concern to use resources for the benefit of the community as a whole and the urge to respond to the needs of individuals faced with the prospect of death. The importance of ethical values and of "due process" are brought into sharp relief, particularly when decisions regarding access to subsidised care end up in a Court of Appeal. While it is always hazardous to generalise from individual experience,

equally it would be an oversight not to draw out the lessons for those who maybe faced with similar decisions in the future.

Finally, in Section 6.5 the lessons from this empirical experience are drawn together as the pragmatic rationale (P) to guide the selection of criteria for the checklist documented in Chapter Seven.

6.2 Overseas Experience:

6.2.1 The Oregon Plan

Background

A decade ago the State of Oregon in the USA attracted worldwide interest when it began an ambitious attempt to set priorities for health care on a systematic explicit basis. A key part of the strategy was to increase eligibility for Medicaid, a publicly funded health care program for people with low incomes, while staying within acceptable budgetary caps on expenditure. The lack of universal health care coverage in the USA means that a minority of residents in each State has either inadequate health insurance or none at all. In the 1960's the Federal Government attempted to provide cover by introducing Medicare (for the aged) and Medicaid (for the poor), under co-funding arrangements with the States. The latter requires each State to provide health insurance for people below the federal poverty line, but allowed each State to determine the precise level below the poverty line at which people gained eligibility. As medical costs escalated, the States found it increasingly harder to maintain access levels and responded by adjusting both eligibility and/or service coverage. By the late 1980's, for example, only 50% of Oregon residents below the poverty line were eligible for health cover (Welch and Larson 1988; OHSC. 1991).

Oregon's priority setting initiative was also a direct response to a previous more painful attempt at altering accepted priorities of its Medicaid system. In 1987, the Joint Ways and Means Committee of the Oregon Legislature voted to discontinue funding for organ transplantation (liver, bone marrow, pancreas and heart) and instead extend coverage for basic health care to a further 1500 individuals and increase funding for antenatal services (Welch and Larson 1988; Fox, Leichter et al. 1990). The discontinued organ transplantation program was projected to affect 34 patients over the next two years and was characterised by limited success and great expense. No public debate was involved in the decision and little immediate reaction followed. Then a seven year old boy, Coby Howard, was denied funding for a bone marrow transplant for leukemia, and died while a private appeal fund was still US$30,000 short of the US$100,000 needed (Klevit, Bates et al. 1991). The controversy that followed forced the Federal Government to order, from 1 April 1990, the restoration of transplants for those under 21 years of age. The experience led Oregon, already toying with the idea of priority setting through its Oregon Health Decisions program (a network of

concerned citizens who organised a "Citizen's Health Care Parliament" (Crawshaw, Garland et al. 1990)) to a full priority setting exercise across all conditions and treatments.

What came to be called "The Oregon Experiment" was conceived as a solution to a particular problem faced in the US – how to widen health insurance coverage to individuals presently uncovered either privately or through the federal Medicaid system, whilst remaining within a fixed budget and incorporating public values. At the time the Oregon experiment began, approximately 450,000 Oregonians were estimated to have no health care coverage (McBride 1991). In the words of two Australian commentators, Oregon was faced with the dilemma of "all for some or some for all" (p127) (Street and Richardson 1992). In 1989 the Oregon Senate passed three pieces of legislation known as the Oregon Basic Health Services Act (OHSC. 1991). Senate Bill 534 established a risk pool for coverage of the uninsurable chronically ill. Senate Bill 935 required all employers to offer health insurance to their workers by 1994. Senate Bill 27, and the focus of interest from a priority setting perspective, expanded Medicaid coverage to ALL those below the federal poverty line and mandated a prioritised list of health services. The Oregon Health Service Commission (OHSC) was established to develop the methodology for ranking the services and to oversee the development of the prioritised list of services that would be funded under Medicaid. The work of the OHSC was to be conducted in public and was to consider both the advice of experts as well as the views of the public.

Three subcommittees were formed: the Social Values Subcommittee to obtain information on public preferences; the Health Outcomes Subcommittee to seek an objective system to measure the clinical effectiveness of treatment and to develop methods to value benefit; and the Mental Health Care and Chemical Dependency Subcommittee to assist the OHSC with the prioritisation of these services. The OHSC began its task by reviewing a number of approaches to priority setting and initially concluded that "cost-benefit with a quality of life component" (p. 15) was the best available method (OHSC. 1991).

Cost Utility Analysis: The Initial Process Used to Define the Basic Health Care Package

The work began with the formation of some 1600 condition/treatment pairs, categorised using the ICD-9 (International Classification of Diseases, Ninth Revision) and the CPT- 4 (Current Procedural Terminology, Version Four). The OHSC noted that ranking treatments or conditions independently was illogical because the effectiveness of a particular treatment was dependent upon the condition of the patient (OHSC. 1991). Unfortunately, the OHSC did not go on to embrace marginal analysis as part of its evaluation approach, but stayed with approximations for average cost and average benefit for its condition/treatment pairs. All condition/treatment pairs were ranked with the greatest benefit per unit of cost at the top of the list. The cost utility of a service was calculated as the ratio of the cost of the treatment to the treatment benefit – with health gain measured in QALYs using Kaplan's Quality of Well-

Being Scale (Kaplan and Bush 1981; Kaplan and Anderson 1990). QALYs were chosen because they encapsulated treatment effectiveness together with individual values. The OHSC was conscious of the ethical conflict between the needs of the society and the needs of the individual patient, but recognised the importance of adopting a societal perspective (OHSC. 1991). In using the QALY as the measurement device to assess "societal welfare", the OHSC assumed an extra-welfarist foundation (although its doubtful whether economic theory entered its deliberations).

The cost side of the CUA ratio was based on the entire episode of illness and included diagnosis, hospitalisation, medical services, allied health and ancillary services. Because of the sheer size of the assessment task, however, together with the limited time available to the OHSC, rigour in the costing process was sacrificed, particularly in the measurement phase. The costs included focused on "C1" costs (i.e. health service provider costs) using the Drummond et. al. nomenclature (Drummond, Stoddart et al. 1987). Costs falling on individuals and their families (i.e. "C2" costs) and costs falling outside the health sector (i.e. "C3" costs) were excluded. Given that the research question focused on dispersal of government funds, a "C1" focus is realistic, but it is hardly consistent with the purported "societal" perspective. More serious reservations than this somewhat academic point arise however, in relation to the measurement process. Rather than attempt point estimates, Oregon opted for cost intervals with ever increasing interval ranges (eg $0-$250; $251- $500; $501- $1,000; $1,001 - $2,000; $2,001 - $3,000; $3,001 - $5,000; $5,001-$8,000; $8,001 - $12,000; ... $40,001 - $100,000; $100,001 - $250,000; $250,000 and over). It was assumed that the distribution of costs was uniform over time and not distributed near either end of treatment. The median of each interval was used as the estimated cost of a particular treatment, no marginal analysis was undertaken and no provision for discounting was incorporated. The costs of non-treatment were not estimated, so all cost estimates were gross rather than net and/or incremental. At best the cost estimates could only be regarded as very approximate "ball-park" estimates and threatened the validity and usefulness of the resulting CUA ratios.

More effort was certainly put into the outcome measurement process, but whether this was rewarded with more sensitive estimates is debatable. The QALY measure was calculated from two terms, the "net benefit" and the "expected duration of treatment". The OHSC reviewed the medical literature but found insufficient studies to support an evidence-based medicine (EBM) approach to assessing treatment effectiveness. The OHSC commented:

> *"It became apparent this approach was unwieldy and counterproductive because of the 'shelf-life' of the data and a lack of conclusive studies of effectiveness." (p. 10)* (OHSC. 1991)

Judgements by providers of health care were therefore used to obtain information about treatment effectiveness and health outcomes. Not surprisingly, this decision became the subject of intense and sustained debate, particularly as the EBM movement gathered

momentum. Alan Maynard, for example, referred to the CUA list as a "crude guesstimate" created in a "data free environment" (p. 28) (Maynard 1991). The OHSC nonetheless proceeded by surveying local professional health care organisations and asking them about the spectrum of treatments available for each condition, together with the probable outcomes of treatment and non-treatment over a timeframe of five years. The five-year timeframe was chosen somewhat arbitrarily – it reflected current practice in the analysis of cancer treatments and seemed a "reasonable time frame for assessment" that enabled "comparable information" to be collected (p. 23) (OHSC. 1991). Up to five outcomes could be specified: return to former health state (which may or may not be perfect health); death; or up to three points in between where some residual effects remained that impacted on the quantity or quality of life. The residual effects were defined using Kaplan's Quality of Well-Being Scale. Outcome estimates were made for an "average person" and conditions were thus defined using a cohort approach rather than population-wide data. The method adopted ignored the heterogeneity of patients, particularly as patient characteristics might impact on marginal analysis of key treatment design and coverage issues. By specifying the people most likely to be affected, the OHSC argued this to be an equitable approach to the measurement of effectiveness, but one suspects its selection had more to do with feasibility than ethics. To complete the process, the providers were asked to estimate the probability that treatment or non-treatment would result in the various health states they had specified.

The QALY weights to be attached to each health state were obtained from a telephone survey of 1001 residents. Unfortunately, the response rate was poor, with only 23% completing the survey (23% refused to participate, while 54% could not be contacted). The survey was developed to collect public values for particular symptoms and levels of functional impairment associated with illness. No attempt was made to rate specific condition/treatment pairs because it was felt the public did not have the appropriate knowledge to make such judgements (Honigsbaum 1991). The public's values were fed into the QWB Scale and linked with information about the outcomes of particular treatments to derive utilities. Valid reasons were given for the selection of the QWB at the time (in terms of practicality; proof of reliability and validity; feasible alternatives), although its choice today would be far more suspect (Richardson, Olsen et al. 1998; Richardson 1999; Richardson, Olsen et al. 1999).

The "net benefit" of treatment was then defined as the difference between the average health state resulting from treatment and the average health state resulting from non-treatment, viz:

$$\text{Net Benefit} = [\Sigma Pi * QWBi] \text{ minus } [\Sigma Pj * QWBj]$$
$$\text{[with treatment]} \qquad \text{[without treatment]}$$

Where:

Pi = Probability of the ith outcome occurring;

QWBi = Quality of Well Being value associated with the ith outcome

The "net benefit" was then combined with the "duration of benefit" to compute the QALY. The OHSC defined the duration of benefit as the length of time a treatment is effective. If the treatment did not reduce the individual's life expectancy, it was calculated as: "life expectancy" (specified as 75 years) minus "expected age of onset of condition"; where the median age of the age cohort assigned to the condition was used as the expected age of onset (OHSC. 1991). If life expectancy was reduced, the duration of benefit was modified using the following rules:

- If the condition shortened life expectancy, the standard life expectancy (75 years) was replaced by the estimated shorter life expectancy;
- If the condition was self-limited, the duration was set at 5 years, unless there was the likelihood that a small percentage might die, in which case a lifetime benefit was used; and
- If a treatment needed to be repeated during a patient's lifetime, the duration of the treatment benefit was estimated (eg ten years for a hip replacement).

The prioritised list of 1680 condition/treatment pairs was published in May 1990 (as required by legislative mandate). The strict adherence to the cost-utility formula alone (and its use of crude cost and outcomes data) ensured that the list appeared to be primarily ordered by cost rather than the perceived value of the intervention. This impression was increased by the OHSC expressing the results as "QALYs per unit of cost", rather than the more conventional "cost per QALY", which places the emphasis, more appropriately, on benefits/benefits forgone. This first list based on CUA (albeit very crude CUA) appeared counterintuitive to Commissioners and provoked a high level of critical comment[70]. The counterintuitive results placed inexpensive (but relatively unimportant) treatments for conditions like thumb sucking or tooth capping, above life-saving interventions such as appendectomy or surgery for ectopic pregnancy (Hadorn 1991; Buist 1992). The OHSC itself considered the list to be "fundamentally flawed". Harvey Klevit, a member of the OHSC is reported as saying that he:

> "... looked at the first two pages of that list and threw it in the trash can (p. 468)." *(Morell 1991)*

The first list was immediately abandoned, not only because of the counterintuitive ordering of condition/treatment pairs, but also due to "the presence of numerous flaws, aberrations and errors (p. 915)" (Klevit, Bates et al. 1991). Difficulties in obtaining cost and outcome information with any degree of accuracy was raised by many commentators as an important reason for the perceived failure of the CUA approach. The OHSC saw the futility of trying to

[70] See, for example (Hadorn 1991; Klevit, Bates et al. 1991; Eddy 1991a; Eddy 1991b; Daniels 1992; Haas and Hall 1992; Street and Richardson 1992; Nord 1993).

improve the list by changing individual items; it abandoned the deadline and set about trying to improve both the faulty data and the methodology. The Alternative Methodology Subcommittee was created to investigate changes in the prioritisation method.

The Second Approach to Determining the Basic Health Care Package:

For the second list the reliance on an economic approach (via CUA) was abandoned and the number of condition/treatment pairs was reduced to 709 lines. The OHSC adopted a three-step process to determine its revised list (OHSC. 1991). First, seventeen broad health service categories were created and ranked in order of their "importance" (refer Table 6.1); second, the 709 condition/treatment pairs were placed within these broad categories and ranked; and third, Commission judgement was used to fine-tune the resulting list.

The first step involved using a ranked categorisation method recommended by Hadorn (Hadorn 1991; Hadorn and Brook 1991). Two kinds of broad categories were created: the first type included care that could not be defined fully by condition/treatment pairings (i.e. "maternity care" or "comfort care"); the second type separated condition/treatment pairs on the basis of severity or importance. "Importance" was determined by whether or not services were chronic or acute; whether the condition was likely to be life threatening with or without treatment[71]; and whether an improvement in quality of life could be expected from treatment. Seventeen categories were developed using these descriptors and ranked by Commissioners using a modified-Delphi technique[72]. The ranks were based on the score each category received for three attributes: "value to society"; "value to an individual receiving the service"; and "importance to basic health care package". The three attributes were derived (using an undocumented method) from 13 health related values gleaned from a series of 47 community meetings[73]. Categories 1 to 9 in Table One were considered "Essential", categories 10 to 13 were considered "Very important", and the remaining were considered as "Valuable to certain individuals, but significantly less likely to be cost-effective or to produce long term health gain" (OHSC. 1991).

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[71] Fatality was defined as chance of death without treatment of 1% or more.

[72] Each of the eleven Commissioners distributed 100 points between each of three attributes to establish the relative importance of each. The three attributes (which were derived from values expressed in 47 community meetings) were: "value to society"; "value to an individual at risk of needing the service"; and "essential to a basic health care package". When all commissioners had completed the exercise and discussed their numbers (to allow the opportunity to revise their ratings), scores were summed and divided by 11 to obtain a relative weight for the importance of each attribute. The resulting weights were: "value to society" 40%; "value to the individual" 20%; and "importance to health care package" 40%. Each of the 17 categories of care was then rated by the 11 Commissioners for each of the three dimensions on a scale from 1 to 10. Each attribute weight was multiplied by the score given to each attribute for every category to obtain each Commissioner's scores for the 17 categories. Finally the overall averaged scores for the 17 categories were compared and the categories ranked. (Buist 1992)

[73] The concerns expressed at the community meetings were summarised by OHSC staff into 13 most commonly expressed themes. They were: prevention; provide benefit to many; impact on society (social costs); personal responsibility; cost effectiveness; effectiveness of treatment; community compassion; mental health & chemical dependency concerns; equity; personal choice; length of life; ability-to-function; and quality of life. (Buist 1992)

Table 6.1: Oregon categories of health care

Category	Description
ESSENTIAL	
1. Acute Fatal	Treatment prevents death with full recovery (eg appendectomy)
2. Maternity Care	Includes disorders of the newborn (eg obstetrical care)
3. Acute Fatal	Treatment prevents death without full recovery (eg burns)
4. Prevention Care for Children	(eg immunisations and periodic health checks)
5. Chronic Fatal	Treatment improves life span and quality of life (eg non surgical treatment for insulin dependent diabetes; drug therapy for HIV)
6. Reproductive Services	Excludes maternity & fertility services (eg birth control)
7. Comfort Care	Palliative treatment for which death is imminent (eg pain management & hospice for end stages of cancer and AIDS)
8. Preventive Dental Care	Adults and Children (eg exams, cleaning and fluoride treatment)
9. Proven Effective Preventive Care for Adults	(eg cervical cancer and breast cancer screening)
VERY IMPORTANT	
10. Acute Non-fatal	Treatment causes return to previous health (eg non-surgical treatment for acute thyroiditis; medical treatment for vaginitis)
11. Chronic Non-fatal	One-time treatment improves quality of life (eg hip replacement)
12. Acute Non-fatal	Treatment without return to previous health (eg relocation of dislocated elbow; repair to cut of cornea)
13. Chronic Non-fatal	Repetitive treatment improves quality of life (eg migraine headaches)
VALUABLE TO CERTAIN INDIVIDUAL	
14. Acute Non-fatal	Treatment expedites recovery of self-limiting condition (eg medical treatment for viral sore throat)
15. Infertility Services	Medical treatment for infertility (eg in-vitro fertilisation; artificial insemination)
16. Less Effective Preventive Care for Adults	(eg routine screening for people not otherwise at risk)
17. Fatal or Non-fatal	Treatment causes minimal or no improvement in quality of life (eg aggressive treatments for end stages of diseases such as cancer and AIDS)

Source: Based on (Buist 1992) (p. 12) and (Coast 1996) (p. 43).

The second step involved assigning the condition/treatment pairs to the seventeen categories and ranking them within each category on the basis of their "net benefit". Net benefit was intended to measure the differences in quality of well being between two average people who have experienced the same condition, one of who has treatment, and the other who has not. It was calculated using the outcome information provided by medical specialists (health states and their probability of occurrence) and the QWB values from the telephone survey (refer

earlier discussion). While the net benefit calculation is taken from the first approach, cost and duration of benefit were no longer taken into account. Rankings of condition/treatment pairs within the categories in the second approach were based on outcomes five years after diagnosis. What the OHSC called "net benefit" could more accurately be described as the "net quality adjusted survival rate after five years" (Buist 1992) (p.21).

Third, the listing created by steps one and two was reviewed by the Commissioners and adjustments were made to those condition/treatment pairs considered to be out of position. The Commissioners were concerned to ensure that the list was not just a formula-produced combination of values and data, but also an intuitively sensible ranking that reflected relative value in the context of scarce resources. These "professional judgements" were based on a range of factors, including "their interpretation of the community values"; including cost and effectiveness of the treatments; incidence of the condition; impact on public health and social cost (p. 28) (OHSC. 1991). The original CUA ratios used to rank condition/treatment pairs in the first approach, were now only one of several factors used in the final judgement phase (Sipes-Metzer 1992). Cost became a consideration only when the Commissioners questioned the ranking of an item, or when two items were ranked equally according to the net benefit.

The new list of 709 condition/treatment pairs was published on 1 May 1991 and actuaries were contracted to cost the list to assist with the funding decision. Estimates of projected costs with different levels of service coverage were produced. The cut-off line, and hence the components of the basic health care package, was determined to be the first 587 services, which included all those services deemed to be "essential" and most of those deemed to be "very important". The proposed program was estimated to cost approximately 25% more than the current program at that time (Eddy 1991a). Oregon then applied for a federal waiver of Medicaid requirements, in order to authorise introduction of their new program, hoping to commence in July 1992 for a five-year demonstration period (Steinbrook and Lo 1992). Oregon was proposing to monitor the impact of the new program on access, utilisation, outcomes, health status and costs during the demonstration period.

The US Health Care Financing Administration (HCFA) decided on 3 August that the plan was unacceptable in its current state, however, as it discriminated against individuals with physical and mental disabilities (Dixon 1992). The federal administration had come under intense pressure from groups representing people with disabilities, who argued that the Oregon plan devalued life with disability (because of the role of the QALY weights in the rankings)[74] and was therefore contrary to the Americans with Disabilities Act (Dixon 1992). Oregon was asked to re-submit a plan without the community-based quality of life weights. The HCFA action could be interpreted as a rejection of the incorporation of public preferences into the priority

[74] This was disputed in several academic papers (Kaplan 1993; Broome 1994).

setting process, but in reality, it probably reflected more the role of political factors in an election year.

The OHSC responded by removing all references in the net benefit calculation to "quality of life" and "ability to function". Treatment benefit was based purely on the prevention of death. Cost was used to separate services where net benefit was tied. As in the second list, judgement was used to adjust items that Commissioners believed to be wrongly positioned. A revised list was re-submitted in November 1992 and federal approval was given in March 1993 (following President Clinton's election to the White House). A condition of the waiver required Oregon to develop a process for reviewing treatments that fell below the funding cut-off, but which were deemed to be medically appropriate in certain circumstances. The Oregon trial began in February 1994. Since then the OHSC has kept the list under review, adding mental health and chemical dependency services into the basic package and moving treatments up and down in the light of experience.

Lessons from the Oregon Experience

The priority setting processes trialed by Oregon generated considerable debate within the health care literature, both of a theoretical and practical nature. Some authors debated the merits of implicit verses explicit priority setting approaches, including the usefulness of CUA and the ethics of rationing (Hadorn 1991; Maynard 1991; Eddy 1991b). Those opposed to explicit rationing, such as Hunter, criticised the Oregon Plan as replacing a system which was "clearly irrational" with one which was "spuriously rational" (Hunter 1991). Others questioned the implementation of the Oregon Plan and/or the need for any form of rationing at all (Tartaglia 1992). To their credit the OHSC was explicit about its methods and assumptions, and openly acknowledged many of the problems discussed.

The quality of the arguments put forward varied. Some of the criticisms implicitly used the "ideal" as the comparator, rather than the more relevant issue of whether the Oregon Plan improved current practice (Eddy 1991c). This was certainly evident in the debate about whether the Oregon Plan was fair and equitable. Oregon was heavily criticised, for example, for achieving greater coverage[75] by taking away services from a sub-group of the population that was already disadvantaged (Rosenbaum 1992). The inequity of the existing Medicaid system seemed to be overlooked in this attack (Garland, Klevit et al. 1991). Others failed to apply the same rigour to their own alternatives as they applied to the Oregon Plan (Dowie 1995). Often the criteria used for judging whether the Oregon Plan was "successful" or not was unclear (Dougherty 1991).

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[75] The eligibility was expanded by 120,000 to cover all those below the federal poverty line, albeit with a limited package of care (Department of Human Resources 1994)

The success of Oregon could be judged in a number of ways. These include, for example, whether Oregon achieved the policy goals it set itself; whether its priority setting approach has been adopted elsewhere; whether it brought priority setting onto the health agenda; and whether its approach met agreed guidelines as to what constitutes an "ideal" approach to priority setting. This section does not attempt to appraise Oregon's success (for such is beyond the scope of this thesis) rather it takes the more modest objective of drawing out the lessons from the Oregon experience.

A key problem clearly encountered by the OHSC was the lack of published efficacy and treatment outcome information. The consequent reliance on medical opinion reduced the scientific credibility of the net benefit scores for many commentators. The problem was compounded by the lack of a suitable classification system to define homogeneous patient and/or treatment classes (see earlier discussion). The OHSC was aware of these problems, but the time constraint together with the huge task it had set itself, meant that using alternative information bases or classification systems was infeasible (Hadorn 1991). Some commentators acknowledged that despite poor data, decisions have to be taken and that the establishment of priorities cannot await the appearance of perfect data (Welch 1989; Hadorn 1991). As David Hadorn pointed out:

"Oregon's planners merely asked physicians to make explicit the outcomes estimates on which they currently (and implicitly) base their decisions." (Buist 1992)(p. 34).

This more realistic position still leaves unanswered, however, important issues for priority setting, such as what constitutes adequate data; whether the data needs of technical approaches to priority setting are tractable; and whether the technical approaches are adequate as stand-alone methods? Oregon's experience certainly highlighted that there is no easy technical fix to the question of setting priorities (Klein 1991) and that priority setting is likely to be a dynamic process rather than a final solution (Crawshaw 1992). The inherent heterogeneity of patients and treatment responses, together with the importance of marginal analysis, creates a major data hurdle for economic approaches, particularly if applied on the scale attempted in Oregon. Coast concludes, for example, that there is often a conflict in technical approaches to priority setting between the assumptions made about patient/treatment heterogeneity and the acquisition of good quality data (Coast 1996). She argues that technical approaches based on decision rules can become inflexible (particularly when applied to a large number of interventions) and that this inflexibility is more questionable and more damaging the poorer the information base becomes.

A related point exposed by Oregon is that technical rationing based on decision rules may produce results that are unexpected and/or unacceptable to some, particularly if the program objectives and the concept of benefit are not clearly discussed in advance. Including elements of judgement (and what Coast calls "pluralistic bargaining") into the process is one way of

introducing flexibility and maintaining the intuitive appeal of results (Landsdown 1992; Coast 1996). The exercise of Commissioner judgement in the Oregon process clearly illustrates this approach, but brings with it the issue of whether such judgement should be implicit or explicit.

Other economists have drawn a different message from the Oregon data problems. Eddy, for example, concedes that the available CUA methods and published outcome evidence are not up to evaluating the entire domain of health care as was tried in Oregon (Eddy 1992). He urges an approach focussed on change at the margin, rather than attempting such a comprehensive approach (such as assessing the condition-treatment pairs that are close to the funding cut-off (Eddy 1992)). The development of PBMA, with its focus on a limited number of increments and decrements selected in relation to current expenditure patterns, is one approach in tune with this suggestion. Other commentators also focussed on the need to better identify beneficial services, but emphasized the importance of developing clinical guidelines (Hadorn 1991).

A second area of criticism has been the community valuation of the health states. Few have disputed that the involvement of Oregonians in the meetings process was a valuable experience in understanding and incorporating public opinion. The way in which the information was gathered and analysed, however, has certainly been questioned. The validity of ranking social values according to their frequency of mention at public meetings, for example, was queried by several authors (Dougherty 1991; Coast 1996). The important transformation of these values into the three key attributes[76] used in ranking the seventeen categories remains undocumented. The telephone survey used to obtain the QALY scores was questioned on a number of grounds, including the framing of the questions (Cromwell, Halsall et al. 1995) and whether it was representative of the general public or of households below the poverty line (Haas and Hall 1992). Others queried whether the QWB was the most appropriate tool to measure community valuations of health states because it failed to compress non-severe health states into the upper range of the scale (Nord 1993).

By and large, however, this area of the OHSC's methods received relatively minor attention. This probably reflects the popular acceptance of the use of quality of life measures in medical outcome studies (Buist 1992) and the importance placed on community participation. It also reflected the way in which the OHSC used the quality of life data. Despite the recurring theme in the community meetings about "benefits many"; the OHSC avoided frequency or utility maximisation as prime criteria for ranking in its second approach. Thus procedures producing small or short-term gains in QWB (such as common colds) were considered less important than treatments providing large increases in QWB, regardless of the number of people who will benefit (or the cost). The second method adopted by the OHSC moved away from

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[76] As discussed earlier, these three attributes were "value to society"; "value to the individual at risk of needing the service"; and "essential to a health care package".

efficiency (i.e. utility maximisation) and clearly embraced the "rule of rescue" and need defined as ability-to-benefit as underlying principles. Further, while the OHSC accepted the usefulness of the QWB as a point in time measure of health status, it was reluctant to accept the implied trade-offs of a full QALY calculus (i.e. ten years with a QWB of 0.1 equals one-year at full health). The Oregon experience confirms the ethical dimensions of the benefit measure discussed in Chapter Five. While the role played by consumer opinion voiced in the community meetings cannot be precisely quantified, the Commissioners undoubtedly used it throughout the whole priority setting process. This was evidenced by the rankings of the seventeen categories (with preventive and maternal care rating so highly), together with when the Commissioners hand moved individual items. As the OHSC's report to the Governor claimed, the community meetings "were useful for understanding the general tone of community needs and concerns" (Buist 1992) (p 38).

The fact that Oregon was widely perceived as a move to explicit rationing is interesting for two reasons. Firstly, the plan in reality was a move from rationing based on the percentage of individuals covered to rationing based on the extent of procedures covered. The rules by which Medicaid operate have not generally been acknowledged in America as a form of explicit rationing, although this is how they are perceived by many overseas commentators (Coast 1996). The fact that some US commentators have come to recognise the existence of rationing under both systems has increased the level of support for the Oregon Plan (Callahan 1991). Second, the Oregon Plan still retained important dimensions of implicit rationing. Implementation of the Plan is heavily linked with capitation via physician care organisations (PCO's) and health maintenance organisations (HMO's) (Bodenheimer 1997). The priority list defines the benefit package on which the capitation payment is based, but physicians may still prescribe outside the benefit package if they so choose (without receiving an increase in payment). Further, the basis on which Commissioners juggle individual items on the list is only loosely proscribed and retains an implicit element. Some authors have criticised this final step in the process as "opaque" (Klein 1992) or have likened it to a "black box" (Granneman 1991; Daniels 1992). As Coast argues, the problem is that lack of explicitness in the Commissioners' judgements makes them difficult to challenge. "Open discussion on the other hand would have brought pluralistic bargaining into the Oregon experiment and ultimately made the process more acceptable to many critics" (p. 54) (Coast 1996).

Finally, before moving to the next empirical example of priority setting, it is worth pausing to consider whether or not the CUA approach failed in Oregon, as interpreted by some commentators (Hadorn 1991). Although, as discussed, there were certainly problems familiar to all technical methods concerning inadequacies of data used in the analysis, together with classification problems in adequately defining the condition/treatment pairs, it is unlikely that these issues were the main obstacles. Certainly for economists the lack of rigour in the

measurement approach to costs and benefits, the omission of discounting and the absence of marginal analysis were all significant limitations. For non-economists, however, the over-riding concern was the counterintuitive ordering of the condition/treatment pairs, and it is important to recognise that this same situation may have arisen if the CUA approach had been quite rigorous.

The ordering of a priority list based on the "efficiency principle" is based on both the benefits obtained from a treatment and the cost of that treatment. At the top of the list there will not only be those treatments that provide high levels of benefit at reasonable cost, but also treatments for minor ailments which are available at minimal cost. Intuition, particularly for non-economists, would suggest that those treatments that address serious conditions and which confer significant benefits should be at the top, irrespective of their costs. The apparent inconsistencies in the CUA list, may have been more the result of applying such intuition, than they were the result of inconsistencies in the CUA method. As David Eddy (Eddy 1991a; Eddy 1991b) explains:

> *"[I]t is important to understand that a priority-setting process based on cost-utility ratios should not be expected to rank services according to our intuitive sense of their 'importance' or degree of benefit... .If you want to check the results against your intuition, you should compare the volumes of different services that can be offered with a particular amount of resources... The intuition to compare adjacent services (one to one) is not only inappropriate, it is misleading." (Eddy 1991b)(p. 2135-41)*

David Eddy's argument is easily comprehended and accepted by economists. The failure of the Commissioners on the OHSC and many other commentators to comprehend and accept it, however, gives rise to an important implication of the Oregon experience. If the only people to whom a priority list based on an efficiency principle looks acceptable are economists, then setting priorities based on efficiency is unlikely to be successful.

Fortunately, however, this issue also involves the key discussion in Chapter Four about the appropriate arguments that should be included in the societal welfare function. More particularly, it relates to the legitimate criticism of the extra-welfarist approach (which underlies CUA) in terms of its failure to reflect community concerns for equity and procedural justice. In this context, equity focuses on the community's preparedness to give priority to severe conditions over minor conditions and the role played by the "rule of rescue" (Hadorn 1991). It reinforces the importance of clarity about which theoretical foundation is being employed in defining "efficiency" in economic evaluation. If the concept of value employed was broader than simply health gain (as provided for in the Decision-Making Approach), and this broader concept of benefit became the maximand, then rankings based on economic analysis are more likely to be acceptable to stakeholders.

6.2.2 The New Zealand experience

Background

A key aspect of New Zealand health policy in recent years has been the proposed development of an explicit core of services to which all New Zealanders would have access (Cumming 1997). New Zealand's interest in the specification of core services reflects the two themes that have dominated health policy discussions around the world in recent times. The first is health care reform, often with an increased focus on market mechanisms (OECD 1994; Jerome-Forget, White et al. 1995). The second, and subject of this thesis, relates to issues of priority setting and rationing. Underlying both these themes was ongoing concern at rising levels of health care expenditure, concern over variations in medical practice and at continued uncertainties over which services contributed most to improved health outcomes (Cumming 1997).

In July 1991, the New Zealand government announced a package of health care reforms based around a framework of managed competition, involving the development of a national explicit core of services to which all New Zealanders would have access (Upton 1991; Enthoven 1993). The New Zealand government also gave four additional reasons for its focus on "core services"; each relating to perceived problems with the pre-reform health care system. These focussed on the variations in access to services around New Zealand; the provision of information to New Zealanders on what health care services they could expect to receive from their publicly funded health care system; the prevention of cost-effective services from being cut in favour of less cost-effective services; and the need to make explicit the rationale for priority setting (Upton 1991). While the need for an explicit core as part of the proposed managed competition reform was removed when these plans were shelved, interest in "core services" remained nonetheless (Cumming 1994). This interest reflected the four additional reasons outlined above, together with the ongoing possibility of health sector reform.

The work on priority setting in New Zealand thus began in the early 1990's and has continued ever since. Like Oregon, New Zealand's experience involved an ongoing process in which policy makers adjusted or refined their course several times. While Oregon's experience involved a decreasing focus on economic methods, New Zealand's experience has seen the reverse. Unlike Oregon, New Zealand did not attempt a comprehensive review of all its health services; rather it opted for gradual incremental change from the status quo. While New Zealand's experience has not generated anything like the same level of comment in the international literature as Oregon, it offers nonetheless an important experience in priority setting from which to learn. This is so particularly for those countries that might be attracted to gradual change, with a strong focus on public consultation, supported by technical analysis.

Stage One: Creation of the Core Services Committee (CSC)

In November 1991 the New Zealand government sent out a consultation document detailing various options for the development of its proposed "core services" (Minister of Health 1991). There were two broad options canvassed. The first was the option of a detailed list as per the Oregon example, involving highly centralised decision-making. The second option was described as a "general" list that would specify only broad categories of health service while leaving the detailed decisions about specific priorities for decision at the local level. The second approach thus allowed for regional variations and greater individual choice by clinicians and patients (Minister of Health 1991).

A report based on the consultation process[77] was published in May 1992 (The Bridgeport Group 1992) in which it was concluded that:

> *" The clear preference is for a general positive list, allowing for regional prioritisation, coupled with a short negative listing of those services to be excluded from public funding." (Foreword, p. v) (The Bridgeport Group 1992)*

There was little support for detailed priority lists for administrative (cost and complexity), medical and ethical reasons (both centering on lack of attention to the needs of the individual). The "general list" was advanced by respondents on the arguments that it would be more widely understood; more amenable to community participation; less open to capture by stronger interest groups; and allow scope for independent clinical judgement (The Bridgeport Group 1992). The need for flexibility in priority setting was noted, not only in terms of clinical decisions reflecting the needs of individual patients, but also the desirability of tailoring services to individual regional needs (eg different urban/rural mix and cultural requirements). There was strong support for a scheme of universal access, with provision of health services to those in need, regardless of financial or other circumstances. The necessity for a framework of moral and ethical values upon which to base core services was also discussed. The recommendation that this framework should be developed in consultation with the community was a reflection of the clearly stated desire among respondents for ongoing consultation.

In March 1992, while the submissions were still being analysed, the government created the National Advisory Committee on Core Health and Disability Support Services[78] to determine what the priorities should be and how they should be set. Like the Oregon Legislature, the New Zealand government created a specific ongoing capacity to manage the priority setting task (National Advisory Committee on Core Services and Disability Support Services 1992).

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[77] A total of 1586 submissions were received in response to the discussion paper. A total of 821 organisations are listed as having commented, including area health boards, local government, voluntary agencies, public agencies, community-based health groups, Maori, Pacific Islanders, and church groups.

[78] Hereafter called the Core Services Committee or (CSC).

The subsequent work of the CSC has been characterised by an evolving approach and extensive public consultation. The consultation has included ethics forums; public forums; public meetings (including Hui); consensus conferences; questionnaires and consultation documents (Coast 1996; Edgar 2000).

One of the first decisions the CSC took was not to pursue the option of a detailed prioritised list such as that developed by Oregon. The CSC argued that:

> *" [T]he core could not simply be a list of services, treatments or conditions that would or would not receive public funding. Very early on we decided that that approach wouldn't work – it would be impossible to implement as it would either have to be so broad as to be meaningless, or so rigid as to be inflexible and unfair.... The approach we decided to take was one that has flexibility to take account of an individual's circumstances when deciding if a service or treatment should be publicly funded. For example, instead of a decision that says that hormone replacement therapy (HRT) is either core or non core... the committee has decided that in certain circumstances HRT will be a core service and in others it won't be. The committee has decided that HRT be a core service where there is clinical and research based agreement that it constitutes an appropriate and effective treatment."(Jones 1993)*

Instead the CSC decided that current health care services should continue to be funded and that it would make recommendations on services that should receive priority in the budget setting process (National Advisory Committee on Core Services and Disability Support Services 1992). The key assumption of the CSC's approach has been that current service provision should comprise the "core", but that, gradually over time, this core would change to reflect the priorities determined by the Committee. While some commentators have interpreted this as a rejection of technical priority setting methods (for example, (Coast 1996)), this is not necessarily the case. While clearly different to Oregon's first approach based on crude CUA methods, New Zealand's approach is very much in line with that advocated by Eddy in response to the Oregon experience (Eddy 1991b) (Eddy 1991a). The incremental change approach both facilitates the application of marginal analysis and makes more tractable the application of rigorous approaches to CUA.

In its first reports the CSC published a "stocktake" of current services and focussed its public consultation on why rationing was necessary, together with distilling what service priorities communities had (National Advisory Committee on Core Health and Disability Support Services (b) 1992; National Advisory Committee on Core Services and Disability Support Services 1992). Six clear priority service categories emerged from the town hall discussions and questionnaires (although exactly how these choices were distilled is not documented):

- mental health and substance abuse services;
- children's health services;
- integrated community care services, including culturally appropriate services responsive to Maori needs;

- emergency ambulance services;
- hospice services; and
- habilitation/rehabilitation services.

Importantly, communities demonstrated a willingness to make trade-offs. In particular they emphasised quality of life rather than quantity of life; basic care services over high technology services; and community-based services over in-patient care. Access to emergency services was deemed important by people in rural areas. Edgar reports that by 1998:

> *"[T]hose early priorities have translated into various policy and purchasing initiatives, which have given identified service areas increasing emphasis. Support has continued for their legitimacy. More latterly, as people's concerns are being addressed, other priorities are starting to emerge (such as the need for a focus on families, youth health, and adequate funding for people with disabilities). The challenge for policy makers and funders is to identify the next areas where worthwhile investments can be made, at the same time maintaining progress on the early priorities. " (p. 180) (Edgar 2000)*

Initially the CSC had aimed to publish the general list together with a short list of exclusions (as per the Bridgeport Group report). The ongoing public consultations had revealed that lower priority had been accorded to maintaining life at any cost; to unnecessary high technology interventions; to surgical interventions benefiting few people; and to pharmaceutical / technology interventions lacking cost-effectiveness credentials. Some specific suggestions for limits included familiar candidates (eg cosmetic surgery; transplant surgery; genetics; fertility services; intensive care at the beginning and end of life) (National Advisory Committee on Core Services and Disability Support Services 1992). This idea was subsequently abandoned as the CSC firmed in its thinking that simple service exclusion was not the way to go. In its 1994 report, for example, the CSC stated that service exclusions were "arbitrary and unsustainable" (National Advisory Committee on Core Health and Disability Support Services 1994). It acknowledged, however, that services that would "not generally be included" in the core were experimental technologies; services without any demonstrated effectiveness; and services not usually ranking as a high priority. Rather than identifying services that would or would not be provided, the aim has been to describe circumstances in which access will be provided to publicly funded services.

The 1992 reports also flagged that different methods would be adopted for horizontal priority setting (priorities between services) and for vertical priority setting (priorities within services). At the level of setting priorities between services, the CSC concentrated heavily on its public consultations - what Coast calls "pluralistic bargaining" (Coast 1996). This is reflected in the choice of the six priority service areas outlined above. It is interesting to note that while both New Zealand and Oregon included broad health service categories as a way of structuring their approach to priority setting, the methods adopted to develop these service categories varied. Whereas Oregon used a ranked categorisation method (Hadorn 1991) that focused on

severity and utilised community values indirectly via Commissioner judgements in a modified-Delphi technique, New Zealand relied on eliciting direct community rankings. The precise way in which the community views were analysed to form and select the priority services is not clear from the available literature.

At the level of setting priorities within services, the Committee chose the route of consensus conferences to develop its recommendations. The guidelines were intended to apply in normal circumstances and acknowledged that clinical discretion was important in any unusual circumstances. The guidelines were intended not only to offer guidance to purchasers and providers, but also to inform the public of the circumstances when services are likely to be publicly funded (National Advisory Committee on Core Health and Disability Support Services 1994). It was also appreciated that the active involvement and support of clinicians was crucial because guidelines are worthless unless they impact on clinical decisions.

The CSC began the process of defining options for change by looking at those high-cost and high-volume services which offered the most potential for improvement and for re-directing resources[79]. This decision was certainly very consistent with an economic approach. In the first two years, 18 topics were selected for detailed evaluation and consultation. This first wave of work has been added to significantly from 1993 through to the present. The CSC's message relating to guidelines had become more strongly related to issues of cost-effectiveness. Statements were included in CSC reports along the lines that some of the guidelines would "offer significant and clinically justifiable resource savings" that could be used to maximise benefit for the available resources (p. 37) (National Advisory Committee on Core Health and Disability Support Services 1994). There is also explicit acknowledgement that technically superior treatments may not be selected where other approaches are more cost-effective.

Findings from the early consensus conferences suggested some important themes which were taken to the people in 1993 via a consultation report entitled "Seeking Consensus" (National Advisory Committee on Core Services and Disability Support Services 1993). These themes included the rationale for national centres for specialist services (rather than multiple local centres); the need to manage waiting times; the importance of evidence-based practice guidelines; and the rationale for a holistic or integrated approach to patient management. The endorsement received for these proposals supported the ongoing (and expanded) guidelines program, together with work on priority criteria for access to elective surgical procedures and the development of booking procedures (Hadorn and Holmes 1997; Dennett and Parry 2000).

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[79] Other factors included the level of public concern; whether adequate information was available; and whether there was a good chance of reaching consensus on issues that would make a difference.

*Stage Two: **Developing the philosophical and ethical framework***

In 1993 the CSC took up the challenge of developing the underlying ethical framework for its priority setting work. The Committee asked the public in its "The Best of Health 2" report, how priorities should be decided – that is, what criteria should be used to set priorities (National Advisory Committee on Core Services and Disability Support Services 1993). Substantial support emerged for the following four-question framework for decision-making set out in that document:

- ***benefit*** or effectiveness of the services (i.e. does it do more good than harm?)
- ***value-for-money*** (i.e. is the service sufficiently effective to justify the cost, especially if an equally effective but cheaper treatment is available?)
- ***fairness*** in access and use of public resources (i.e. is this the best way to use the public resources or should they be used for a different service, or for someone else, or at some other time?)
- ***consistency with community values*** (are these the services most valued by communities?)

The Committee advised the Minister that these principles should underpin all policy advice and health care purchasing decisions and that this should have the practical effect of ensuring that resources go to those who will receive the greatest likely benefit (Edgar 2000). The principles are founded on the idea of what is referred to as an "individual benefit" criterion, with the concern being whether a particular service should be funded for a particular person at a particular time (National Advisory Committee on Core Services and Disability Support Services 1994). Note that the aim has not been to set one overarching objective to be met (or optomised) by the health care system – as would be normal for technical approaches – but to recognise the reality of multiple objectives and the importance of community consultation and consensus building. There is no explicit recognition of "need"[80] or "severity" in the principles, although they would be reflected indirectly through the fairness, effectiveness and efficiency principles. As Coast notes, what is meant by "Is it fair?" is not entirely clear in the "Best of Health 2" report, which focussed on the personal level and the balance between cost and relative benefit (which seems more akin to efficiency) (Coast 1996). Subsequent reports helped to clarify the notion, however, with a focus on issues of regional equity and equity between socio-economic groups (National Advisory Committee on Core Services and Disability Support Services 1994).

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[80] It is interesting to compare these principles with those chosen by other countries. The Dutch Government Committee on Choices in Health Care, for example, used the filter of "necessary care" as its first sieve in prioritising health services (p. 84-87) (Government Committee on Choices in Health Care 1992).

Stage Three: From broad principles to ongoing processes for priority setting:

The "Best of Health 3" report signaled the CSC's[81] intention to take the public debate forward from "why do we need to ration?" and "what principles do we use?" to "what processes should be used to prioritise publicly funded services?"(National Health Committee 1997). Edgar reports (Edgar 2000) that coalescing six years of committee work, the report made four key points that were supported by the general community:

- that rationing of health services is inevitable;
- that the processes for making rationing decisions must be transparent;
- that communities must be involved – their values are essential when rationing decisions mean that some will be denied access to services; and
- that there are transparent tools – such as guidelines and priority criteria – which can help the decisions.

The key tasks of the CSC (now re-named the NHC – see footnote) has been to advance the debate and understanding of the limits of health care funding and to advise the government on health service priorities and how they should be set. This it has certainly done and there is no doubt that priority setting is now definitely on the public agenda in New Zealand. It is important to note, however, that there is a separate health purchaser in New Zealand, the Health Funding Authority[82] (HFA) which also consults the public. The distinction is that the NHC's work in involving the public is at the level of principles, broad service priorities or statements of service effectiveness – as policy advice – while the HFA's consultations are at the implementation level (what specific services it plans to purchase; where; with what access criteria or part charges). The public consultation work of the two bodies has become increasingly complementary over time. Importantly, the HFA has also become more actively involved in the debate about how priorities ought to be set.

In 1998 the HFA released a document of its own containing proposals on how resources ought to be rationed between health and disability support services (Health Funding Authority 1998). Reflecting its more applied role, the HFA proposals are based on a careful assessment of the priority that should be afforded individual services (rather than broad categories) and reflected a strong economic orientation. The key features are:

- the use of five principles (very similar to the CSC/NHC principles) upon which purchasing priorities are to be assessed: effectiveness; cost; equity; Maori health; and acceptability;

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[81] In 1996 the National Advisory Committee on Core Health and Disability Support Services (the Core Services Committee) was re-named the National Advisory Committee on Health and Disability (the National Health Committee). Its brief was expanded to cover public health services, in addition to personal health services and disability support services.

- the use of Program Budgeting and Marginal Analysis (PBMA) as the decision-making framework; and
- the use of cost utility analysis (CUA) as the means of addressing the first two principles (i.e. effectiveness and cost)

Given that its resources are limited, the HFA is seeking to make difficult decisions in a manner that is ***explicit*** (i.e. the rules underpinning decisions are clear); ***transparent*** (i.e. the processes can be held up to public scrutiny); ***consistent*** (the same rules are applied to all cases); and to which it can be held ***accountable*** (Health Funding Authority 1998). The HFA report is thus an important extension of the "Best of Health 3" initiative of seeking clarity on the priority setting processes which should be adopted. It has received cautious support from health economists in New Zealand, who endorse the use of PBMA but caution that CUA cannot provide a quick technical fix. In an important article Devlin, Ashton and Cumming argue that:

> *"The use of PBMA provides a sound economic foundation for these decisions, being based upon two of the most fundamental notions in economics: opportunity cost (a decision to fund one service denies us the health benefits and other outcomes which could have been enjoyed by instead using those resources to fund another service) and 'thinking at the margin' (it is the changes in resource use and the effect of these change that matters). (p. 369) (Devlin, Ashton et al. 1999)*

> *"[T]he exercise of mapping disease specific outcomes to the kind of generic ways of describing health states underpinning the estimation of QALYs requires an important element of judgement. This problem is exacerbated when dealing with services that comprise multiple interventions." (p. 370) (Devlin, Ashton et al. 1999)*

> *"None of the issues we have raised here mount insurmountable obstacles to explicit prioritisation. We suspect that both those who see the process as a tool-kit solution for priority setting and those who reject the process because of its inclusion of QALYs are guilty of oversimplifying the issues. CUA cannot provide a quick technical fix to prioritisation, and decisions about health service priorities will always involve an element of judgement... The key element of the HFA proposals (and that which may unfortunately get lost in the controversy surrounding QALYs), is the use of PBMA." (p. 370) (Devlin, Ashton et al. 1999)*

It is too early to judge the success or otherwise of the HFA's proposals, and more specifically of its use of PBMA and of CUA in a priority setting context. Unfortunately, little of New Zealand's very recent experience is reported in the published literature. Needless to say, given the similarity of the New Zealand proposals to the ideas presented in this thesis, (which were conceived and developed quite separately), their progress will be of great interest to the present author.

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[82] The HFA was previously four regional health authorities.

Lessons from the New Zealand experience

While there are some important differences between the New Zealand and Oregon experiences, there are also some important similarities. In both experiences, for example, there was an acceptance by government that setting priorities was a dynamic ongoing process that is not amenable to quick fixes. There was also a preparedness to create a planning capacity - an infrastructure - charged with the task of developing the decision processes; of consulting the community; of recommending the service priorities. Both Oregon and New Zealand embraced the importance of involving the community, despite the complexities of that task. Both took important steps towards achieving a more explicit, transparent and accountable decision-making approach. Both saw a role for technical tools, but acknowledged the importance of the priority setting process in gaining legitimacy for the choices made. Both recognised that technical methodologies need to be combined with public and patient involvement. Both recognised that while research based evidence can help to inform decision-making, there are gaps in our knowledge and weaknesses in our methods that may produce anomalous and unacceptable results. Both recognised the need for a balanced approach that accommodated the multiple objectives of key stakeholders and the important role of judgement.

Equally, there are also some important differences. The New Zealand approach was one of incremental change from the status quo, rather than broad sweeping comprehensive change. As a consequence there appeared to be less controversy associated with its implementation. New Zealand provides a model in which simple service exclusion is rejected in favour of rationing based on when access to publicly funded services is appropriate. This has led naturally to an emphasis on the development of guidelines, on consensus, and to the recognition of differences in individual need and potential benefit. While, as Coast argues (Coast 1996), the New Zealand experience has emphasised consensus to date, the role given technical analysis, particularly economic approaches, is steadily increasing. Moreover, it is interesting to note that the role given technical analysis in New Zealand was very different to that initially asked of it in Oregon. Through the guideline conferences, technical analysis in New Zealand has focussed on marginal change and vertical priority setting, rather than horizontal priority setting across huge numbers of disparate interventions. This role, while less ambitious, minimises the problem of excessive data requirements and facilitates more rigorous analysis.

The priority setting process adopted in New Zealand also acknowledges that priority setting takes place at different levels and that different approaches may be required. This is most clearly illustrated by the different approaches taken to the determination of 'between service' and 'within service' priorities. The New Zealand experience also illustrates the useful role that can be played by an explicit framework of moral and ethical values.

6.2.3 The Netherlands

Background:

Like New Zealand, the Dutch experience with priority setting started within the context of a broader debate over health care reform. As the country considered a move towards managed competition, debate both for and against reform inevitably raised the issue of the affordability of the basic health care package. The issue of priority setting is important in this regard, because a government concerned with affordability can fix a level of expenditure by deciding where to draw the line on a list of priorities. The Dunning Committee was established to advise the Dutch government on the determination of priorities in the reformed social insurance system. After extensive public consultation it published its report in 1991 (Government Committee on Choices in Health Care 1992).

The Dunning Committee's Report

An approach was proposed that included an investment in health technology assessment; the use of guidelines and protocols to ensure that care was provided appropriately; and the development of criteria to determine priority on waiting lists (Ham 1997). More importantly, the report outlined a framework of principles intended to guide policy-makers in selecting which services should be included in the basic package. Health care services and provisions were to be considered in the context of four basic filters: need; effectiveness; efficiency and personal responsibility (Dunning 1996).

In presenting this framework the Dunning Committee argued that interpretation of whether care was necessary or not should be made from the community's point of view at the macro level; from the professional point of view at the meso level; and from the individual's point of view at the micro level (Government Committee on Choices in Health Care 1992). Given that each level was part of a hierarchy, the Committee advocated that the community perspective of "necessary care" should predominate. Necessary services should be those which "guarantee normal function as a member of the community or simply protect existence as a member" (Government Committee on Choices in Health Care 1992). Like New Zealand, there was recognition in the Dutch approach of the impact of different levels of decision-making, albeit implemented in a different way. As an example of its proposals, the Committee cited in vitro fertilization, where the ability to have children was clearly important to the individuals concerned, but much less so from a societal perspective (Government Committee on Choices in Health Care 1992). As Ham notes:

> *"[T]his echoes the conclusion of the Oregon Health Services Commission that essential services were those that were important for the overall well being of society rather than those desired by specific individuals" (p. 58) (Ham 1997).*

Like New Zealand, The Netherlands also veered away from the Oregon approach of a specific list of services and opted for incremental change. Rather than undertaking an exhaustive study to quantify how each service fared at each filter, the government's report used the filters to focus public attention and debate on the relative merits of services at the margins of inclusion within the basic benefits package. The Health Insurance Council is reported to have utilised economic analysis to inform this process (Dunning 1996). Certain health care services clearly passed through these filters, such as life-saving medicine or those that confer substantial improvements in quality of life. In practice, most current services of the general practitioner or specialist, hospital care and institutional care were included in the basic package. Other services, like in vitro fertilisation, homeopathic medicine, dental care for adults, psychoanalysis, and sports injury treatments were flagged for debate. In the event, most debates in defining the basic package tended to focus on conflicts between communal responsibility and individual preference (i.e. the fourth sieve).

Underpinning the Dutch approach was a belief that explicit priority setting, such as the exclusion of certain services and limitations on access, was necessary if access to essential services was to be guaranteed to all (Ham 1997). Ham reports that like New Zealand economic analysis in The Netherlands has focussed on assessing the cost effectiveness of particular interventions and/or assisting the development of particular guidelines, rather than on choices between services (Ham 1997). In the event, The Netherlands's experience demonstrated that there is often professional and public resistance to suggestions that services should be removed from public funding (Ham 1997). It was this that forced the Dutch government to withdraw proposals to exclude contraceptives from the insurance package and which has held up the more rapid implementation of the Dunning Committee's framework. As a consequence, Dunning reported that:

> *"Decisions on the form of the basic benefits package have rarely sought to exclude entire groups of services, but have tended to restrict these services at the fringes by limiting the extent to which the service is covered. For example, women under 40 years of age are entitled to in vitro fertilisation, but no more than three interventions." (Dunning 1996)*

Like New Zealand, the Dutch government was able to achieve consensus on the need for priority setting by first undertaking an extensive public information campaign. An abridged version of the Dunning Committee's report, for example, was sent to all doctors, hospitals and other health professionals for debate and criticism. It was widely reported in the press and on television over a long period. The public campaign endeavored to engage a wide range of interests, including senior citizen's clubs, women's organisations, trade unions and academics. About 60 organisations were involved in discussions on "Choices in Health Care" over the 1991-1995 period. Unfortunately, it is not clear from available information whether or not the Dutch government used the information from the extensive public consultation process in its decisions. Subsequent discussions of proposed exclusions from government

funding (such as physiotherapy services and the contraceptive pill) have nonetheless kept priority setting in health care very much on the public agenda.

As with Oregon and New Zealand, the ongoing process of priority setting in The Netherlands has experienced changes in course and/or emphasis. The debate has moved away, for example, from political decisions at the macro level on the scope of the benefits package, and towards ensuring that resources are used efficiently by clinicians at the micro level. This has been accompanied by a strong focus on the development of guidelines in collaboration with the professional bodies.

6.2.4 The Nordic Countries (Norway; Sweden; Finland; Denmark)

Background

When the debate about priority setting began in the Nordic countries in the early 1980's, the stated goal was to find solutions to priority setting problems characteristic of health care systems financed through taxation, with a strong government presence in ownership and provision. Public awareness of growing waiting lists, services of questionable quality and availability, and demands for new kinds of services, all brought about a realisation that choices had to be made (Holm 2000). The need for priority setting had previously been criticised as either unnecessary or unethical, but these views slowly changed, particularly given the economic stagnation that afflicted several of the Nordic countries in the late 1980s and 1990s. In 1987 the first Norwegian report (Norges Offentlige Utredninger 1987) on priority setting in health care was published and it set the stage for the ensuing debate across the Nordic countries. The Dunning Committee's report (Government Committee on Choices in Health Care 1992) published by The Netherlands also had a major impact on the debate on whether and how priority setting might be implemented.

The search for solutions: phase one – the technical approach

The Norwegian report[83] argued for a system of priority setting based on five levels of priorities arranged according to the severity of the disease/condition in question and the consequences of not treating it. Similar schemes were later adopted with minor modifications in the official Finnish report[84] of 1994 (STAKES 1995) and the Swedish report of 1995 (The Swedish Parliamentary Priorities Commission 1995). The Swedish scheme (which is reported in English) illustrates the approach. Like Oregon, the categories set out below, emphasised need as the prime priority criterion, with "need" judged by the severity of the disease or condition:

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[83] The Norwegian report is not available in English, so reliance must be placed on the literature reporting and/or discussing its contents.
[84] As with the Norwegian report, this Finnish report is not available in English.

- **Priority Group 1**: Care of life-threatening acute diseases; care of severe chronic diseases; palliative care and care in final stages of life; care of people with reduced autonomy.

- **Priority Group 2**: Prevention, habilitation/rehabilitation.

- **Priority Group 3**: Care of less severe, less acute and less chronic diseases.

- **Priority Group 4**: Care for reasons other than disease or injury.

The Swedish Parliamentary Priorities Commission was appointed in 1992 to advise on how priorities should be set in the Swedish health care system. Like New Zealand and The Netherlands, a discussion paper was published, with comments reported in the 1995 report. The Commission reviewed the overseas approaches, but is reported to have found them wanting in relation to their superficial treatment of ethical issues or their tendency to gloss over methodological problems in measuring efficiency (McKee and Figueras 1996). As the Commission noted in its final report, what was distinctive about its approach was a membership drawn from all political parties, an emphasis on an ethical platform for setting priorities, and the elucidation of its priority categories for use both at the policy/administrative level and at the clinical level[85]. Unlike the Dutch approach, this did not result in recommendations for the exclusion of particular services. Rather, it provided a way of thinking about priority setting to assist those responsible for taking decisions (Calltorp 1995). Three ethical principles were identified in descending order of importance. These were[86]:

- **The human value principle:** All people are of equal value and have the same rights, irrespective of their personal qualities or functions in society. The principle of human dignity is fundamental but not in itself a sufficient basis for prioritisation. If resources are limited, not everyone can obtain what they are entitled to.

- **The needs-solidarity principle:** Resources should be allocated in accordance with needs – to those activities and to those individuals were need is greatest. Solidarity also means paying special attention to the needs of those groups that are unaware of their human dignity, those who have less chance than others of making their voices heard or exercising their rights.

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[85] There were minor variations between the two lists. For the clinical level the first group was sub-divided with life-threatening acute diseases being IA and the remainder of the 1st category becoming IB. The reason given was that acute life-threatening disease in a clinical setting would override all other priorities and would have to be dealt with immediately (The Swedish Parliamentary Priorities Commission 1995).
[86] Description based on two sources: (The Swedish Parliamentary Priorities Commission 1995) and (The Health Care Priorities Committee 2000).

- **The cost-effectiveness principle:** When choosing between different activities or measures, the aim should be to achieve a reasonable relationship between costs and effects, measured in improvements in health and a better quality of life. The cost-effectiveness principle should only be applied in comparisons of methods for treating the same disease. Where different diseases are involved, fair comparison of the effects is impossible.

Some commentators (for example (Klein 1995)) have interpreted these principles, which have since been adopted by the Swedish Parliament in the Health and Medical Services Act, as a rejection of the economic approach. While the Swedish Commission certainly restricted the role of economic evaluation and placed it within a broader priority setting context, it was certainly not intended as a rejection. The following quotes from the Commission's report make this quite clear:

> *"It is only through sound management and effective use of the available resources that the best possible care and attention can be given both to the severely and chronically ill and to persons with slight, temporary illnesses, both to those who can be cured and to those who cannot. Analyses of health economics, therefore, are fundamental to any discussion of priorities. But knowledge of the cost of different measures cannot be made the sole basis of prioritisation. Even so, an economic analysis in which an attempt is made to calculate the cost-efficiency (i.e. to compare the costs and benefits of alternative medical methods), can play an important part in the prioritisation of medical methods for different situations." (p. 13) (The Swedish Parliamentary Priorities Commission 1995).*

> *"The aim of all nursing is humanitarian – to help people afflicted by illness or injury. Funding is therefore allocated for health care: care must be allowed to cost money and resources consumed for this purpose, without any ulterior motives. There is, however, no antithesis between the humanitarian aims of health care and the necessity of conserving the resources available. Economic analyses, therefore, must form an integral part of discussions about priorities. No discussion of the over-arching guidelines for prioritisation can be complete without taking economic facts into consideration." (p. 45) (The Swedish Parliamentary Priorities Commission 1995).*

The report makes equally clear, however, that the cost-effectiveness principle is to be applied within a process guided by the human value principle and the needs-solidarity principle. Thus in discussing alternative principles to those it choose, the Commission makes the following important statement:

> *"The Commission does not accept a benefit principle basically implying that the choice must fall on that which confers the greatest benefit on the greatest number. Thus the Commission rejects the idea of deploying resources to help many people with mild disorders instead of a few with severe injuries, or giving priority to patients who are most profitable to society, e.g. persons of productive age rather than seniors. In both these cases the benefit principle comes into conflict with the principle of human dignity and the principle of need and solidarity." (p. 21) (The Swedish Parliamentary Priorities Commission 1995).*

Since the principle of need and solidarity overrides the cost-effectiveness principle, severe illnesses and substantial impairments must come before milder ones, even though the care of

serious conditions may be more expensive and less efficient. In this way the Swedish approach avoided the credibility problem that Oregon encountered where minor interventions were initially ranked above life-saving interventions. The Commission was concerned to ensure that the cost-effectiveness principle could not be used to exclude services for the dying, for the severely handicapped or for other persons for whom care would not "pay".

It is important to note, however, that the references to cost-effectiveness in these statements are to conventional evaluation techniques that do not include broader notions of benefit, such as equity or social justice, in the decision formula. Defining the social welfare function in a way that, based on community values, includes elements other than simple utility or health maximisation, is certainly not inconsistent with an economic approach based on extra welfarism or the decision-making approach (refer discussion in Chapter Four).

Health economists in the Nordic countries are reported to have complained nonetheless, that these priority-setting systems were "misguided" because they were based almost exclusively on severity of disease, and not on any kind of effectiveness measure, such as marginal expenditure per QALY for the different condition/treatment pairs (Holm 2000). Holm comments that while there may certainly be differences between the approach proposed by the Nordic economists based on efficiency (albeit a narrow concept of benefit) and that based on equity/needs recommended in the official reports, they share one important characteristic in common. This common trait is the belief that it is possible to design priority-setting approaches which can give definitive answers to priority problems based on logical decision rules – what are called "technical approaches" in the international literature (refer discussion Chapter Two). For Holm, this reliance on the technical approach distinguishes the first period of the Nordic country experiences with priority setting, viz.

> *"The first phase in discussions and reports about health care priorities was thus characterised by a search for priority-setting systems that, through a complete and non-contradictory set of rational decision rules, could tell the decision-maker precisely how a given service should be prioritised vis-à-vis other services. Given appropriate information the priority-setting algorithm should be able to give determinate and compelling answers. These answers would be legitimate because they flowed from an objective and rational set of rules." (p. 31) (Holm 2000).*

Phase two: the importance of due process

The second phase of the debates about priority setting began in the mid-1990s according to Holm and was characterised by disillusion with the technical approach and a concern for "due process". It was first expressed officially in the 1996 report of the Danish Council of Ethics on Priority Setting (Danish Council of Ethics 1996). The Danish Council doubted whether the approaches to priority setting produced to that point in the Nordic countries were really operational. In their view all suffered from one or both of two serious flaws, viz. either they were based on a simplistic view of the purpose of the health care system; and/or they did not

give any specific guidance as to how priorities should be set. The Danish Council argued that the goals of a public health care system are inherently complex and multi-dimensional. They argued that one goal may be more important than others in one context (such as disease severity) but that a different goal may be paramount in other circumstances (such as equity for disadvantaged groups). The Council doubted the usefulness of simple maximizing algorithms as the basis for a priority setting system. They saw such a system either requiring a single goal, or a principled way of balancing a number of goals, both of which they questioned (Danish Council of Ethics 1996).

The Danish Council also discussed key concepts such as "severity" and "quality of life" and argued them to be "complex concepts that cannot be operationalised and measured in any simple way" (Holm 2000) (p.32). On severity, for example, they noted that it could be defined to include the present health state (such as chronic pain); whether the illness was lethal without treatment (such as cancer); the urgency of treatment; and/or include an element related to the possibility of treating the condition. While severity is undoubtedly a multi-faceted concept not without its problems, the Danish view should be balanced against the experience of other countries, some of which have found it be a workable construct to guide their priority setting system.

Despite its reservations, the Danish report acknowledges the important need for priorities to be set. But rather than adopt rule-based approaches, they advocated that emphasis should be given to the process by which priorities are set, with the minimal requirements being transparency and accountability, viz.

> *"The Danish Council of Ethics is of the opinion that in planning the operation of the health service, and not least in connection with priority-setting in the health service, openness and dialogue concerning the decisions and concerning the background for the decisions made should be ensured. This openness is to be inward as well as outward. There should be an effort to ensure that decision-makers at all levels be aware – informed – of which priority-setting consequences different decisions entail. The issue is ensuring clearness, the necessary information being available, and that analyses have been executed of which consequences different decisions entail." (Danish Council of Ethics 1996) (p. 95).*

The Danish Council of Ethics report was followed by a second Norwegian report on priorities in 1997 (Norges Offentlige Utredninger 1997), reviewing their experience with the system implemented after the 1987 report. The Norwegian experience also showed that there were substantial practical problems in implementing the system proposed during the first phase of the debates. The severity categories, for example, were used as the basis of a waiting list system, but doctors were willing to game the system to gain advantage for their own patients ((Kristoffersen and Piene 1997) reported by Holm, 2000). There were also several examples of political decision-makers giving in to public pressure groups (eg. IVF treatment) and giving treatments much higher priority than afforded by the severity classifications in the priority

system. The second Norwegian report endorsed the call of the Danish Council of Ethics for transparent and accountable processes that can assist in giving legitimacy to the priority-setting decisions.

Instead of a top-down system, the Norwegian report recommended a bottom-up approach based on specialty-specific working groups. Each working group was to be given the task of explicating the specific meaning of the concepts of severity, utility and efficiency within its specialty. From these definitions the groups should move on to suggest a ranking of the various conditions treated within the specialty, and make recommendations for changes in priorities. The recommendations were to be passed on to the political level, which it was envisaged would make the actual priority decisions. Like New Zealand and Oregon, the task was recognised as an ongoing process (not a one-off exercise), with membership of the working groups to be broad-based. The bottom-up approach proposed is not dissimilar to the New Zealand use of consensus conferences or to the Australian focus on developing strategies within the context of priority diseases. The Norwegian report also saw the need for a general priorities working group with special responsibilities for stimulating public debate and investigating public attitudes and values concerning priorities.

The Danish and Norwegian groups worked independently, but their reports contain similar ideas in terms of the importance of due process. In some ways this is not surprising, because as Holms (2000) notes, the Chairs of both groups were sympathetic to the work of Norman Daniels on contractarian approaches[87] (Daniels and Sabin 1997; Daniels and Sabin 1998; Daniels 2000). It is important to note, however, that neither the Danish report nor the Norwegian report claimed that a good process was, in and of itself, sufficient to legitimise decision outcomes. Both endorse the important role of priority criteria and of identifying community values. Both reports, according to Holm (2000), contain extensive discussions about these values, and try to show how they rule out certain kinds of priority criteria (eg priority according to social status). The approach of all the Nordic countries rules out a lottery system, for example, together with discrimination on the basis of age, birth weight, lifestyle, or whether illnesses were self-inflicted or not. The emphasis on values stands in contrast to other countries, such as New Zealand, where initially the recommendations of the Core Services Committee were made in the absence of an explicit set of principles.

6.2.5 The United Kingdom

There is a large literature on the topic of rationing and/or priority setting in the UK, with an active debate between academics of different disciplines. It is not possible to review all this material or to cover issues comprehensively or in any depth in this brief overview. The

[87] Refer earlier discussion on Daniels in Chapter Two.

intention, rather, is to identify the UK approach to priority setting and flag key issues arising from their empirical experiences with priority setting.

Background:

Of the countries reviewed, the UK is the only one without national guidance on the way priorities might be set. Rather than develop a national framework with explicit criteria to guide the decisions of health authorities and clinicians, successive British governments have sought to diffuse responsibility from the macro level to the meso and micro levels (i.e. to district health authorities and to clinicians). Professor Chris Ham, Director of the Health Services Management Centre, University of Birmingham and President of the International Society on Priorities in Health Care, describes the UK system as "pragmatic incrementalism", with "policy emerging almost as a product of individual decisions" (reported in (Klein 1995)). Rudolf Klein describes the British way of priority setting as:

> *"[A] case study of a system that puts pragmatism before principles, that veils the decision-making process and that diffuses responsibility among various actors at different levels." (p. 121) (Klein, Day et al. 1996)*

In explaining the dynamics of decision-making in the National Health Scheme (NHS), Rudolf Klein argues that the NHS was founded on an implicit understanding between the medical profession and politicians (Klein 1995). As part of this arrangement;

> *"[T]he medical profession relinquished to the government the right to set the overall budget for the NHS and in return politicians agreed to leave to doctors decisions on how those resources would be used in practice" (reported in (Ham 1998)).*

Physicians, aware of the budgetary limits, thus ration implicitly by telling the patient that they are unable to do anything to help them, rather than by explicitly stating that the resources are not available for treatment. Ham comments that while this "arrangement" has begun to break down, Klein's observation is helpful in understanding the UK approach to priority setting[88] (Ham 1998).

For many years doctors in the UK accepted the responsibility to operationalise the government's funding decisions. In recent years, however, challenges to budget limits and to

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[88] Somewhat paradoxically, it is in those countries like the US where government regulation is least developed that clinical freedom is most constrained. Lacking control over resources at the macro level, politicians and health insurers have focused on the micro management of clinical activity as a way of containing costs. By contrast, doctors in the publicly funded systems like the UK have enjoyed considerable latitude, subject only to the budgetary limits placed on the health service by government.

implicit priority setting have arisen, particularly since the 1991 reforms of the NHS[89]. The separation of purchaser and provider roles that resulted brought decisions on priorities out into the open as health authorities were required to negotiate contracts with NHS trusts and other providers. Prior to the 1991 reforms rationing received relatively little public attention because decisions were ostensibly made on clinical grounds, but the arrival of the market-style transactions and GP fundholding[90], combined with managerialism at the expense of professional power, began to undermine the prevailing modus operandi (Hunter 1997). Health authorities became more actively involved in the priority setting process. They were given the responsibility of assessing health care needs in their local populations and of determining how the funds they were allocated should be spent.

Local discretion inevitably involved considerable variety in the decisions that were taken and in the approaches to priority setting that were employed (Ham 1993; Honigsbaum, Richards et al. 1995). While some health authorities drew on overseas experience and/or trialed economic approaches (such as the Southampton and South West Hampshire Health Commission (Honigsbaum, Richards et al. 1995)), mostly authorities tended to avoid the use of explicit criteria (Klein, Day et al. 1996). The various reviews of heath authority purchasing plans (Klein, Day et al. 1996) (Redmayne, Klein et al. 1993; Redmayne 1995) found a mixture of convergence on the rhetoric (reflecting the vocabulary of the central government circulars) and continued divergence in the practice of resource distribution (reflecting local capacities and circumstances). As a consequence local variation in the availability of services has become a major policy concern, attracting the interest, for example, of the Health Select Committee of the UK Parliament (Health Committee 1995).

At the same time clinicians have started to argue for increased funding (Richards and Gumpel 1997) and in some circumstances have been reluctant to take responsibility for decisions that conflict with their view of priorities. Most obviously this has occurred with waiting times, when government policies geared to minimising the period of waiting have conflicted with clinician judgement based on clinical need.

To use Hunter's expression, "with the genie well and truly out of the bottle" (p. 126) (Hunter 1997), substantive debate has arisen on the need for national leadership in priority setting and over the wisdom of locating responsibility at the meso level in a national health service committed to equity.

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[89] Some authors also mention the growth of the private sector in the UK, with now more that one fifth of the UK population covered by private insurance. The NHS's principle of allocating resources according to need is therefore challenged by the private sector, which supplies according to demand.

[90] Budgets are also held by an increasing number of GPs who have the right to buy services on their own, thus reducing the primacy of health authority decisions. The range of services covered by GP budgets is, however, restricted (although expanding) and their spending accounts for only a small fraction (approx. 8%) of the total hospital and community services budget. The scope of purchasing by GP fundholders remains limited and the focus is therefore on the role of health authorities as allocators of resources.

Local priority setting verses national leadership

For the national government the key advantage of devolved management and clinical autonomy is that political problems are converted into clinical problems (Klein 1995). Not surprisingly, managers "at the front line" of priority setting have argued that national leadership is essential if the values of the NHS are to be sustained (Thorton 1997). The medical profession has also found it increasingly difficult to refrain from seeking to influence government decisions on funding levels. Both clinicians and managers, as well as an active academic community, have exerted pressure on the government as the debate on its role has gathered momentum.

To date, at least, UK politicians have not responded to calls to develop an overarching set of principles or values, to define "due process", nor to specify a minimum core of services. The former Conservative government articulated its position in response to a review carried out by an all party parliamentary committee (House of Commons Health Committee 1995). It set out three "key principles" that should guide local decisions about priorities (i.e. equity; efficiency; and responsiveness), but provided no guidance on how they were arrived at, how they were to be interpreted, or how they were to be implemented. The government rejected the adoption of a list of services and argued that service exclusion was not necessary when there remained considerable scope for increasing efficiency within the NHS. It adopted a similar position to that of New Zealand, as evidenced by the following quote from the Department of Health's report:

> *"To attempt to draw up national lists of treatments which will and will not be provided would be an exercise fraught with danger. No one list could ever hope to accommodate the range and complexity of the different cases which individual clinicians face all the time. There would be a real risk of taking decisions out of the hands of the doctors tending to the patient and into the province of others, who, well-intentioned though they may be, possess neither the hands-on experience of caring for patients, nor the expertise to make such decisions."*
> *(Department of Health 1995) (p. 1)*

Instead the government maintained that resources should be concentrated on treatments of proven effectiveness. This included investment in health technology assessment to evaluate effectiveness and the development of clinical guidelines to assist clinicians to act on the evidence of effectiveness. Underlying this position was a belief that variations in clinical practice and the use by doctors of treatments that had not been properly evaluated held out considerable opportunity for making better use of existing resources. The results of cost-effectiveness studies were collated and published by the UK Department of Health (Department of Health 1994) to assist in this process, but no recommendations were made about their use. The Conservative government remained convinced, nonetheless, that year-on-year cost improvements in the region of 3% per annum were achievable (Hunter 1997).

Health Ministers also insisted that there should be no blanket exclusions from the NHS, as evidenced by the following quote from the subsequent White Paper on the future of the NHS, viz:

> *"The Government has made it clear that there should be no clinically effective treatments which a health authority decides as a matter of principle should never be provided. Even where the effectiveness of a particular procedure is not in general judged to be high, it might be both effective and appropriate in certain circumstances for an individual patient."*
> *(Secretary of State for Health 1996)*

The Labour government elected in May 1997 has taken a broadly similar approach in its statements on priority setting. Its White Paper (Secretary of State for Health 1997) rejected arguments that the NHS would not cope with demands arising from demographic change, medical advances and rising public expectations. It also rejected the need for rationing (defined in the sense of denying access to clinically effective services) or the need to impose co-payments. Instead, it identified savings of one million pounds from abolishing the internal market, and proposed the establishment of the National Institute of Clinical Excellence to provide a focus for the work on clinical effectiveness and cost-effectiveness[91]. Applying evidence of effectiveness was also regarded by the new government as a more appropriate policy than to attempt service exclusion or to define core services. While acknowledging the challenges confronting the NHS and the need to make tough choices, the government argued that the NHS could be maintained as a universal service provided that there was a sustained drive to increase efficiency (Secretary of State for Health 1997). The role of economic evaluation in this pursuit of efficiency was not specified in government documents.

Supporters of the current approach argue that it is not a heavy handed top-down approach, but rather a policy that is being pursued through persuasion and an R&D strategy which sets great store by the production of quality evidence and knowledge that clinicians and others can respect (Hunter 1997). Some writers go further to suggest that there is considerable scope to deliver improved services through changes in both managerial and clinical practices (Roberts 1996). Others are more conscious of the gap between knowledge and action, and urge caution against having unrealistic expectations of what EBM can deliver. Sir John Scott, for example, a leading advocate of EBM in New Zealand, is quoted by Hunter (1997) as saying that "The hope that EBM will result in diminished costs is seen as a mirage which it potentially is" (St John 1997).

The difficulty with the current government's position, as with the former Conservative government, is the lack of a clear national direction on priorities in an environment where funding pressures will increase existing inequities in service availability and access. Setting to one side any future pressures, the NHS is already struggling to fulfil its commitment to be a

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[91] The White Paper also announced the establishment of a Commission for Health Improvement to lead the drive to improve quality (Secretary of State for Health 1997).

universal and comprehensive service. Ham cites long term care for the aged and dentistry, for example, as important instances of where the boundaries of the NHS have been redrawn without open policy debate on services of major public importance (Ham 1998). Thus far ministers have maintained that these variations are a reflection of decisions by health authorities in response to their assessment of local needs and that responsibility for priority setting should continue to be located at the meso level. Their position is encapsulated in the following statement by Virginia Bottomley (the then secretary of State for Health):

> *"We can only set the framework in which local decisions are made: clinicians and managers must determine the health needs of the local population and how they are best met. These decisions are given legitimacy when the views of patients and local needs are taken into account... It is not the government's role to lay down local priorities or make local decisions; local purchasers and providers of health care are best placed to do that." (p. 338) (Bottomley 1994)*

There are two key issues raised by this statement. The first is how it satisfies the doctrine of parliamentary accountability, given that the NHS is nationally funded through taxation revenue. Local health authorities are accountable for their decisions to the NHS Executive and its regional offices, which are in turn accountable to the government and the Parliament. The NHS could easily be asked how it ensures that decisions about priorities are taken with due regard for the principles of equity, efficiency and responsiveness. How are these principles interpreted when assessing the performance of health authorities?

Second, is the assumption in this statement that the national government has in fact provided a "framework" for priority setting. The government has issued health improvement targets and general policy statements about the role of EBM and on the need for efficiency, but there has been no overarching statement of values or clear set of principles to guide decision-makers at the meso and micro levels. In this regard, Klein notes, for example, that:

> *"The circulars from the centre, for all their specificity on so many points, did not provide any guidance about the distribution of resources between services." (p. 54) (Klein, Day et al. 1996)*

Contrary to the path taken in several of the countries reviewed, there is a policy of pragmatism rather than of establishing clear principles and underlying values at the national level through sustained community consultation (Klein 1995; New and Le Grand 1996). While encouraging health authorities to consult their local populations, the national government did not embrace any consultation process itself of the sort undertaken by New Zealand, The Netherlands, Oregon or the Nordic Countries. There have been no systematic attempts at the national level in the UK to develop a set of clearly laid-out and weighted principles to guide practice, or even to distill a set of principles from current practice. If the task of drawing up a set of principles along the lines of the Swedish, Dutch or New Zealand examples was regarded as too daunting, then the implications of current practice should at least be

assessed: to examine, for example, the assumptions and values about the allocation of resources implicit in clinical guidelines.

Many UK commentators would go further. Ham's research into priority setting over a number of years has led him to support the establishment of an independent committee appointed at the national level to advise politicians – a National Council on Health Care Priorities (Ham 1998). This is an idea first recommended by the Royal College of Physicians (Royal College of Physicians 1995) and supported by other researchers (Klein, Day et al. 1996; Lenaghan 1996). The aim of such a council would be:

> *"[T]o find ways and methods for improving priority setting in the NHS, bearing in mind the need to involve, educate and inform the public, the professions and the government. It would have the practical function of examining the evidence relating to resource allocation in health care.....and it would review the basis and methods for determining allocations and their implications. Its role in society would be to identify all the relevant issues, analyse them publicly and comprehensively, and satisfy all the interested parties that their views are being considered. ((Royal College of Physicians 1995) reported in (Klein, Day et al. 1996)(p. 134))*

The advantages of such an approach, like the New Zealand model are threefold. First, it conceives of priority setting as a continuous process rather than as a search for once and for all solutions. Second, it acknowledges the pluralism of both values and interests that are involved. Third, it provides a realistic way in which information on efficiency and effectiveness can be integrated into the decision-making process. Such a National Council could take the lead in developing explicit criteria, in teasing out what constitutes "due process" and in promoting consistency in decision-making on priorities. By adopting rigorous and consistent procedures, health authorities are more likely to earn support and legitimacy for controversial decisions (Ham and Pickard 1998).

The working group appointed by the former Conservative government recommended that the values for the NHS should be clearly articulated, widely debated, understood and promulgated (Academy of Medical Royal Colleges 1997). Little has been done to this day in furtherance of this recommendation. The National Council recommendation would provide a vehicle for this debate to take place, together with infrastructure to sustain it.

6.3 Australian Experience

6.3.1 Background

There have been no systematic national efforts in Australia to set health care priorities analogous to the initiatives in Oregon, New Zealand, The Netherlands, or the Nordic countries. While there is increasing interest in strategies for setting priorities (Commonwealth Department of Health and Family Services 1997), the advantages and disadvantages of different approaches has received relatively little attention, and widespread acceptance of the

need for explicit priority setting is still lacking. Like the UK, there is no national framework in which explicit criteria are clearly laid out or underlying values established through a process of community consultation. Rather, national efforts at priority setting were focused initially on establishing goals and targets, and more recently on agreeing *priority problems* and associated strategies to deal with them.

The development of national goals and targets were the focus of national attention in the early 1990's (Australian Health Ministers Forum 1994; Commonwealth Department of Human Services and Health 1994). The logic underlying a goals and targets approach includes the objective of re-allocating health system resources to achieve the agreed goals and targets. The problem is that the approach does not address the fundamental question of how this is to be accomplished. It is unlikely that any State health department or regional health authority, for example, would have the resources to address all the nominated areas, and yet published goals and targets (Australian Health Ministers Advisory Council Subcommittee on Women and Health 1993; Nutbeam, Wise et al. 1993) contained no priority order or information on the cost and effectiveness of interventions that might achieve the specified targets. As a consequence, it is difficult to avoid the conclusion that goals and targets have been developed more to inspire, motivate and encourage cooperation, than to achieve clear directions for resource allocation.

Similarly, Australia, along with a number of countries, has pursued the development of clinical guidelines as the evidence-based medicine movement (EBM) has taken hold. But whereas in several of the countries reviewed in this chapter, their experience in developing national approaches to priority setting contributed to this initiative, this motivation has been lacking in Australia.

In more recent years national activity in priority setting has focussed on the priority diseases initiative. Thus cardiovascular disease, cancer, injury, asthma and diabetes have been established as the national priority health problems and five committees exist under the auspices of the Australian Health Ministers Advisory Council (AHMAC) to develop strategies to minimise their health burden. One of these committees, the Cancer Strategies Committee, is associated with the case study presented in Chapter Twelve. While these committees all submit their strategy plans to the National Health Priorities Committee, and from there approval is sought from AHMAC and Ministers, there is little or no guidance available to them on appropriate criteria, principles, methods, or processes that should be employed. Thus it falls to each committee, using methods and underlying values of their own choosing, to develop their respective strategies quite independently. The role afforded the goal of efficiency and economic evaluation in the development of these strategies is likely to vary between the committees, possibly quite substantially. For some economic evidence would be integrated in a rather ad hoc way. There would be in principle support for the objective of

efficiency as one of several relevant objectives, but not supported in any coherent way in terms of integrating economic evaluation into the priority setting processes adopted[92]. For others, such as the Cancer Strategy Committee, there has been a serious commitment to trial the use of an economic approach in assisting the specification of priority actions. The role and presence of economic expertise would similarly vary from committee to committee.

While priority setting activity at the national level is focused on these nominated national problems, similar disease or problem specific strategies are developed for other issues of perceived national importance – such as HIV/AIDS; palliative care; or risk factors related to the nominated priority diseases. Occasionally individual organisations have undertaken priority setting initiatives on a specific disease within the nominated priority disease groups (such as the NHMRC National Breast Cancer Centre (Redman, Carrick et al. 1997) or the National Stroke Foundation (Mihalopoulos, Carter et al. 1999)). The approaches adopted by the various auspicing committees would similarly vary from committee to committee, with varying reliance on priority setting methods and data available from the relevant disciplines (such as health economics; epidemiology; behavioural science; political science; or ethics).

Apart from the dominant focus on developing strategies to ameliorate individual priority diseases, there have been sporadic attempts to discuss and apply priority setting methods across multiple diseases/problem areas – but again restricted to one component of the disease pathway (eg. health promotion/public health) or one treatment modality (eg. pharmaceuticals). These initiatives have come from various sources, including:

- the Commonwealth and State/Territory departments of health (Commonwealth Department of Health and Family Services 1997; Peacock, Richardson et al. 1997b; Beaver, Williams et al. 1999; Commonwealth Department of Health and Family Services 1999; National Public Health Partnership 1999; NSW Health Department 1999);
- regional health promotion units (Brown and Redman 1995); and
- academia (Cromwell, Halsall et al. 1995; Richardson, Segal et al. 1996; Segal, Robertson et al. 1997; Cromwell, Viney et al. 1998; George, Harris et al. 1999).

It is not possible to review all these various endevours or to cover issues comprehensively or in any depth in this brief overview of Australian experience. The intention, rather, is to sample Australian empirical experience that involves attempts at explicit priority setting and to flag any key issues that arise. Reliance has been placed on those studies that have been published, either as reports/working papers or in the refereed literature.

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[92] For these committees, the most that is likely to happen is a search of the available economic literature for evidence that might support favored interventions.

6.3.2 Health Promotion in the Hunter Region of NSW

An interesting endevour at explicit priority setting in health care in Australia involved the Hunter Region of New South Wales (Brown and Redman 1995). The approach was developed in 1992 in response to the need to identify priority areas for health promotion for women and reflected a heavy behavioural science orientation. The approach enabled epidemiological data on disease incidence and distribution, together with views from the community, to be synthesised and integrated with those of experts from health and social services (key informants), using a nominal group process (Delbecq and Va der Ven 1971). While focussed on goals and targets, the investigators believed the method appropriate to inform resource allocation decisions, and their consensus-based approach has influenced several other attempts at explicit priority setting in Australia (Redman, Carrick et al. 1997; NCCI 1998). For this reason the three-stage model involved is assessed in some detail in Chapter Eight and only previewed here.

The nominal group approach utilised clearly has some advantages in terms of its potential to achieve consensus; to synthesise important data sets; to involve community input; and to achieve legitimacy for the results in the eyes of stakeholders. Aspects of its operation are, in fact, quite similar to the way the economic approach of PBMA can be carried out (Peacock, Richardson et al. 1997b; Carter, Stone et al. 2000). These include the reliance on a working group of key informants to assess information and to make judgements about the merit of various options before it; the use of a research team to assist the working group by assembling key data sets; and a set of principles to guide the working group in its deliberations.

There are, however, also some important differences that from an economic perspective would compromise the role of the three-stage model as a guide for resource allocation decisions. These relate principally to the type of information provided to guide decision-making (eg. omission of cost data); the omission of key economic principles (i.e. marginal analysis; opportunity cost); the lack of precision in how criteria were to be used in ranking options; and the primary focus on size of the problem rather than on health gain. While the principles for target selection included a generic reference to effectiveness and cost-effectiveness, it is by no means clear how these judgements were informed or their intended weight in the ranking process.

While this consensus-based model founded in principles of behavioural science is assessed in Chapter Eight as having potential, it is an important illustration of where inter-disciplinary cooperation would have yielded a superior method. Adaptation of this approach to incorporate economic data and economic principles could have achieved a form of PBMA where the behavioural scientists' strength in achieving consensus and stakeholder satisfaction, was

blended with the technical strength of economic evaluation in guiding resource allocation decisions.

6.3.3 The NHMRC National Breast Cancer Centre

The National Health and Medical Research Council (NHMRC) National Breast Cancer Centre (NBCC) was established to improve health outcomes for women by keeping stakeholders in touch with recent research findings, developing best practice guidelines and resources, and developing a national monitoring system (Redman, Carrick et al. 1997). Given its broad mandate, the Centre used a national consultative approach based on the nominal group technique to identify its priorities for action. Thirteen consultative workshops were held with over 300 participants, including special workshops for women from Aboriginal and Torres Strait Islander and non English speaking backgrounds and those living in rural and remote areas of Australia.

The NBCC was conscious of the need for an explicit structured approach in defining its priorities, as evidenced by the following quote from an article published on its initiative:

> *"Historically, priority setting has frequently been undertaken through an informal process dependent on lobby groups or the views of influential clinicians, researchers or health administrators. This approach is very open to bias from idiosyncratic views of influential individuals and tends to select priorities reflecting those problems that present in specialist clinical practice rather than those which are most common in the community." (p. 250) (Redman, Carrick et al. 1997)*

The nominal group technique was selected and implemented along very similar lines to that used in the Hunter Region (refer 6.3.2 and details in Chapter Eight). The technique achieved a reasonably high level of agreement on priorities across the workshops and was well regarded by most participants. While methods for demonstrating the reliability and validity of explicit approaches to priority setting are not well established, the process appeared to be reliable (in that there was considerable agreement across the various workshops) and to have concurrent validity (in that similar key issues in relation to breast cancer were identified by other priority setting exercises, including a House of Representative Inquiry (House of Representatives Standing Committee on Community Affairs 1995)).

Behavioural scientists have been active in Australia in exploring explicit approaches to priority setting and it is important for economists not to ignore achievements that employ the techniques of other disciplines. The experience of the Hunter Centre for Health Advancement and the NBCC both illustrate that when opinion-based approaches are required to integrate data (or in the absence of quantitative data), the nominal group technique has merit. When the priority setting exercise is undertaken with the specific intent to advise resource allocation decisions, however, it is equally important for those other disciplines to recognise the

important contribution of economics. To the extent that achieving efficiency in resource use is an objective (and it usually is) there are often deficiencies in the behavioural science approach. As outlined above, these relate principally to the type of information provided to guide decision-making; the omission of key economic principles necessary to achieve efficiency (i.e. marginal analysis; opportunity cost); the lack of precision in how criteria are to be used in ranking options; and the primary focus on size of the problem/level of concern rather than on gain in a clearly defined "benefit".

6.3.4 The National Cancer Control Initiative

These same issues arose in relation to the National Cancer Control Initiative (NCCI), which was the precursor to the case study presented in Chapter Twelve. While the NCCI is reviewed in more detail in Chapter Twelve, it is also important to acknowledge it in this section on Australian empirical experience. National attempts at explicit priority setting involving broad-based consultation are not commonplace in Australia, and in this regard the NCCI provides an important precedent.

The NCCI was launched in 1997 and was based on the conviction that it should be possible to get a better return for expenditure on cancer control measures than was currently being achieved. The NCCI undertook an extensive consultation process involving organisations in Australia with an interest in cancer control and developed a set of consensus-based priorities for cancer control that would have an effect within five years. The findings were published in the "Cancer Control Towards 2002" report (NCCI 1998). Subsequent discussion of the strengths and weaknesses of the NCCI report included the issue of whether an economic approach could be utilised as part of the ongoing decision-making process for developing cancer control priorities. In particular, the discussion focussed on whether the concept of benefit was clearly understood by all the participants and whether it could be related to resource use in a clearer and more overt way. While the NCCI articulated various criteria by which the options for change should be judged (such as size of the problem; equity; acceptability; cost-effectiveness; etc) it is questionable whether participants were suitably briefed on these criteria or had a common understanding of what the criteria meant.

In mid-1999, the Cancer Strategies Committee resolved to trial the use of an economic approach to priority setting. The trial was led by the current author and forms the major case study for this thesis.

6.3.5 The Illawarregon Project

The aim of the Illawarregon Project was to develop an economic model that could assist explicit priority setting in the Illawarra Area Health Service (IAHS) of New South Wales. It is important to clarify that the IAHS is not the only funder/provider of health services for the

Illawarra population and that the project was targeted only at those services provided by the area health service. Further, to date, only services in the acute care sector (i.e. hospital inpatients) have been included (Cromwell, Halsall et al. 1995; Cromwell, Viney et al. 1998).

A computer-based linear programming approach was used, with QALYs as the maximand, subject to various constraints, such as budget, the availability of beds and shortages of skilled staff. The model was designed to find the mix of services that would maximise health gain from the available resources. The model incorporates data for each service on its *average benefit* per patient and *average resource* use per patient. All data is collected on a one-year time frame. The development of the model involved two principal tasks: the classification of services into iso-benefit and iso-resource classes; and the collection of the data required for each class. The classification of services was based on the iso-benefit classification developed by Oregon (hence the name Illawarregon) and the national casemix cost weights (AN-DRGs (KPMG Peat Marwick 1993)), with some adjustment to reflect IAHS public/private patient mix. Average benefits were determined by mapping 709 Oregon condition/treatment pairs onto the AN-DRG classes, to which Oregon QALY estimates[93] were applied. A total of 470 classes were identified for which cost-utility ratios could be developed, representing 56% of acute inpatient activity.

The main output of the model is a list of acute care services (both mix and quantity) that will maximise QALYs given the specified constraints. The method used to calculate the mix of services is similar to a QALY League Table in that the ratio of the cost to benefit is important in determining which services are provided. The services are not ranked in a list, however, as they would be in QALY League Table, because of the inclusion of more than one constraint. Alternative scenarios can be explored for their impact on the level of activity and gain or loss in QALYs – such as budget changes; priority to waiting list reduction; change in demand; and change in effectiveness of treatment. The model also provides information on how much an attribute of a service (such as cost or benefit) needs to change before it would be included or excluded. This is an important feature because it supports the analysis of different resource allocation scenarios. (Cromwell, Halsall et al. 1995).

The Illawarregon project shares two important elements with the Oregon approach (Stage One) on which it was based. First, both attempt to define a set of services that should be provided by restricting the scope of services offered. Second, both draw on cost-effectiveness information (albeit relatively crude C/E data) to achieve this. The Illawarregon methodology

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[93] The first approach used by Oregon was utilised, involving the calculation of a net benefit, together with a duration of benefit (refer 6.2.1). The Oregon duration of benefit was modified to better fit local life expectancy.

has also developed the Oregon (Stage One) approach by including constraints and allowing the population coverage of a service to vary[94].

While an interesting model with potential for development, the authors acknowledge that the main contribution of their work is as a planning tool to investigate the likely impacts of various scenarios, rather than as a priority setting approach to support actual resource allocation decisions (Cromwell, Halsall et al. 1995). Because the Irrawarregon is not functioning as an approach to priority setting, it is not assessed in Chapter Nine against the checklist developed in Part C. The key limitations of the model fall into four main categories:

- first, like Oregon (Stage One), the use of averages on treatment benefit and cost, rather than marginal data, is a serious limitation as it compromises the pursuit of both allocative and technical efficiency[95];
- second, the limited scope of the model (restricted to acute inpatient care and to services funded by the IAHS) limits its ability to assist with horizontal priority setting across different service sectors (such as community health services; outpatient services; or sub-acute services).;
- third, despite its limited scope, the Illawarregon project faces serious data availability issues (ideally, for example, Australian QALY data should be used[96]; and the benefit and cost data should relate to the outcomes of treating a particular condition, rather than providing a given procedure or inpatient episode). Like Oregon, the data availability issues compromise the integrity of the cost effectiveness results and reinforce Eddy's concern (Eddy 1992) as to whether economic evaluation should be focussed on change at the margin rather than entire domains of health care; and
- fourth, the traditional focus on health gain fails to address the value that society places on "the rule of rescue", distributional equity and procedural justice.

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[94] In Oregon a service was either provided to all the target population or not provided at all.

[95] The extent of this limitation could be explored through sensitivity analysis by i) determining what changes in costs and benefits are necessary to affect the funding status; ii) determining what the key marginal classes are and whether there is evidence that there may be significant variation in costs and benefits; and iii) using the marginal analysis to model the key variations.

[96] There are several weaknesses with the QALY estimates used in Oregon Stage One, including:

- The use of Kaplan's Quality of Well-Being Scale has been criticised because it fails to compress non-severe conditions into the upper-most range, which in turn leads to counter-intuitive results when frequently occurring minor ailments rank above life-threatening conditions (Nord 1993);
- The estimates of health outcomes were made by Oregon clinicians reflecting clinical practice and expectations in Oregon, not Australia;
- The valuations of health states reflects the judgements of the Oregon community, not the Australian or Illawarra community

6.3.6 The Use of Program Budgeting and Marginal Analysis (PBMA)

Over the last five years PBMA has been applied in various contexts in Australia, mostly at the regional or local area level or within individual organisations. The starting point for most PBMA studies has been to examine how resources are currently spent before focusing on incremental gains and costs of changes in that spend, through comparison across or within programs. While some of this activity has been published[97], some of it is only available in unpublished form. The application of PBMA within various area health services in NSW[98]; together with projects in the Northern Territory, Victoria, Western Australia and South Australia, has largely reflected cooperative initiatives between State/Territory departments of health or individual organisations and academics supporting its trial and development (particularly from CHERE[99] and HEU[100]). It is not intended in this chapter to review the PBMA method, as a comprehensive review is provided in Chapter Nine. A few comments are appropriate, however, in order to place these Australian studies in context and to focus on the lessons they provide.

First, it needs to be acknowledged that most of the Australian PBMA studies have been undertaken as trials to test the suitability of the technique, rather than with any expectation that resources would be re-allocated based on their results. Both academics and management have been loathe to recommend or adopt new approaches to strategic planning and priority setting without trialing their strengths and limitations. While some early conclusions can be drawn on the basis of experience to date, it is too early to judge any long-term impact of PBMA in Australia.

Second, the Monash Health Economics Unit (HEU) behind a number of the Australian studies has been conscious of various criticisms of the PBMA approach (refer Chapter Nine) and has trialed various developments in methodology to improve the rigour of the PBMA approach. HEU has sought, for example, to improve the evidence base (Carter, Stone et al. 2000) and to improve methods by which multiple objectives are specified and brought together into a single benefit score (Peacock, Richardson et al. 1997b; Edwards, Peacock et al. 1998). As with any evaluation approach, there is no simple "cookbook recipe" of how PBMA should be applied in any given setting, and expertise in the selection of appropriate methods takes time and practical experience.

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[97] For example: (Viney, Haas et al. 1995; Haas, Mooney et al. 1997; Peacock and Edwards 1997a; Peacock, Richardson et al. 1997b; Peacock and Edwards 1997c; Edwards, Peacock et al. 1998; Wiseman, Mooney et al. 1998) (Newberry 1996; NSW Health Department 1997; Liverpool Health Authority 1997/1998; Carter, Mihalopoulos et al. 2000; Carter, Stone et al. 2000)

[98] Including the Liverpool Health Authority; Central Coast Area Health Service; Greater Murray Health Service; Hunter/England/Western Sydney Area Health Services; Macquarie Area Health Service; and Mid-Western Area Health Service

[99] Centre for Health Economics, Research and Evaluation (CHERE), Sydney University, Sydney..

[100] Health Economics Unit (HEU), Monash University, Melbourne.

Third, despite some progress in recent times, explicit priority setting is not commonplace in Australia and management, whether in government or elsewhere, will need time to trust explicit approaches, particularly if they are time and resource intensive. To expect managers, working in an often reactive and stressful environment, to immediately adjust their practices to incorporate an external framework, no matter how impeccable its logic, is unrealistic. This is particularly so when that framework has implications for current financial reporting practice (eg. program structure and associated cost centres); for current data collections (eg. the collection of activity and outcome data); for research activity (eg. establishing the evidence base); and the visibility of their decisions. A recent review of 78 PBMA studies undertaken in 59 health regions worldwide, for example, concluded that while the impact of the PBMA approach has been generally positive:

> *"[A]ddressing organizational and managerial issues would seem to be central to successful implementation in a given health region" (p. 1) (Mitton and Donaldson 2000).*

Given this background, it should come as no surprise that the PBMA technique is regarded in Australia as having important potential, but that there is as yet no large-scale commitment for its application (either by academics or government departments). While there are certainly advocates of PBMA (including the present author), much remains to be done before PBMA could be recommended as an established and effective priority setting technique. There are, for example, no critical appraisal guidelines published anywhere that prescribe what constitutes an acceptable or rigorous PBMA study (let alone widely accepted guidelines, such as those published on conventional economic evaluation techniques (Drummond, O'Brien et al. 1997)). There is no published assessment of the impact of PBMA studies on decision-making in Australia or of the various factors that influence that impact. Nonetheless, PBMA is an important part of the economic toolkit and its development deserves ongoing attention.

The key issues that emerge from the Australian experience are:

- a variety of approaches have been used under the general PBMA framework, particularly in regard to the source and quality of data on efficacy/effectiveness, and the way in which benefit is defined and measured;
- most PBMA studies in Australia have focussed on vertical priority setting (i.e. within programs), rather than addressing the more challenging horizontal priority setting across different programs;
- where PBMA activity has commenced and fallen away in Australia, it has reflected the movement of key personnel, expertise or a PBMA "champion"; and
- as with overseas experience, options for change that involve decreased expenditure have been harder to generate, assess and implement than increments.

6.3.7 The Pharmaceutical Benefits Advisory Committee (PBAC)

The health economic framework adopted by the Australian Government for the listing of drugs on the Medicare Pharmaceutical Benefit Scheme (PBS) is an important example of the systematic use of economic analyses to inform resource allocation decisions, often cited in the international literature. Drugs listed on the PBS receive a substantial government subsidy, reducing the cost to the consumer to either a maximum of $20 or $2:50 per script, depending on patient status. A request for listing of a new drug must be supported by an economic analysis, submitted in accordance with published guidelines (Commonwealth Department of Health and Family Services 1995). Drugs may be refused or approved, and approval may be at the proposed price or subject to a price reduction and/or restricted access. Drugs that were on the schedule in 1993 do not require a cost-effectiveness analysis in support of continued listing.

The Guidelines require an incremental cost-effectiveness analysis (or cost-utility analysis) of the drug required for listing, against a suitable comparator, preferably another drug of the same class already listed on the PBS. The Guidelines are quite detailed, defining how costs and outcomes are to be identified, measured and valued. They ensure a suitable level of rigor and comparability between the economic analyses provided. The decision rule for the listing of a new drug is not defined, however, with the economic analysis forming only one input (albeit a major one) in the final decision. Listing a drug is a two-step process. In the first stage the Pharmaceutical Benefits Advisory Committee (PBAC) decides whether to recommend that a drug be listed. In doing so the Committee considers the need for the drug, its effectiveness and safety, together with its cost effectiveness. In the second stage the final decision about listing on the PBS is made by the Commonwealth Minister of Health, informed by the PBAC and the Pharmaceutical Benefits Pricing Authority[101] (PBPA) (Salkeld, Mitchell et al. 1999). The Minister also considers whether to restrict the drug's subsidised use to specified types of patients and whether to accept the drug's proposed price for subsidy.

While the general criteria that the PBAC and the PBPA are required to consider in making their recommendations to the Minister are available (Salkeld, Mitchell et al. 1999), the detail of how they influence any particular decision is not published[102]. There thus remains a major implicit element in the PBS priority setting process, on issues such as what weight is given to the different criteria and what dollars per QALY constitute acceptable value. In relation to the economic decision rule implied by decisions, such analysis as is available suggests that till end 1996 no drugs had been listed at a cost per life year gained (or cost per QALY) above

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[101] The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent, non-statutory body whose objective is to secure a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers.

[102] Brief resumes of positive decisions (i.e. recommendations to support listing) are available on the Department's web site, generally within a week or two of the PBAC meetings. Negative decisions are not published in any form.

$69,000, with a listing almost guaranteed at a cost per life year (or per QALY) of $36,500 or less (George, Harris et al. 1999). Matters of distributive equity cannot readily be incorporated into individual submissions for listing or into the PBAC/PBPA recommendations, but may enter into considerations of need for the drug and decisions taken by the Minister. Because of the narrow mandate of the PBS process, the selection of interventions for analysis are restricted to drug treatments, which weakens the PBS process as a means of addressing allocative efficiency.

While an important example of the use of economic evaluation in informing government decision-making, the PBS has important limitations as an explicit approach to priority setting. It is interesting in that despite the mandating of economic evidence, the decision-making process is still largely implicit. The PBS listing process provides another example of the trend observed internationally, that where economic evaluation has been found to be useful, it is within a restricted role addressing vertical priority setting and marginal change, rather than broad-based health care services.

6.3.8 Northern Territory Health Service (NTHS) Model of Health Benefit Groups/ Health Resource Groups

As with PBMA, the Health Benefit Group (HBG) / Health Resource Group (HRG) approach was one of a range of tools established by UK economists to help inform resource allocation decisions in the new internal market (Sanderson 1996; Sanderson and Mountney 1998; Mountney 1999; Northern Territory Health Services 1999). The HBGs are designed to categorise the population on the basis of their need for healthcare. HBG categories, for example, would normally cover the following: "population not at risk"; "population at risk"; "population with symptoms"; "population with confirmed disease"; and "population with ongoing consequences" (Beaver, Williams et al. 1999; Deeble 1999; Northern Territory Health Services 1999).

The HRGs (similar to casemix) are treatment/ intervention groups that are clinically similar and use similar amounts of resources. The general approach is to select a disease and to map HRGs onto the HBGs as a matrix so that health care needs and their resource consequences can be planned. The rows describe the types of service available and the cell entries are the cost of resources used at each level of care (see Figure 6.1). Thus for the "population not at risk" health promotion interventions are available; for the "population at risk" illness prevention/screening interventions are available; for the "population with symptoms" investigation and diagnosis procedures are available; for the "population with confirmed disease" clinical management procedures and services are available; and for the "population with ongoing consequences" continuing care services are available.

Figure 6.2: Health Benefit Groups/ Health Resource Groups Approach

Services	Not At Risk	At Risk	Symptomatic	Acute Illness	Chronic Illness/ disability
Promotion Prevention Investigation & Diagnosis Acute treatment Continuing care Palliation					

Source: Based on (Beaver, Williams et al. 1999; Deeble 1999)

The UK NHS has conducted pilot studies in which multi-disciplinary teams have worked through major conditions such as cancer, CHD and stroke (Mountney 1999). The Northern Territory Health Service has developed a computer-based HBG/HRG model with an illustrative application in diabetes (Beaver, Williams et al. 1999; Northern Territory Health Services 1999). Based on a descriptive mapping of current health status and management patterns, the future call on health care resources can be investigated. The aim is to investigate where health care resources could be invested in the disease pathway from prevention through to palliation for greatest return in terms of health gain and cost per DALY (or other nominated objectives). The HBG/HRG model is assessed further in Chapter Nine against the checklist.

6.3.9 Disease Based Models of Priority Setting

Disease based models are quite similar to the HBG/HRG approach in that they focus on patient needs structured via the disease pathway, but the analysis in centred on specific health care interventions, rather than broad health resource groups.

A Health Sector Wide Disease Based Model has been developed by Segal & Richardson (Segal and Richardson 1994; Segal 2000), which embraces a traditional economic approach to priority setting and has considerable potential within the limits of a purely technical approach. It has been applied in detail to Non-insulin Dependent Diabetes Mellitus (Segal 2000) and at a broader level to colorectal cancer and hypertension (Segal, Robertson et al. 1997). Framing the research question to encompass the entire health and community services sector and ensuring comprehensiveness in the selection of interventions were considered important in the development of this model. Empirical experience in a variety of

countries has shown this to be a very daunting task, however, in which economic evaluation has not fared well. This model, nonetheless, has some innovative aspects that endeavor to make its potentially huge data needs more tractable. It provides a framework to structure the task, for example, by dealing with diseases sequentially, together with a two-stage evaluation process that involves; first, a crude ranking of interventions with best available cost effectiveness data; followed by detailed economic evaluation of only the most marginal interventions. Not surprisingly, the authors found that limitations in the available cost effectiveness literature compromised their approach to some extent, together with the sensitivity of their marginal analysis. The data requirements of such ambitious technical approaches will remain a fundamental problem for some time to come. This model is reviewed further against the checklist in Chapter Nine.

A quite different disease model dedicated to stroke has been developed by Mihalopoulos and Carter (Mihalopoulos, Carter et al. 1999) for the National Stroke Foundation of Australia. Drawing on a three-year cohort study of stroke patients, this model builds on a detailed description of the care pathways and resource utilisation patterns, to embrace prediction and economic evaluation roles. The model combines epidemiological data, demographic data and economic data in a series of 18 nested spreadsheets. The model can be used as a stand-alone costing model (and in this sense is a bottom-up cost of illness study) or as an adjunct to economic evaluation of options for change to current care patterns. The evaluation phase requires the input of additional data on the cost and efficacy of the interventions under analysis. Within the context of a specific disease such as stroke, this approach has potential as an important aid to planning and priority setting. It is best utilised within a multi-disciplinary research context that provide its data inputs, such as a component of RCT or observational studies.

6.4 Lessons from Notorious Individual Cases

6.4.1 Background

Well-publicised cases of individuals being denied treatment, particularly children, have been instrumental in bringing priority setting into the public domain and on to the policy agenda. The approach taken in Oregon, for example, followed the death of a young boy with leukemia – Coby Howard – who was denied a bone marrow transplant under Medicaid (Fox, Leichter et al. 1990; Klevit, Bates et al. 1991). A similar case in the UK involving a young girl – Jaymee Bowen – prompted a lively debate about the decision to deny treatment and the way in which it was taken (Ham and Pickard 1998). In New Zealand media pressure forced the reversal of a decision to deny access to renal dialysis for a 76 year-old man with heart disease, originally refused on the basis of guidelines drawn up under the aegis of the Core Services Committee (Cumming 1997).

While it is always hazardous to generalise from individual experiences, equally it would be an oversight not to seek to learn and draw out the lessons from this empirical evidence. In their different ways such cases highlight the challenges for decision-makers in setting priorities, particularly where difficult choices are involved. The case of Jaymee Bowen is selected as an important example of this evidence.

6.4.2 Jaymee Bowen (Child B)

Jaymee's Story

Jaymee Bowen was an articulate and lively little girl who was diagnosed with non-Hodgkin's lymphoma in 1990 at the age of six. She was treated, but unfortunately was diagnosed with a second cancer – acute myeloid leukaemia – in 1993. Jaymee underwent chemotherapy and a bone marrow transplant. Only nine months later, at the beginning of 1995, she relapsed, and the paediatricians responsible for her care advised that she had between six and eight weeks to live. Their view was that a child with Jaymee's medical history was unlikely to benefit from further intensive treatment and recommended palliative care as the preferred option.

Jaymee's father, David Bowen, was not prepared to accept this advice and dedicated his time to saving his daughter. He investigated alternative treatment methods and pursued the advice of other specialists around the world. He found two specialists in California who were prepared to recommend that Jaymee should receive a second bone marrow transplant. The US specialists thought Jaymee's chances of going into remission following a second bone marrow transplant were more favorable than the UK specialists. David presented the results of his research to the treating paediatricians, who maintained their opinion that palliative care was the best option for Jaymee. They assessed that the potential harm of further invasive care was not worth the small chance of benefit. To quote Ham:

> *"Their experience of treating similar cases had led them to be cautious in undertaking heroic interventions in the final stages of life and they were therefore not willing to acquiesce to David's request that they should proceed with a transplant." (p. 108) (Ham and Pickard 1998)*

At this point David arranged to see an adult leukaemia specialist in the UK recommended to him by his California specialists. This specialist also took a more positive view of Jaymee's chances of going into remission with further chemotherapy. Buoyed by this opinion, David approached the Health Authority to ask if it would authorise the treatment. The Health Authority declined on the grounds that the paediatricians treating Jaymee were in the best position to assess treatment options. The Health Authority "was not prepared to use resources on experimental procedures with a limited chance of success" (Ham and Pickard 1998) (p. 109). The Health Authority gave the same response when David presented the opinion of a private specialist that further treatment should be undertaken. David then

contacted his solicitors to see if an appeal for judicial review was a viable option to challenge the Health Authority's decision. Leave for judicial review was duly granted, and with legal aid in place, preparations were made for court proceedings.

The High Court took the view that the Health Authority should reconsider its decision, arguing that "the right to life was so precious that the Health Authority should think again even though the chances of success were acknowledged to be low" (p. 109) (Ham and Pickard 1998). The Health Authority took this decision of the High Court to the Appeal Court and the judgement was overturned. The Appeal Court held that the Health Authority had followed due process in weighing the advice it has been given and that there was no basis for the decision to be reviewed. The decision not to fund a second transplant was analysed extensively in the press, with the Health Authority usually presented in a poor light (Entwistle 1996). By this stage the intense media coverage of Jaymee's story brought forward an anonymous donor and treatment started in the private sector. In the event the private specialist who took over Jaymee's case opted in favour of a new experimental treatment (donor lymphocyte infusion) rather than the second transplant. The treatment enabled Jaymee to enjoy a few extra months of life. She fell ill again and eventually died in May 1996.

For some observers, the fact that Jaymee had lived for over a year after the return of her leukaemia, most of it with a reasonable quality of life, vindicated David's struggle. The "consumerist" challenge launched by David came to exemplify the increasing reluctance of the community to accept that 'doctor always knows best' and the importance of reviewing each case on its merits. The paediatricians who had looked after Jaymee originally, continued to maintain that palliative care was the treatment of choice. This view was supported by the Health Authority, which continued to pay for Jaymee's continuing care after her intensive treatment had come to an end.

The issues

Jaymee's story illustrates a series of ethical and practical issues of ongoing relevance for the NHS, and for priority setting generally. In particular, it demonstrates very poignantly the tension between a concern to use resources for the benefit of the population as a whole and the urge to respond to the needs of individuals faced with the prospect of death. As the body responsible for taking a community perspective on health care needs, the Health Authority felt that further intensive treatment was not only low priority, but also inappropriate as it was not recommended by the doctors who knew her best. Although David Bowen did not use this language, he was unconsciously invoking the "rule of rescue" (Hadorn 1991) in seeking help for Jaymee. This suggests that when life is threatened, there is a community obligation to intervene, regardless of the cost and adverse impact on limited community resources.
The ethical dilemmas faced by health authorities have been reviewed by Draper and Tunna (1996), who note that health authorities are expected to ensure justice in the use of their

resources, as well as respect each person as an individual in his or her own right. In the case of Jaymee Bowen they comment:

> *"In adjudicating a special claim on resources, by an identifiable individual, who is likely to die quickly if resources are not forthcoming, commissioners may feel compelled to assist, even if they would not consider the small possibility to benefit worth the cost under other circumstances, perhaps where death is not imminent."(p. 44) (Draper and Tunna 1996)*

In Jaymee's case the arguments involved were more complex because of the disagreement between the medical specialists. For the pediatricians, the potential harm involved in the act of rescue was likely to exceed the potential benefit. They were concerned that Jaymee, an intelligent and mature ten-year old by this time, was not consulted by her father on the alternative courses of action open to her. David, for his part, wanted to protect his daughter from the full knowledge of her condition, in order to keep her as happy as possible. In this situation, the pediatricians felt it was incumbent on them to assess Jaymee's best interests, drawing on their experience with similar cases.

It is also important to note that the Health Authority was successful in defending its decisions because it had put in place prior to Jaymee's illness, a clear process and set of values for taking such difficult decisions. These values enabled the managers involved to discuss and judge the appropriateness of the options in relation to six criteria: equity; appropriateness; effectiveness; efficiency; responsiveness; and accessibility. Like the pediatricians, the Health Authority felt that the evidence available on appropriateness and effectiveness was of particular significance in the decision not to fund a second transplant. The existence of these values was seen by the Health Authority as crucial in assisting it to arrive at a choice which was rigorous and defensible, and which provides a template to promote consistency in its decisions. When the case went to Court, the Health Authority was able to demonstrate that it had considered the evidence carefully and that the decision was not simply the result of one individual's judgement.

Given that there will always be controversy over difficult decisions, it is advisable for those charged with such decisions to be able to demonstrate that they have followed due process in a fair and rigorous way. In this context, the research of several authors discussed in Chapter Five is relevant. The work of Daniels and Sabin on the decisions of managed care organisations in the US, for example, offers an interesting parallel (Daniels and Sabin 1997; Daniels and Sabin 1998; Daniels 2000). Their arguments that decision-makers have to ensure "accountability for reasonableness" have met with widespread support and have been influential in several countries. Like Daniels and Sabin, Hadorn also argues that consistent procedures need to be adopted in health care, particularly given its inherent complexity (Hadorn 1992). He argues that these procedures should be based on the consideration of evidence concerning outcomes of care, and the formulation of judgements based on this

evidence. He suggests that "in the selection of a standard of proof... the fundamental balance between individual claims of need (that is pursuit of individual good) and the greater public good is achieved" (p. 83) (Hadorn 1992). For Hadorn, the standard of proof adopted should reflect the decision context, including resource availability and the views of policy-makers.

Among the issues to emerge from the empirical evidence of individual cases like Jaymee Bowen, the importance of "due process" stands out. Explicit approaches to priority setting are always likely to generate debate and disagreement, and therefore, as Chris Ham argues:

> *"What therefore matters is to structure this debate to enable different points of view to be articulated, to promote transparency and consistency in decision-making, and to build trust, confidence and legitimacy in the process. In the longer term, these characteristics of due process in decision making should enhance public understanding of choices in health care and promote more informed discussion of the issues." (p. 116) (Ham and Pickard 1998)*

6.5 Summary of key points for inclusion in the pragmatic rationale (P) for the checklist

The emergence of explicit priority setting is exemplified by the experiences of Oregon, The Netherlands, New Zealand, and the Nordic countries. In each of these systems priority setting is high on the health policy agenda, as the scope of publicly financed health services has come under review. The international experience reviewed in this chapter suggests one obvious conclusion: there is no ready-made solution waiting to be taken off the shelf. Some aspects of the strategies adopted by other countries may nonetheless be suitable for adaptation to the Australian context.

In Australia, like the UK, there have been no similar systematic efforts to establish a national framework in which explicit criteria are clearly laid out, with ethical values established through community consultation. There are, nonetheless, relevant empirical experiences in priority setting from which lessons can be drawn, particularly in regard to the primacy afforded efficiency as an objective and the acceptance of economic evaluation as an aid to decision-making. Empirical experience is an important litmus test for any model that seeks to inform decision-making in the real world. The key points of guidance that can be gleaned from this empirical experience are set out below.

6.5.1 Priority setting needs to combine technical methodologies, such as economic evaluation, with a concern for due process for decisions to have legitimacy across multiple stakeholders

The debate between the technical[103] and process oriented[104] approaches to priority setting reviewed in Chapter Two is fuelled by the experiences of those countries that have trialed explicit approaches to priority setting – particularly the experiences of those countries reviewed in this chapter. It also reflects a growing public and media interest, agitated by individual cases that have come to epitomise the challenge of making tragic choices in health care. The empirical evidence available suggests that while the various technical approaches have undoubtedly made an important contribution, no country has adopted a purely technical approach. No country has relied purely on economic analysis or needs-based approaches. All countries have come to recognise that if their decisions were to have legitimacy for patients, for providers, and for the general public, then a balance had to be struck between techniques and decision rules drawn from disciplines like economics, and a concern for due process and consultation, such as the "accountability for reasonableness" approach of Daniels (Daniels 2000) or the procedural rights approach of Hunter (Hunter 1997).

Disillusion with the technical approach is most pronounced in recent reports from Denmark and Norway, which recommend an emphasis on transparent and accountable processes. Like New Zealand and Oregon, the Nordic countries are increasingly conscious that priority setting is an ongoing task (see 6.5.8) that requires infrastructure support and careful development of appropriate processes of decision-making. In addition to increasing support for the contractarian approach of Daniels[105], several countries are adopting a bottom-up approach that develops priorities within disease and/or specialty specific groups (i.e. vertical priority setting).

In Australia the appeal of the consensus-based approaches of the behavioural scientists (see 6.3.2 to 6.3.5) has much to do with their concern for due process and for the effective involvement of participants in the decision-making process. Similarly, while PBMA is still an emerging technique, its potential to combine both technical and consensus-based approaches is an important element of its appeal.

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[103] As outlined in Chapter Two, technical approaches are characterised by a reliance on rational decision rules and the development of technical frameworks in which they are applied. Economists pursuing the goal of efficiency and epidemiologists pursuing the goals of effectiveness and needs-based equity have in large part driven technical approaches.

[104] Advocates of due process believe that technical approaches are based on a simplistic view of the health care system and challenge the possibility of definitive answers. They emphasise accountability, visibility, the contested nature of rationing and the role of judgement in making decisions. The key task is seen as achieving a process that enables proper debate and discussion of objectives and values, rather than refining technical data sets and applying decision rules.

[105] Daniels argues that market accountability is not able to ensure fairness or the legitimacy of priority setting decisions in health care. He argues for "accountability for reasonableness," by which he means that decision-makers have to explain the rationale for their decisions, demonstrating that these are based on reasons and principles (including value-for-money) that are accepted as "relevant by people

6.5.2 Economic evaluation has been regarded as useful and fundamental to the priority setting process, but within a restricted role

The role of economic evaluation in the countries reviewed has reflected the significance afforded efficiency as an objective of the health care system, together with difficulties encountered in the practical application of economic evaluation techniques.

All countries reviewed, including Sweden, embraced efficiency as an important objective, but clearly not the only objective, and often not the most important objective. Primacy has been given, for example, to human dignity (Sweden) and more often to illness severity (Oregon, the Nordic countries, The Netherlands) over efficiency. Some countries have rejected a focus on any one objective, preferring to recognise the reality of multiple objectives, with their relative importance changing according to decision context (New Zealand, The Netherlands, Denmark). For most countries, the importance placed on different objectives reflected the underlying ethical values (see 6.5.6).

Turning to the practical application of evaluation techniques, all countries were conscious of the restrictions flowing from the paucity of efficacy evidence and the availability of associated data sets required for meaningful economic analysis. The inherent heterogeneity of patients and treatment responses, together with the importance of marginal analysis, creates a major data hurdle for economic approaches, particularly if applied on the scale attempted in Oregon. Most countries recognised that the broader the priority setting task attempted, the more likely economic evaluation would encounter severe data availability problems. This was most apparent in the different approaches adopted by Oregon and New Zealand. The use of cost utility analysis (CUA) in the first Oregon plan raised the question of whether conventional CUA methods are up to the task of evaluating an entire domain of health care. Experienced evaluators like David Eddy have concluded that economic evaluation should be focussed on change at the margin, rather than attempting comprehensive assessments across hundreds of condition/treatment pairs. Those countries that have employed economic evaluation in a more restricted role have been more comfortable with the results. Several countries (New Zealand, Nordic countries) preferred to focus economic evaluation on vertical priority setting (i.e. on interventions for dealing with the same disease or problem) and/or within the context of guidelines or dealing with new technologies. In addition to the data issue, this reflected reservations about the adequacy of QALYs in an allocative efficiency context, together with pragmatic judgements on how best to proceed with the priority setting tasks at hand.

The Australian experience is similar. The use of economic evaluation within a restricted role, such as assisting administration of the Pharmaceutical Benefits Scheme or as an input to

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who are disposed to finding terms of cooperation that are mutually justifiable" (refer Ethics rationale for

PBMA studies, has been well regarded. Those initiatives which have sought a much broader application, such as the Illawarregon, the HBG/HRG approach, and the Health Sector Wide Disease Model, have encountered significant data problems which has limited their usefulness. These approaches have either sought to make the task more tractable by limiting the scope of the research question or have accepted their inability to provide realistic advice on priority setting – withdrawing to a general planning and scenario assessment role.

The experience to date with the application of economic evaluation in priority setting contexts thus raises important issues about what constitutes adequate data and whether the data needs of technical approaches are tractable? It raises the suitability of available economic evaluation techniques in application to different research questions, particularly when applied to a large number of interventions. It also raises the need for economic protocols (which should serve as the basis for applied work) to have specific regard to the demands of priority setting as opposed to one-off studies.

A different, but somewhat related point, is that conventional economic evaluation may produce results that are unexpected and/or unacceptable to some, particularly if the program objectives and the concept of benefit are not clearly discussed in advance. This was certainly true in the case of Oregon, when utilitarianism meet the "rule of rescue" (Hadorn 1991). It is related to the perception held by some commentators that CUA "failed" in Oregon. If the only people to whom a priority list based on an efficiency principle look acceptable are economists, then setting priorities based on efficiency is unlikely to be successful.

Fortunately, this is largely a reflection of how economic evaluation is presently carried out, rather than an inevitable consequence of economic theory. The discussion in Chapter Four establishes that broader issues of concern to the community can legitimately be included in the social welfare function that economic evaluation attempts to measure. The empirical experience thus focuses attention on the relative merit of newer techniques, such as cost value analysis (Nord 1999), together with the important role that might be played by PBMA.

6.5.3 Specifying a core set of services to be funded has proven difficult

Attempts to make priority setting more explicit have also revealed the difficulty of defining a basic package of services by excluding some treatments from public funding. Oregon did go down this route and decided to restrict the services to be funded under Medicaid in order to include more people within the scope of the program. The approach adopted in Oregon, however, has proved difficult to transfer to other health care systems. New Zealand and The Netherlands started down this same road, but it was soon abandoned in New Zealand and proved to be very problematic in The Netherlands. The experience to date suggests that

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further detail).

where exclusions have been achieved they have tended to be interventions involving minor ailments and/or interventions for which the evidence was lacking. They are all marginal to mainstream medicine. Making trade-offs between the comprehensiveness of service provision and the extent of population coverage is more difficult outside the USA, because in most developed countries there is already a commitment to universal coverage. Setting priorities by excluding services therefore poses real political problems because no compensating benefits of real substance are on offer. While not preparing detailed lists of the type adopted in Oregon, several countries have adopted health service classification systems based on illness severity/perceived importance (Sweden, Norway, Finland, Denmark)

Quite apart from the empirical evidence, there is also an important theoretical reason to question the "exclusion" approach. Specifically, the selection of a core set of services to be funded based on a QALY League Table containing average cost-utility results is inconsistent with the importance placed on marginal analysis in finding "efficient" solutions. Contrary to early economic guidance[106] on the use of League Tables (Weinstein 1976) the efficient solution is unlikely to involve the allocation of resources in a simple sequential basis down the League Table. That is to say, the efficient solution is unlikely to involve investment in the service at the top of the league table until all opportunities for care in that service are exhausted, only then moving to invest in the service with the next highest average C/E ratio, and so on down the table until all the resources are exhausted. Such a simplistic approach ignores the variation in cost-effectiveness ratios with patient needs; population sub-group; program size and design; health service setting, etc. There are few treatments that are wholly effective or wholly ineffective and the challenge is to ensure that the services that are funded are provided to those patients who stand to benefit. For both sound practical and theoretical reasons, those charged with the responsibility for rationing have usually declined to use the exclusion approach.

6.5.4 Developing guidelines (rather than service exclusion) has attracted widespread support

The natural consequence of the difficulties inherent in rationing by exclusion is the increasing interest being shown in setting priorities by drawing up guidelines for the provision of services. The focus has changed from which services or types of care should be provided, to which patients should be selected for what kinds of treatment and at what level of intensity. What is clear from the work done in the countries reviewed, is that a focus on guidelines requires the active involvement and support of clinicians, because guidelines are worthless unless they

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[106] "The ratio of costs to benefits, expressed as the cost per year of life saved or cost per quality adjusted year of life saved, becomes the cost-effectiveness measure. Alternative programs or services are then ranked, from the lowest value of this cost-per-effectiveness ratio to the highest, and selected from the top until the available resources are exhausted. The point on the priority list at which the available resources are exhausted, or at **which** society is no longer willing to pay the price for the benefits achieved, becomes society's cutoff level of permissible cost-per-effectiveness." *(Weinstein 1976)*

impact on clinical decisions. In the case of New Zealand, consensus conferences have been the main method employed, with well over 20 service guidelines completed. Similarly, as the debate in The Netherlands has moved away from restricting the scope of the benefits package through political decisions at the macro level to ensuring services are used efficiently by clinicians at the micro level, rationing has focused on the development of guidelines by professional associations. Much the same applies in the UK where successive governments have declined the core service option and encouraged the development of clinical guidelines in conjunction with health technology assessment. Similar guideline initiatives are developing in the US and the Nordic countries. The focus on rationing by guidelines also reflects the wider movement to strengthen the scientific basis of medicine and the associated concern to reduce variations in clinical practice patterns. In Australia, the guidelines approach is gaining momentum, but more as a by-product of the evidence-based medicine approach than any conscious approach to priority setting.

6.5.5 The role of judgement

The review of empirical evidence highlights the reality that explicit rationing at all levels involves both the use of techniques and the application of judgement. The need for judgement reflects a range of factors. Judgement is required, for example, in the selection and application of technical methods, due to difficulties inherent in matching method with the research question and available data. Judgement is required for assessing what "due process" means. Judgement is required in the assessment of objectives that do not lend themselves easily to quantitative measurement (such as procedural justice, equity or political feasibility). Judgement is required in the balancing of multiple objectives and associated value systems. Judgement is crucial in the development of consensus between conflicting viewpoints of different participants and stakeholders.

The exercise of Commissioner judgement in the Oregon process is a clear illustration of the role of judgement. It highlights also the associated issue of whether such judgement should be implicit or explicit. The Commissioners were concerned to ensure that the list was not just a formula-produced combination of values and data, but also an intuitively sensible ranking that reflected relative value in the context of scarce resources. The same issue arises in Australian empirical experience, with the PBAC process (refer 6.3.7), for example, having important implicit elements. Considerations of accountability and visibility would suggest that both decision criteria and their application should be clearly specified. As Chris Ham concluded in his review of the international evidence:

> *"Ultimately, priority setting rests on judgement informed by evidence, and those responsible for making judgement need to be held accountable for their decisions. (P.64) (Ham 1997)*

The PBMA approach provides one vehicle in which the role of judgement can be accommodated and where its exercise can be made quite explicit. While Australian experience with PBMA is limited, this potential has been demonstrated.

At the other level of empirical experience, the notoriety that has surrounded particular cases where patients, particularly children, have been denied treatment, also reinforces the crucial role of judgement. Weighing the needs of individuals against the interests of the community can be very difficult, especially if the case ends up in the court of appeal or becomes the centre of media attention. The experience of the Cambridge and Huntingdon Health Authority in the UK illustrates that the clear specification of a set of values and a thorough process cannot take away the need for judgement, but it can greatly aid its application and legitimacy in the eyes of stakeholders.

6.5.6 The central role of ethical values in priority setting

The recognition of the central role of judgement in priority setting has also drawn attention to the importance of clarifying ethical values and notions of social justice in resource allocation choices. This is because the relative priority attached to different services or treatments depends in part on the value attached to different outcomes (such as palliative care for the terminally ill as opposed to life saving care for infants). The need to make these kinds of choices about the type of health gain and who receives it, illustrates the ethical dilemmas in rationing and the reason that decision-makers have sought information from the public on what values should underlie their judgements.

The form and content of the right to health care involves a complex set of forces. One is the tension between a perspective that individuals are responsible for their own health and the perspective that people should have equal health and social opportunities and should live with a sense of responsibility towards others in the society. Another is what constitutes "need" and what principles should underlie its definition. This is related to the willingness on the part of the population to support collective financing for services verses the user-pay principle.

While certain values are perceived to be important in all systems, there is as yet little apparent agreement on the core values that should inform priority setting, nor about their relative importance. Most countries reviewed give prominence to need/severity; effectiveness; equity and efficiency (see Table 2), but their specification and role varies. The contrast between those countries like Sweden that attach particular importance to the rights of the individual, with the approach of The Netherlands and the US State of Oregon, which focuses on benefit to society as a whole, illustrates the importance of decision-makers in Australia being clear on Australian values.

Table 6.2 : Summary of ethical values

Country	Severity/Need	Fairness/ Solidarity/Equity	Effectiveness	Efficiency	Other Values
Oregon, USA	"Value to Society" principle & via classification system	No specific principle.	Minor role, no specific principle	Minor role, no specific principle	"Value to Individual Receiving Service" & Importance to Basic HealthCare Package.
The Netherlands	"Necessary Care" is 1st filter	Via Needs filter	"Effectiveness" is 2nd filter	"Efficiency" is 3rd filter	"Individual Responsibility" is 4th filter
New Zealand	Via "Fairness" principle	"Fairness"	"Benefit or effectiveness"	"Value-for-Money"	"Consistency Community Values"
Sweden	"Needs-Solidarity Principle"	Via "Needs-Solidarity Principle"	Via "Cost Effectiveness Principle"	"Cost Effectiveness Principle"	"Human Value Principle"
UK	None specified at national level				
Australia	None specified at national level				

Establishing an explicit ethical framework is important, not because it will necessarily enable decision-makers to simply read off priorities as a consequence, but because as Ham (Ham 1997) has argued, it will help to make clear the nature of the trade-offs involved. The extent to which explicit approaches to priority setting have embraced their ethical foundations varies from country to country. The notable example in this regard is Sweden, where the committee appointed to advise on rationing proposed an explicit ethical platform centred on respect for human dignity and equity, with efficiency having a subordinate role. Other countries have sought a different balance of values illustrating the inherent contested nature of this debate (Ham 1997).

6.5.7 Consulting the public

Once the role of judgement is accepted, the questions then arise of "whose judgement"; "involvement for what purpose"; and "what is the appropriate process of involvement?" While the views of medical practitioners and other "experts" are drawn on extensively, there is increasing interest in widening the circle to include the representatives of the public and/or of patients (Coast and Donovan 1996). In part, this is due to the general democratic ethic that health authorities in publicly funded health care systems should be answerable to their actual and potential consumers. In part, there is also an ethical concern to utilise the community's values in the difficult choices that deny treatment to individuals. Some authors however, such as Jonathan Lomas (Lomas 1997), see the motivation of governments less as a question of ethics and more as one of pragmatics – i.e. of getting the public to share ownership in the tough choices. Coast (Coast and Donovan 1996) takes a middle course and concludes that the advantages argued for lay participation revolve around the changes in service provision that might result, together with their likely acceptance by the community. By incorporating public preferences into the priority choices the resulting services may be better suited to local

needs. Priorities set in this way, she contends, will reflect what people want, including their preferences, concerns and values.

The renewed interest in public participation is reflected in government actions around the developed world, particularly in the UK and Canada, that stress individuals' rights as patients and as consumers. The NHS Management Executive in the UK, for example, has released a "Patients' Charter" (UK Department of Health 1992) and attempted to make things easier for those planning public participation by providing a set of documents describing the range of methodologies that could be used to obtain public views (Sykes, Collins et al. 1992).

In relation to the second question on purpose, the empirical evidence suggests a variety of reasons. In some cases the purpose has been to educate and inform citizens about the need for rationing; in others the task has been to agree values and principles that should guide rationing; and in others it has been to contribute a user perspective to specific problems and choices. In Edgar's account of the experience in New Zealand during the 1990's, for example, she explains that the objectives ranged from information sharing and awareness raising in the first instance, through opinion gathering, to input on specific questions or identification of service priorities (Edgar 2000).

A range of methods and approaches has been employed to seek this participation. Health care reformers have been experimenting with diverse principles and methods for involving "community values" in resource allocation decisions. These have ranged from survey research, town hall public consultations and ad hoc committees with diverse stakeholder representation, through to citizen juries (Klein 1993; Both 1996; Lomas 1997; Mullen 2000). This experimentation is related to the question of what the "lay viewpoint" actually consists of. Lay participation is a complex issue that reaches well beyond the scope of this thesis. There is debate about whether lay views properly come from random surveys, from focus groups or whether interested individuals and/or community representatives are the appropriate course to follow. Much depends, of course, on clear specification of the research question, the purpose of the involvement, together with the budget and time available.

6.5.8 The inherent complexity and ongoing nature of priority setting

The empirical experience confirms that there are no simple solutions to the challenges posed by the need for priority setting. Complexity is inherent in the range of stakeholders involved; the various levels at which decisions are taken; the need for both vertical and horizontal priority setting; and the importance attached to values and principles. As Ham has noted, the international experience:

> *"[C]an be likened to an exercise in policy learning in which policy makers have tried out a range of methods and approaches and have adjusted course several times in the process.*

What is also apparent is that explicit priority setting is a continuing process which is not amenable to 'once and for all' solutions. To use a sporting metaphor, it is more like a marathon than a sprint, and those systems that have recognised this, like Oregon and New Zealand, have put in place mechanisms to ensure that the issues involved are kept under continuous review." (p.63) (Ham 1997)

The most important conclusion from this recognition, is that if priority setting is to be seen as legitimate by citizens and other stakeholders, then a strategic approach is required that can employ techniques drawn from economics as well as debate and recognition of the need for due process. Like countries reviewed in this chapter have discovered, this is likely to require infrastructure support and a long-term commitment.

6.5.9 The need for an inter-disciplinary approach

Priority setting is thus an inherently contested area in which no one discipline is likely to possess all the answers. Australian experience has demonstrated that approaches founded in behavioural science, such as the three-stage model adopted in the Hunter Region of NSW (6.3.2) and the nominal group technique (6.3.2; 6.3.3) have been well regarded by participants. While these approaches have important limitations from an economic perspective[107], their success in consensus building, highlights the potential for an inter-disciplinary approach that draws on the respective strength of each discipline.

Similarly the MOROCUS study (refer 6.3.9) demonstrates the significant potential for cooperative research between economics and epidemiology to develop approaches to priority setting that go beyond a passive trawling of the published literature for evidence of efficacy.

6.5.10 Priority setting has important management and organisational dimensions

Despite some progress in recent times, explicit priority setting is not commonplace in Australia. Management, whether in government or elsewhere, will need time to trust explicit approaches to priority setting, particularly if they are time and resource intensive. To expect managers, working in an often reactive and stressful environment, to immediately adjust their practices to incorporate an external framework, no matter how impeccable its logic, is unrealistic. This is particularly so when that framework has implications for current financial reporting practice (eg. program structure and associated cost centres); for current data collections (eg. the collection of activity and outcome data); for research activity (eg. establishing the evidence base); and the visibility of their decisions.

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[107] As outlined in sections 6.3.2 and 6.3.3, these relate principally to the type of information provided to guide decision-making; the omission of key economic principles necessary to achieve efficiency (i.e. marginal analysis; opportunity cost); the lack of precision in how criteria are to be used in ranking options; and the primary focus on size of the problem rather than on health gain.

6.5.11 The importance of individual cases

Well-publicised cases of individuals, particularly children, have been instrumental in bringing priority setting into the public domain and on to the policy agenda. The approach taken in Oregon, for example, followed the death of a young boy with leukemia – Coby Howard – who was denied a bone marrow transplant under Medicaid. A similar case in the UK involving a young girl – Jaymee Bowen (refer 6.4.1) – prompted a lively debate about the decision to deny treatment and the way in which it was taken. Again in New Zealand the case of a 76-year old man denied renal dialysis became the focus of media pressure and public attention.

In their different ways, individual cases such as these epitomise the difficulties in priority setting. They demonstrate the tension between a concern to use resources for the benefit of the population as a whole and the urge to respond to the needs of individuals faced with the prospect of death. They provide lessons for those involved in difficult choices – particularly if the cases end up in the Court of Appeal and/or under intense media scrutiny. Individual cases can be an important source of empirical learning. The key lesson is the importance of a clear set of values to inform decisions of this kind and a thorough process for assessing the evidence and considering alternatives.

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Chapter Seven: The Checklist – Rationale and Criteria

"The hope is that within the area of normative analysis in health, the taxonomic principles envisaged could offer both a middle ground for sound reasoning that reflects the real world of social values and the flexibility to respond to the particularities of different decision contexts while providing enough rigour to be meaningful." (Hurley 1998)

7.1 Introduction

The primary purpose of this thesis was to address the question of what constitutes an appropriate approach to priority setting in the health care sector. Two separate but related tasks were undertaken to contribute to the resolution of this question. First in Part B, and culminating in this Chapter, a checklist is developed to help identify the features of an ideal approach to priority setting. Second, in Part D, the development and trial of a suggested model of priority setting – the Macro Economic Evaluation Model or MEEM - is presented. Part D includes an assessment of the success of MEEM in meeting the ten criteria of the priority setting checklist. Prior to the presentation of MEEM, Part C addresses the question of whether there are existing models of priority setting that meet the ten criteria. The conclusion is that while there are existing approaches with considerable merit in relation to some criteria, none of the current models of priority setting perform well against all the criteria.

A useful starting point for any checklist on priority setting is to examine the format and approach of existing checklists created to facilitate applied micro economic evaluation. The checklist of Gold and colleagues (Gold, Siegel et al. 1996) was the most useful of those examined, as it included both assessment criteria together with the rationale on which the criteria were based. The clear specification of the rationale on which assessment criteria were based was considered an essential requirement of any rigorous attempt to assess the features of an ideal approach to priority setting.

In the rationale for their checklist Gold et al. mention five categories, viz: theory, ethics, empirical evidence, user considerations and conventions[108]. It was considered premature to employ the "conventions" rationale, as priority setting is still a very contested area. The difference in context between economic analysis applied to individual projects – the focus for the Gold et al. checklist – and economic evaluation applied specifically within a priority setting decision context, is reflected in the literature and empirical experience reviewed, as well as the resulting criteria. This chapter draws together the discussion in Parts A and B of the thesis, particularly Chapters Four to Six, and presents the key findings under the four categories of rationale and as a checklist for practical application. The ten criteria of the

[108] Gold et al describe the "conventions" rationale as "recommendations designed to establish standardised methods and procedures"(Gold, Siegel et al. 1996).

checklist are provided first (in Section 7.2), followed by the rationale on which they are based (Sections 7.3 to 7.6).

7.2 Checklist for assessing models of priority setting

Based on the four rationales set out in Sections 7.3 to 7.6, ten criteria have been developed that specify the features of an ideal approach to priority setting in health care. For each criterion, the letters in square brackets indicate the relevant rationale, viz: theoretical rationale [T]; ethical rationale [E]; pragmatic rationale [P]; and user considerations [U].

7.2.1 Criterion One: Is There A Well-Defined Research Question? [T; P; U]

- Does the model seek a well-defined research question in answerable form?
    - Are the objectives of the health care system and of the specific choice problem clear?
    - Is the perspective of the decision-maker clear?
    - Are comparators clearly identified?
    - Is the choice of evaluation technique(s) appropriate to the research question?
- Is the model adaptable to variations in decision context and setting? If not, are the general settings and purposes for which the model is appropriate specified?
- Is the model appropriate to the specific research question of the decision-maker(s) and the context in which it occurs?

7.2.2 Criterion Two: Is There A Clear Concept of Benefit? [T; E; U]

- Does the model have a mechanism or process to clearly define the concept of benefit in a way that captures the perspective and objectives of the decision-maker(s)?
- Does the model establish a clear logical connection between the concept of benefit, the research question and the priority setting objectives?
- Are the ethical values underlying the concept of benefit made explicit?

7.2.3 Criterion Three: Is There An Acceptable Process For Generating The Options For Change? [T; U; P]

- Does the model have an explicit mechanism for generating options for change that embodies the principle of "opportunity cost" in a theoretically acceptable and tractable way?
- Do the options generated pay specific regard to the choice problem of the decision-maker(s) and the legitimate interests of stakeholders?
- Do the options for change meet the following criteria:
    - comprehensiveness (important alternatives are not omitted; inclusion of both increments and decrements)?

- relevance (to choice problem and decision-maker needs)?
- evidence-based (including a process for establishing and dealing with the evidence base of options for change)?
- defined in concrete terms so that the pathway of activities can be clearly determined? and
- manageable (the evaluation task is tractable in the time available)?

7.2.4 Criterion Four: Is Marginal Analysis An Integral Component? [T]

- Does the model utilise incremental analysis in comparing the options for change?
- Does the model operationalise the measurement and analysis of the costs and benefits associated with the options for change through marginal analysis?
- Does the marginal analysis cover (or is it able to cover)
  - the scale and scope of the interventions?
  - the target/user groups?
  - mode of service delivery?

7.2.5 Criterion Five: Are The Decision Rules Clearly Specified? [T, E]

- Does the model clearly articulate the decision rules by which the options for change are ranked (maximisation through equating MC and MB; maximisation with equity weights; maximisation subject to constraints; two stage decision process, etc) ?
- Does the model specify how any multiple dimensions of benefit are weighted and aggregated?
- If outcomes are weighted for equity, are the equity principles, data sources and methods clearly specified?

7.2.6 Criterion Six: Is The Role of Judgement Recognised? [E; P; U]

- Does the model check the need for judgement in the specification, application and interpretation of the technical analysis, particularly in relation to underlying assumptions and value judgements?
- Does the model make explicit the basis on which judgement impacts on the technical results?

7.2.7 Criterion Seven: Are The Data Needs Tractable? [P; U]

- Does the model have a mechanism for making the data needs of the evaluation process tractable?

7.2.8 Criterion Eight: Is The Need For Due Process Recognised? [E; P; U; T]

- Does the model check the need to place the technical analysis within a process for decision-making that contributes to the legitimacy of the decisions taken and their acceptability to stakeholders?
- Is this process characterised by:
    - Transparency and openness?
    - Accountability?
    - Fairness and reasonableness (unbiased; consideration given to all relevant factors; disregarding of irrelevant factors; accessing of relevant information)?
    - Involvement of key stakeholders?
    - Consistency in decision-making?
    - An appeal or review mechanism, where this is appropriate to the decision context?

7.2.9 Criterion Nine: Do The Measurement Methods Demonstrate Appropriate Rigour? [T; P; U, E]

- Does the model demonstrate a rigorous approach to the measurement of costs and benefits that strikes a reasonable balance between expense, difficulty and timeliness? Rigour, care and effort should be proportional to the size and importance of the costs and benefits under analysis.
- Does the model involve:
    - A clearly specified evaluation protocol?
    - Standardised evaluation methods appropriate to the research question?
    - Sensitivity analysis of key design parameters and evaluation assumptions?
    - Rigour in the implementation of both efficiency and equity objectives?
    - Recognition that the choice of outcome measures has important ethical implications?

7.2.10 Criterion Ten: Reporting/Implementation [U; P; E]

- Does the model produce and report results that address issues of likely concern to the decision-maker(s), including:
    - the ethical implications of decisions taken or proposed?
    - feasibility of implementation?
    - acceptability to stakeholders?
    - importance of the problem addressed?
    - financial implications?

- Is the reporting format designed to assist with judgements on what weight might be placed on the results, including
    - the generalisability to other settings and contexts?
    - the consultation processes adopted?
    - the strengths and weaknesses of the technical analysis, including comparison with similar evaluation studies in the literature?
    - the levels of evidence for the efficacy assumptions?
- Does the model clearly document the results, together with their rationale, to facilitate the development of a "case law" on priority setting?

7.3 The theoretical rationale (T)

Criteria reflecting the theoretical rationale (T) are based on the discussion in Chapter 4; and particularly the summary of key points provided in Section 4.4. Normative economics is at the heart of priority setting, providing the connection between suggested action and desired outcomes. Normative theories provide the theoretical rationale for ranking from better to worse the policies, interventions and associated resource allocations under consideration.

Whereas the normal way of testing the validity of a theory in positive economics is to assess the realism of both assumptions and conclusions; in normative economics the conclusions are untestable (as they are normative). For normative theories, validity rests on the realism and relevance of their factual and ethical assumptions. Accordingly, the assessment of allocative efficiency (i.e. "value-for-money") should be based on evaluation frameworks that reflect what society truly values. The different ethical bases from which priority setting can be conducted were discussed in Chapter Five and are integrated into the ethical rationale (Section 7.4). The key points from Chapter Four on the contribution of economic theory are presented under this rationale. There is inevitably some overlap between Chapters Four and Five, because the place of ethics in a reference standard for judging societal welfare is an important aspect of normative economics – whether there is an attempt to sanitise out ethics as with traditional welfarism, or an attempt to integrate ethics and social justice under extra-welfarism or other theoretical foundations.

7.3.1 The Decision-Making Approach (DMA) is the preferred conceptual foundation (relevant to most criteria in the checklist)

Welfarism and extra-welfarism represent the two most prominent approaches to normative economic analysis in the health sector and have been the focus of sustained debate and intellectual development. A newer framework – the decision-making approach (DMA) – has been put forward in recent years. While intuitively appealing, it must be acknowledged that

this framework has been subject to limited intellectual development and debate. Welfarism and extra-welfarism derive from two distinct conceptual foundations: welfare economics is utility-based and gives primacy to individual preferences; while the dominant form of extra-welfarism (i.e. Culyer's "healthism") is health-based. The DMA, on the other hand, focuses attention on the decision-maker as the arbiter of what arguments should be included in the social welfare function and what weight should be afforded each element. It is important to note that "extra-welfarism" is not a precise term, with Culyer himself defining it in different ways in different articles (i.e. as both subsuming and replacing utility). The term "non welfarist" has been adopted in this thesis as a general category that includes Culyer's extra-welfarism, together with anything else that is not welfarism (such as the DMA).

There exist alternative ways to define and assess "value" within the key economic notion of allocative efficiency. Within the welfarist approach value is assessed using individual utility; within non-welfarist approaches value is assessed using measures other than or in addition to utility. While the DMA does not in theory preclude either a welfarist or non-welfarist approach to what constitutes value (as the objective function is determined by the decision-maker), in practice it has been closely associated with the non-welfarist framework. The DMA framework also allows the inclusion of procedural justice, provided the values involved are endorsed by the decision-makers.

The traditional Pareto concepts of efficiency and optimality, while endowed with a precise technical meaning, have little practical usefulness for economists who wish to inform the decision-making process in the real world. The neoclassical building blocks of utility maximisation, consumer sovereignty/revealed preference, consequentialism and welfarism do not provide a satisfactory theoretical basis for normative analysis in the health care sector. While individual utility is a relevant argument for inclusion in the social welfare function, it needs to be supplemented by information on other issues of concern to society – such as need, health status, equity and procedural justice. Chapter Six confirms that in health care, society usually favours approaches to decision-making that are seen as "fair and reasonable". The importance given to decision context and individual rights in such cases, as evidenced by "the rule of rescue", conflicts with the assumption of consequentialism. Yet without the assumption of consequentialism, the welfarist concept of efficiency is undermined, as an outcome might be considered unacceptable because of the process by which it was derived, not because of the outcome per se.

Non-welfarist approaches provide a theoretical framework to broaden the information base. There is a capacity in Culyer's "healthism", for example, to accommodate distributive equity through weights based on the characteristics of people (such as socio-economic status; aboriginality; remoteness; or ethnicity. "Healthism" provides a well-developed theoretical framework that has been accepted and widely applied by health economists. In part, this

reflects features of the health care market that render questionable major elements of the welfare framework, and in part it reflects the greater scope for third-party judgement in the health production function than for many other goods. Other stakeholders in the health sector have also been receptive to Culyer's ideas, probably reflecting the widely held belief that the health system is primarily about achieving health. To the extent that health gain is the prime objective of society in relation to the employment of health sector resources, then healthism provides a satisfactory framework for evaluative judgements. This is essentially an empirical matter that is likely to vary with context and issues of practicality. If health gain is judged by decision-makers in the health sector to be the prime outcome of concern, setting other considerations to one side may do little damage. This emphasises the importance of deciding whose values are to be used and how these values are to be elicited. Healthism can be criticised, however, for its continuing pre-occupation with consequentialism and monism (uni-dimensionality in the outcome measure) and for its neglect of societies concern for procedural justice.

Rejection of the welfarist approach, limitations of the extra-welfarist approach, together with researcher interest in communitarian values, focuses attention on the DMA as the theoretical framework that potentially enables most concerns to be addressed. For Sugden and Williams the role of the economist becomes one of clearly eliciting the objectives of the decision-maker and matching the form of analysis to the decision context (rather than forcing the problem to match the technique). Richardson in his work on "empirical ethics" (Richardson 2000c) adds an important additional role for the economist - that of gathering evidence on community values. Richardson agrees there is no option but for economists to turn to government for final adjudication on ethical and social issues, but sees this happening at the end of a process of information gathering with respect to population values. Thus for Richardson, community consultation is an integral part of the first best solution, with DMA as per Sugden/Williams, a second best when resources for community research are constrained. The Richardson variant of the DMA is appealing, because the ultimate objective for the economist remains the efficient achievement of social objectives, rather than employee to the government as employer.

The challenge for normative economics is to develop an evaluative framework with enough rigour to be theoretically meaningful, but with enough flexibility to accommodate the range of complex elements that are relevant to evaluations of societal welfare. Economists working under the DMA framework are able to select from the full range of applied economic techniques (whether they are linked to welfarist or non-welfarist foundations) restricted only by the relevance of the techniques to the research question. The DMA framework also allows analysts to go beyond the limitations shared by welfarism and extra-welfarism provided the values involved are endorsed by the decision-makers. The DMA framework, particularly the Richardson variant, is the preferred conceptual foundation.

7.3.2 The choice of evaluation technique (relates to most criteria, particularly one to five and nine)

The various economic evaluation techniques available either derive from, or can be related to, the three normative frameworks emphasised thus far – welfarism, extra-welfarism and the decision-making approach. Each normative framework implies important differences in the specification of the economic protocol, including the delineation of the study perspective, the choice of comparators and selection of evaluation technique. But there are also important similarities between any evaluation methods that purport to be classified within the economics discipline. The concepts of "opportunity cost" (Criterion Three), "marginal analysis" (Criterion Four) and a "clear concept of benefit" (Criterion Two) are central to an economic approach to evaluation and priority setting. Similarly, at a more applied level, rigour in the measurement of costs and benefits (Criterion Nine), together with the use of methods such as sensitivity analysis, are characteristics of a quality study, rather than reflections of the underlying normative frameworks.

There would, however, be heated debate about what the components of benefit should be and how that benefit should be valued and aggregated. An important element of this debate involves distinguishing the question of how best to allocate resources across quite different programs (i.e. allocative efficiency) from the question of how best to pursue a chosen objective (i.e. technical and/or productive efficiency). The choice of evaluation technique is not arbitrary from a priority setting perspective, for some techniques have greater credentials to address the issue of allocative efficiency than others, and their theoretical foundations will reflect quite different concepts of societal welfare.

Three key techniques form the foundation of economic evaluation: cost-benefit analysis (CBA); cost-utility analysis (CUA); and cost-effectiveness analysis (CEA). The recent emergence of cost-value analysis (CVA) is also significant, because while not an established technique, it continues the evolution of the outcome measure in an attempt to take on board other elements of social preferences (such as severity, needs or "fair innings"). The re-emergence of Program Budgeting and Marginal Analysis (PBMA) is also significant, but more from a priority setting perspective, than from a techniques perspective. This judgement reflects PBMAs role in providing an appropriate decision-making process, as well as its ability to incorporate various techniques for assessing value (such as CBA, CUA, CBA, or CVA).

Welfarists see CBA as the gold standard of economic evaluation, because in principle, with both costs and benefits determined in dollar terms, CBA can determine whether a particular project is "worthwhile". A CBA measures worth, however, based on the monetary equivalent of individual utility and individual preferences are not necessarily the only or most important outcome of health care interventions. As a number of health economists have pointed out, it

might be regarded as paradoxical that as a society we have rejected market valuations of health care by providing public funding, yet are willing to consider surrogate market values in the economic evaluation of social programs[109]. Further, at the measurement level, CBA is increasingly based on the "willingness-to-pay" technique, which recent reviews suggest is not sufficiently advanced to engender confidence that the values provided are valid and reliable estimates (Smith, Olsen et al. 1999).

Both CEA and CUA were embraced by health economists because of the difficulties (conceptual, ethical and practical) in placing a dollar value on life and because of the emergence of extra-welfarism which emphasised health as the primary outcome for normative analysis in the health sector. Costs are still measured in dollar terms, but outcomes are measured in either natural units of outcome for the programs being evaluated (for CEA) or quality-adjusted life years (for CUA). The result is summarised in a ratio, which represents additional cost per unit of outcome achieved. CEA can be quite powerful where the treatment objective is not being questioned directly (i.e. to assess productive efficiency) and where the uni-dimensional outcome measure is accepted as a reasonable proxy for the benefits of the interventions being assessed. But the limitations of CEA also need to be recognised, both in regard to its ability to address allocative efficiency, and as conventionally applied, for its neglect of social justice issues.

CUA lies somewhere between CEA and CBA in terms of the problems it can address, but exactly where, is an issue of some debate (Butler 1992; Gold, Siegel et al. 1996). It can be seen as either a form of CEA which can cope with more than one form of output (i.e. combining quantity of life and quality of life); or as a form of CBA[110] where QALYs are the criteria of value (rather than dollars) and where rankings can be made for setting priorities within a fixed health sector budget. CUA can certainly address problems of technical and productive efficiency, and is clearly important to use when quality of life is a significant outcome. Whether CUA is also a suitable technique to assess if a health service is 'worthwhile' (i.e. allocative efficiency) has been debated by economists and is closely related to the view taken as to appropriate theoretical foundations of CUA.

Most health economists would agree that CUA can address allocative efficiency, but within a constrained environment – that is to say, for allocative decisions within the health sector. All else being equal, the most desirable options are taken to be those which result in the cheapest QALYs (or the most QALYs if the budget is fixed). CUA does not, however, tell us what a QALY is 'worth' and therefore defines no threshold money value of cost per QALY

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[109] There is the counter view, however, that one could believe that utility is the preferred outcome but that markets fail to allocate properly. Thus governments should intervene, but should be guided by shadow prices to indicate value.

[110] One of the reasons this issue is contentious, is that CUA endevours to treat all life equally, irrespective of to whomsoever it accrues, whereas CBA does not.

beyond which a given intervention is not worthwhile[111]. Whether or not this is a serious limitation depends, among other things, on one's view about the method of determining the size of the health care budget. If it is accepted that the size of the health budget is politically determined, then the main task for economic appraisal is to advise on how the assigned budget can be spent efficiently, and CUA is well suited to this task. While serious attempts have been made to place CUA in a welfarist framework, the result is not appealing for those who seek a practical measure of health gain to inform policy planning and priority setting. In contrast, the extra-welfarist framework, together with the decision-making framework to the extent that decision-makers rate health gain as the prime objective, provide a sound theoretical foundation for CUA with substantial practical and policy advantages.

While there are certainly important conceptual and practical questions associated with CUA, the technique can no longer be considered as being in an experimental stage and warrants serious consideration as the preferred evaluation technique for the health sector. Final selection of technique, however, cannot be divorced from the decision context. If health-related quality of life is of small importance for the interventions in a particular decision context, then CEA may well be a more efficient use of research dollars. Similarly, the added expense of going to CVA may be unnecessary if there are no societal issues involved over and above those that can be satisfactorily captured by CUA (or CUA within a PBMA process that broadens the concept of benefit).

7.4 The ethical rationale (E)

Criteria with an ethical rationale (E) are based on the role of ethics and social justice in priority setting discussed in Chapter Five. The key points to emerge are set out below, together with the criteria to which they relate. As with the theoretical rationale, some conclusions provide the ethical underpinning for a number of criteria and there is evidence of overlap with economic theory.

7.4.1 Ethical reasoning supports an explicit approach to priority setting (underlies a number of criteria, particularly Criterion Ten: Reporting)

Moral reasoning, like economics, involves the use of logical argument whereby decisions and their rationale are made explicit. Ethicists are likely to be divided, however, on the importance of empirical evidence in agreeing values and societal objectives. Some would accept the proposition that the starting point for judgements about whether society is better of worse off is a framework of normative analysis that is congruent with the fundamental values that prevail in that society. On the other hand, some would stress the role of moral reasoning as

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[111] Although it is possible for dollar values to be assigned to QALYs and some researchers are exploring this issue.

opposed to community preferences. Richardson's view that these normative values need to be established through what he calls "empirical ethics" – the intermingling of empirical evidence on what the community values and ethical debate – is a sensible way to proceed. Combined with a concern for procedural justice, particularly the development of "case law" as outlined by Daniels, acceptable reason-governed practices could be developed over time in the process of making actual decisions. There is a need for clarity in the reporting of both decision outcomes and the associated rationale for the decisions, and this information needs to be publicly accessible.

7.4.2 Ethical reasoning offers no decision rules to choose between conflicting ethical theories or principles (Criterion Two: Concept of Benefit; Criterion Six: Role of Judgement and Criterion Eight: Due Process)

It is important to recognise that while ethical reasoning involves a rational approach to problem analysis, it offers no decision rules to choose between alternative ethical approaches. Deontology and consequentialsim, together with distributive justice[112], stand out amongst the ethical issues of relevance to priority setting in health care. Deontology focuses on duty, process and the rights of the individual; consequentialsim focuses on outcomes and the collective good of society; while distributive justice involves the idea of balancing the competing claims of individuals in a way that is seen as impartial and fair. Most stakeholders in priority setting exercises will hold views that reflect a combination of these ideologies, with the particular combination likely to vary with their background and experience, together with the choice problem and setting.

Despite their importance to the content and acceptability of decisions, the choice of one ethical approach over another, or as is more likely, the particular blend of ethical values, remains a matter of judgement. The ethics discipline is not able to provide a consensus view on the "right" approach or an ethical theory that is demonstrably superior to all others. Analysts must use their judgement, therefore, in selecting from the menu. There is no logical way of resolving these divergent ethical views other than a convergence of thinking through structured discussion and recognition of the legitimacy of alternative viewpoints. This recognition reinforces the importance of:

- due process in priority setting exercises, whereby objectives, the concept of benefit and values are clarified and deliberative judgements are taken after meaningful discussion;

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[112] Distributive justice is not a separate ethical approach vis-à-vis deontology or consequentialism. Distributive justice could be justified on deontological grounds (i.e. it is just "right" that citizens have access to health care); likewise distributive justice focuses on outcomes and therefore implies consequentialsim. The line of least resistance is to recognise this, but for practical purposes, view distributive justice as a particular form of consequentialism. In this thesis I focus in particular on equity aspects of distributive justice – what I term "distributive equity".

- the important role for empirical evidence on the values that are held to be important by the community, particularly in relation to concepts of distributive and procedural justice;
- the role of government (and ultimately the Parliament) as "circuit breaker" (Richardson 2000c) to decide ethical values; and
- understanding the context-specific nature of ethical judgements.

While ethical reasoning and economic theory may lead to similar answers, it is important to acknowledge that an agreed ethical rationale may on occasions justify practices that differ from economic theory and its associated decision rules (particularly economic orthodoxy). Further, utilitarianism is a subgroup of consequentialism developed by both economists and philosophers. Consequentialism is a group of moral theories where widely divergent views are held about i) the need for outcome maximisation, particularly having regard to how concerns over distributive justice might be integrated; and ii) whether only individual preferences count or whether other consequences also matter, including the moral status of consequences (such as virtue, desert, justice).

There are, potentially, fundamental and unresolved conflicts in the ethics literature. In reality there is probably no choice but to accept Richardson's notion of the Parliament as "circuit breaker" and this is one of the virtues of the DMA[113].

7.4.3 The incorporation of ethical values into economic appraisal, particularly notions of distributive justice, requires measurement rigour and judgement. (Criterion Nine: Measurement Rigour)

There is widespread agreement about the importance of distributive equity, but this does not translate easily into agreement about what the relevant concept of equity should be. The choice of focal variable (or 'distribuendum') is critical, because achieving equality in respect of one equity dimension usually means accepting inequality in regard to other dimensions. There is no scientific basis[114] for choosing between rival notions of equity as normative principles. Judgement is required having regard to policy objectives, decision context, community values and the theories of social justice held to be the most appropriate. The need for judgement in the selection of the appropriate equity concept, however, in no way diminishes the need for rigour in the measurement of the concept chosen (i.e. using

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[113] As noted in the theory rationale, Richardson views (Richardson 2000c) are very similar to the DMA. He agrees there is no option but for economists to turn to government for final adjudication on ethical and social issues, but sees this happening at the end of a process of information gathering with respect to population values. Community consultation is an integral part of the first best solution, with DMA as per Sugden/Williams, a second best when resources for community research are constrained.

[114] An important compromise position could be that when analysts are aware of conflicting views, they provide data that allows both views to be illuminated and evaluated. The feasibility of this compromise will depend on the time and resources available.

measurement instruments that have been validated; using surveys where sample size allows statistically significant results to be obtained, etc).

Concepts of equity that have received the most sustained attention are: i) allocation according to need; ii) allocation according to health status; and iii) allocation to ensure equality of health access. The principle that health care resources should be prioritised according to need has strong intuitive appeal, and for this reason "need" is a popular approach used both on its own and in combination with the health status and access definitions. To be of practical use, however, the concept of "need" has to be clearly defined, with at least three definitions existing in the literature. These range from need defined as extent of illness or size of the problem (based on epidemiological data and/or community surveys); need as defined by disease severity; and need as defined by the existence of an effective intervention / capacity-to-benefit. Under the principle of allocation according to need, horizontal and vertical equity call for equal treatment for equal need and unequal treatment in proportion to unequal need. While these various concepts are useful to decide when a need exists, they are less useful in deciding how much health care is required to meet that need. This provides for a natural coalition between needs-based concepts of equity and the efficiency principle in assisting policy decisions.

Given that health care is mostly consumed for instrumental reasons – that is, to promote good health – there is a strong argument to consider equity in terms of health status. In policy terms, this equity principle is often expressed as minimising inequalities in health status. The question of differential aggregation weights to implement this equity principle has received considerable attention in the literature, particularly by extra-welfarists, and particularly in the context of weights to adjust QALYs (or similar concepts) in economic evaluation. To the extent that distributive concerns can be linked to the characteristics of people (such as age, ethnicity/aboriginality, rurality/remoteness; socioeconomic status) a system of weights may be able to reflect these concerns. An important issue in designing weights is the appropriate source and rationale for the equity principle(s) involved. In this regard, equity weights can be developed based on community preferences and/or reflect an equity principle selected by the researcher/decision-maker based on moral reasoning. Recent work based on community preferences has focused on illness severity and health potentials, while the "fair innings" approach is a good example of weights based on both moral reasoning and empirical evidence (see discussion in Chapters Five and Eight).

The third major approach to distributive equity is allocation to achieve equality of access. The ethical basis is one of ensuring a "fair chance" and is commonly found in policy statements in the form "equal access for equal need." While there are certainly issues in defining "access", the principle carries strong egalitarian overtones and enjoys strong empirical support.

7.4.4 The plurality of moral values emphasises the need for procedural justice (Criterion Eight: Due Process)

It is important to note that the three approaches to distributive justice will generally lead to different answers for the allocation of resources. Nowhere is this more apparent, for example, than in the "fair chances verses best outcomes" trade-off. When general principles of distributive justice fail to give clear-cut answers, either because of the plurality of moral values and/or because of the difficulty of the choices faced, then the focus of social justice shifts to fair procedures and to the legitimacy provided by a just process for making decisions. The work of Daniels on "accountability for reasonableness", together with notions of procedural rights offered by Bynoe, Hunter and others, offers useful guidance in this regard.

The issue of legitimacy of priority setting decisions in the eyes of stakeholders leads on to the pragmatic rationale – to what lessons can be learnt from empirical experience with priority setting.

7.5 The pragmatic rationale (P)

Criteria with a pragmatic rationale (P) reflect the empirical evidence discussed in Chapter Six and summarised in Section 6.5. The experiences of Oregon, The Netherlands, New Zealand, and the Nordic countries exemplify the emergence of explicit priority setting as a national initiative. In each of these countries priority setting is high on the health policy agenda, as the scope of publicly financed health services has come under review. In Australia and the UK there have been no similar systematic efforts to establish a national framework in which explicit criteria are clearly laid out, with ethical values established through community consultation. There are, nonetheless, relevant empirical experiences in priority setting from which lessons can be drawn.

The key points of guidance that can be gleaned from this empirical experience are set out below, particularly in regard to the primacy afforded efficiency as an objective and the acceptance of economic evaluation as an aid to decision-making. The criterion to which each point relates is indicated.

7.5.1 Priority setting needs to combine technical methodologies, such as economic evaluation, with a concern for due process for decisions to have legitimacy across multiple stakeholders (Criterion Eight: Due Process)

The empirical evidence available suggests that while the various technical approaches have undoubtedly made an important contribution, no country has adopted a purely technical approach. All countries have come to recognise that if their decisions were to have legitimacy for patients, for providers, and for the general public, then a balance had to be struck between techniques and decision rules drawn from disciplines like economics, and a concern for due

process and consultation[115]. The prominence given due process could reflect (i) a practical means of resolving conflict between underlying ethical theories (7.4.2 above); and/or (ii) the failure of the economics discipline to develop satisfactory evaluation frameworks for priority setting. It is argued in this thesis that the latter is an important explanation and needs to be addressed if economics is to achieve its potential in guiding policy decisions.

In Australia the appeal of the consensus-based approaches has reflected their focus on due process, particularly the effective involvement of participants in the decision-making process. Similarly, while PBMA is still an emerging technique, its potential to combine both technical and consensus-based approaches is an important element of its appeal.

7.5.2 Economic evaluation may produce results that are unexpected and/or unacceptable to some, particularly if the program objectives and the concept of benefit are not clearly discussed in advance (Criterion Two: Concept of Benefit)

This was certainly true in the case of Oregon, when interventions dealing with minor ailments were rated higher than those dealing with life-threatening conditions. If the only people to whom a priority list based on an efficiency objective looks acceptable are economists, then setting priorities based on efficiency is unlikely to be successful[116]. The empirical experience thus focuses attention on the appropriate concept of "benefit", together with the need for practical and robust methodology[117]. This in turn focuses attention on the relative merit of newer techniques, such as cost value analysis (Nord 1999), together with the important role that might be played by PBMA.

7.5.3 Economic evaluation has been regarded as useful and fundamental to the priority setting process, but within a restricted role (Criterion One: The Research Question)

The role of economic evaluation in the countries reviewed has reflected the significance afforded efficiency as an objective of their health care systems, together with difficulties encountered in the practical application of economic evaluation techniques. All countries reviewed, including Sweden, embraced efficiency as an important objective, but clearly not the only objective, and often not the most important objective. For most countries, the importance placed on different objectives reflected their underlying ethical values.

In relation to evaluation techniques, most countries recognised that the broader the priority setting task attempted, the more likely economic evaluation would encounter technical

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[115] Such as the "accountability for reasonableness" approach of Daniels (Daniels 2000) or the procedural rights approach of Hunter (Hunter 1997).

[116] Fortunately, this is largely a reflection of how economic evaluation is presently carried out, rather than an inevitable consequence of economic theory. The discussion in Chapter Four establishes that broader issues of concern to the community can legitimately be included in the social welfare function that economic evaluation attempts to measure.

[117] The crude evaluation techniques adopted in Stage One of the Oregon trial, for example, was an important contributing factor to the failure of the QALY League Table approach.

problems. Several countries (New Zealand, Nordic countries) preferred to focus economic evaluation on vertical priority setting (i.e. on interventions for dealing with the same disease or problem) and/or within the context of guidelines or dealing with new technologies. The Australian experience is similar. The use of economic evaluation within a restricted role, such as assisting administration of the Pharmaceutical Benefits Scheme or as an input to PBMA studies, has been well regarded.

7.5.4 The empirical experience raises important issues about what constitutes "adequate" data and how the data requirements of technical approaches can be made tractable (Criterion Seven: Data Needs)

The suitability of available economic evaluation techniques in application to entire domains of health care has been questioned by experienced evaluators. Those initiatives which have sought a much broader application, such as Oregon, the Illawarregon, the HBG/HRG approach, and the Health Sector Wide Disease Model, have encountered significant data problems which has limited their usefulness. These approaches have either sought to make the task more tractable by limiting the scope of the research question, restricting the role of economic evaluation, or withdrawn to a general planning and scenario assessment role. In the context of priority setting, economists need to develop methods that have specific regard to evaluation of multiple interventions, in addition to the current focus on one-off studies.

7.5.5 Ultimately, priority setting rests on judgement informed by evidence (Criterion Six: Role of Judgement)

The review of empirical evidence highlights the reality that explicit rationing at all levels involves both the use of techniques and the application of judgement. The Oregon Commissioners, for example, were concerned to ensure that their list was not just a formula-produced combination of values and data, but also an intuitively sensible ranking that reflected relative value in the context of scarce resources. The same issue arises in Australian empirical experience, with the PBAC process having important implicit elements. The role of judgement highlights the associated issue of whether such judgement should be implicit or explicit. Considerations of accountability and visibility would suggest that both decision criteria and their application should be clearly specified.

At the other level of empirical experience, the notoriety that has surrounded particular cases where patients, particularly children, have been denied treatment, also reinforces the crucial role of judgement. Weighing the needs of individuals against the interests of the community can be very difficult, especially if the case ends up in the Court of Appeal or becomes the centre of media attention. The experience of the Cambridge and Huntingdon Health Authority in the UK illustrates that the clear specification of a set of values and a thorough process cannot take away the need for judgement, but it can greatly aid its application and legitimacy in the eyes of stakeholders.

7.5.6 The importance of clarifying ethical values in resource allocation choices (Criterion Six: Role of Judgement)

The recognition of the central role of judgement in priority setting has also drawn attention to the importance of clarifying ethical values and notions of social justice in resource allocation choices. This is because the relative priority attached to different services or treatments depends in part on the value attached to different outcomes (such as palliative care for the terminally ill as opposed to life saving care for infants). While certain values are perceived to be important in all systems, there is as yet little apparent agreement on the core values that should inform priority setting, nor about their relative importance. Most countries reviewed give prominence to need/severity; effectiveness; equity and efficiency, but their specification and role varies. The contrast between those countries like Sweden that attach particular importance to the rights of the individual, with the approach of The Netherlands and the US State of Oregon, which focus on the benefit to society as a whole, illustrates the importance of decision-makers in Australia being clear on Australian values.

7.5.7 Consulting the public (Criterion Eight: Due Process)

While the views of medical practitioners and other "experts" are drawn on extensively, there is increasing interest in widening the circle to include the representatives of the public and/or of patients. The empirical evidence suggests a variety of reasons. In some cases the purpose has been to educate and inform citizens about the need for rationing; in others the task has been to agree values and principles that should guide rationing; and in others it has been to contribute a user perspective to specific problems and choices. Health care reformers have been experimenting with diverse methods for involving "community values" in resource allocation decisions.

7.6 User considerations (U)

Criteria with a user rationale (U) stem from an effort to ensure that models of priority setting respond to the particular needs of health care decision-makers. The recognition of the important role played by decision-makers is reflected in:

- the selection of the decision-making approach as the preferred theoretical foundation for priority setting;
- the recognition of the government's role in the development and agreement on ethical values to underpin priority setting; and
- growing recognition amongst economists that the impact of economic evaluation on policy could be improved markedly by "listening to the bureaucrats" (Mooney and Wiseman 1999).

The summary points given below reflect the empirical evidence in Chapter Six; applied micro economic theory from Chapter Four; and key context issues from Chapter Two.

7.6.1 Specifying a core set of services to be funded has proven difficult (Criterion One: The Research Question)

Attempts to make priority setting more explicit have also revealed the difficulty of defining a basic package of services by excluding some treatments from public funding. The approach adopted in Oregon has proved difficult to transfer to other health care systems. New Zealand and The Netherlands started down this same road, but it was soon abandoned in New Zealand and proved to be very problematic in The Netherlands. The experience to date suggests that where exclusions have been achieved they have tended to be interventions involving minor ailments and/or interventions for which the evidence was lacking. They are all marginal to mainstream medicine. While not preparing detailed lists of the type adopted in Oregon, several countries have adopted health service classification systems based on illness severity/perceived importance, that have proven to be useful (Sweden, Norway, Finland, and Denmark).

Quite apart from the empirical evidence, there is also an important theoretical reason to question the "exclusion" approach. Specifically, the selection of a core set of services to be funded based on a QALY League Table containing average cost-effectiveness results is inconsistent with the importance placed on marginal analysis in finding "efficient" solutions. Reliance on average cost-effectiveness results ignores the variation in cost-effectiveness ratios with patient needs; population sub-group; program size and design; health service setting, etc. There are few treatments that are wholly effective or wholly ineffective and the challenge is to ensure that the services that are funded are provided to those patients who stand to benefit. For both sound practical and theoretical reasons, those charged with the responsibility for rationing have usually declined to use the exclusion approach.

7.6.2 Developing guidelines (rather than service exclusion) has attracted widespread support (Criterion One: The Research Question)

The natural consequence of the difficulties inherent in rationing by exclusion is the increasing interest being shown in setting priorities by drawing up guidelines for the provision of services. The focus has changed from which services or types of care should be provided, to which patients should be selected for what kinds of treatment and at what level of intensity. The focus on rationing by guidelines also reflects the wider movement to strengthen the scientific basis of medicine and the associated concern to reduce variations in clinical practice patterns. In Australia, the guidelines approach is gaining momentum, but more as a by-product of the evidence-based medicine approach than any conscious approach to priority setting.

7.6.3 The importance of a strategic approach to deal with the inherent complexity and ongoing nature of priority setting (Associated policy/infrastructure issue)

The empirical experience confirms that there are no simple solutions to the challenges posed by the need for priority setting. Complexity is inherent in the range of stakeholders involved; the various levels at which decisions are taken; the need for both vertical and horizontal priority setting; and the importance attached to ethical values and principles. If priority setting is to be seen as legitimate by citizens and other stakeholders, then a strategic approach is required that can employ techniques drawn from economics as well as debate the need for due process. Most countries reviewed in Chapter Six discovered that this requires infrastructure support and a long-term commitment.

7.6.4 A need for inter-disciplinary research (Relevant to criteria seven, eight and nine)

Many authors and reviewers of international experience endorse the call for multi-disciplinary research (eg Daniels, Hurley, Mooney, Richardson, Coast, Ham, Coulter, etc). Australian experience has demonstrated that approaches founded in behavioural science, such as the three-stage model adopted in the Hunter Region of NSW (6.3.2) and the nominal group technique (6.3.2; 6.3.3) have been well regarded by participants. While these approaches have important limitations from an economic perspective[118], their success in consensus building highlights the potential for an inter-disciplinary approach that draws on the respective strength of each discipline. Similarly the MOROCUS study (6.3.9) demonstrates the significant potential for cooperative research between economics and epidemiology to develop approaches to priority setting that go beyond a passive trawling of the published literature for evidence of efficacy. The nature of the collaboration and the disciplines involved will depend, of course, on the research issue.

7.6.5 Priority setting has important management and organisational dimensions (Relevant to criteria one, three, and six to ten)

Despite some progress in recent times, explicit priority setting is not commonplace in Australia. Management, whether in government or elsewhere, will need time to trust explicit approaches to priority setting, particularly if they are time and resource intensive. For many, explicit priority setting is not part of the current organisational culture. To expect managers, working in an often reactive and stressful environment, to immediately adjust their practices to incorporate an external framework, no matter how impeccable its logic, is unrealistic. This is particularly so when that framework has implications for current financial reporting practice (eg. program structure and associated cost centres); for current data collections (eg. the collection of activity and outcome data); for research activity (eg. establishing the evidence

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[118] As outlined in sections 6.3.2 and 6.3.3, these relate principally to the type of information provided to guide decision-making; the omission of key economic principles necessary to achieve efficiency (i.e.

base); and the visibility of decisions. There needs to be recognition that explicit approaches to priority setting require infrastructure and a long-term commitment from senior management.

7.6.6 The importance of individual cases (Criterion Eight: Due Process)

Well-publicised cases of individuals, particularly children, have been instrumental in bringing priority setting into the public domain and on to the policy agenda. The approach taken in Oregon, for example, followed the death of a young boy with leukemia – Coby Howard – who was denied a bone marrow transplant under Medicaid. A similar case in the UK involving a young girl – Jaymee Bowen (refer 6.4.1) – prompted a lively debate about the decision to deny treatment and the way in which it was taken. In their different ways, individual cases such as these epitomise the difficulties in priority setting for decision-makers. Explicit approaches to priority setting are always likely to generate debate and disagreement, and what therefore matters is to structure this debate to enable different points of view to be articulated, to promote transparency and consistency in decision-making, and to build trust, confidence and legitimacy in the process.

7.7 References

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marginal analysis; opportunity cost); the lack of precision in how criteria are to be used in ranking options; and the primary focus on size of the problem rather than on health gain.

PART C: HOW DO EXISTING MODELS OF PRIORITY SETTING PERFORM AGAINST THE CHECKLIST

Chapter Eight: Models of Priority Setting Proposed by Non-Economists

8.1 Introduction

In Part B of the thesis a checklist was developed to help identify the features of an ideal approach to priority setting. In Part C existing models of priority setting that adopt an explicit approach are briefly outlined and assessed against the ten criteria of the checklist. In Chapter Eight models proposed by non-economists to guide resource allocation are reviewed, while in Chapter Nine models proposed by economists are assessed. The review of existing models is undertaken to help determine both the need for, and potential significance of, the Macro Economic Evaluation Model (MEEM) presented in Part D.

In introducing Chapter Eight, it is important to acknowledge that models proposed by non-economists are unlikely to perform well against a checklist developed from an economic perspective. To a large extent, this simply reflects the fact that their "raison d'être" and primary purpose is to pursue objectives other than efficiency (such as achieving social justice in allocating resources). It could be argued, therefore, that to criticise these approaches on the basis that they do not meet efficiency-based criteria is, in a sense, to set up a "straw man".

Notwithstanding this qualification, there are valid reasons for including a brief review of models proposed by non-economists. First, these models are prominent in the international literature, both in theoretical papers and in reports of empirical experience with priority setting. Second, the models reviewed have all been put forward as appropriate models to guide decision-makers in their resource allocation decisions. As guidance on resource allocation is a primary function of the economics discipline, it is reasonable to argue that an assessment from an economic perspective will assist a balanced judgement of their relative merit in this role.

Contributions from non-economists come from a number of disciplinary bases, with epidemiology, philosophy and behavioural science figuring prominently. It would be impossible in a brief review to discuss comprehensively all the potential approaches and their various permutations. Instead the chapter focuses on two distinctive non-economic approaches to priority setting, viz: models that adopt equity as their primary objective; and models that adopt the achievement of consensus as their primary objective.

8.2 Equity as the basis for priority setting

The notion of equity has already figured prominently in this thesis, particularly in Chapters Four and Five. In those discussions, however, equity was discussed within the economic context of efficiency; that is, in the context of defining and maximising the social welfare function. In this section, equity is discussed as the primary objective in its own right. Two contributions are reviewed: needs-based rationing from epidemiology; and age-based rationing from philosophy.

8.2.1 Needs-based models from epidemiology[119]

Traditional epidemiology was mostly concerned with examining the distribution and determinants of disease. Modern epidemiology has extended the discipline to include assessment of the efficacy of health care interventions (Coast, Bevan et al. 1996). The setting of priorities is not, however, a question that has normally been considered by epidemiologists. As Coast notes:

> *"While traditional epidemiology offers an account of what to choose between, it does not offer grounds for the choice. It has tended to concern itself with the technical question of assessing need rather than the judgemental question of determining priorities."(p. 144)(Coast, Bevan et al. 1996)*

Despite this, one means of setting priorities equitably has been perceived as being through the assessment of need employing epidemiological techniques. Needs assessment, for example, was given a pivotal role in the development of purchasing in the NHS internal market reforms of the early 1990s (refer Section 6.2.5) and is utilised by public health units in various states of Australia. Need, however, is a complex concept, with many different definitions provided in the literature (refer Section 5.3.3). The crucial distinction is between defining need as the extent and/or severity of illness (i.e. "*health* needs") and defining need as the capacity-to-benefit (i.e. "*health care* needs"). Health needs reflect the size and severity of ill health in the community, while health care needs reflect the potential ability to benefit from particular interventions. A range of techniques can be utilised to describe health needs, including summary measures of population health (such as DALYs or health expectancy) discussed in Chapter Eleven. Similarly, various techniques have been utilised to estimate capacity-to-benefit, particularly the notion of "avoidable mortality and morbidity"[120] and these

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[119] It is acknowledged that other disciplines can also offer approaches to describing health needs – such as cost-of-illness studies from economics and community surveys from behavioural science – but needs as defined from epidemiological approaches was chosen to illustrate the genre.

[120] Avoidable mortality analysis emerged in 1976 when Rutstein and colleagues proposed the categorical attribution of diseases and injuries using sentinel-health-events (Rutstein, Berenberg et al. 1976; Rutstein, Berenberg et al. 1980). This was subsequently expanded to include causes amenable to medical or surgical treatment to age 65 and was intended to serve as a health care system performance indicator (Charlton, Hartley et al. 1983; Holland, Fitzgerald et al. 1994). The "avoidable mortality" concept was later expanded to cover hospitalisation (Weissman, Gatsonis et al. 1992; Billings, Anderson et al. 1996) and DALYs (Hollinghurst, Bevan et al. 1999). Various countries have utilised the

have often been integrated into national goals and targets (Nutbeam, et al. 1993; Commonwealth Department of Health & Family Services 1997).

Coast reports that need as a basis for explicit priority setting has been utilised in two basic ways. First, through population-based proxies purporting to summarise the composite of individual morbidity; and second, through the epidemiological examination of individual diseases in the ICD-9 (Coast, Bevan et al. 1996). The major use of population-based proxies of need in the context of priority setting has been for the broad allocation of resources. Resource allocation formula (RAF) linking need and expenditure, for example, are widely used at the population level by central and/or state governments to distribute resources to their regions based on each region's relative need[121]. The average expenditure on residents in each region is designed to correspond to the need for care in each region, compared to other regions. The widespread use of such RAF illustrates the close relation at the population level between the principle of allocation according to need and the principle of allocation to achieve equal access. In practice RAF aim to equalise resources for defined populations taking account of differences in the risk of their requiring health services. While much has been written about the strengths and limitations of RAF, such formulae are unlikely to form a way forward to assist purchasing decisions (as opposed to their use in the distribution of regional budgets). This reflects the lack of attention to option generation/selection; the absence of decision rules to guide purchasing; and reliance on burden of disease data (as opposed to information on the costs and benefits of specific interventions).

The second way epidemiological concepts of need have been utilised in explicit priority setting is through the development of descriptive data on individual diseases. Disease epidemiology can offer information on disease incidence, risk factors, prevalence, duration, health burden (eg QALY/DALY), health service use and efficacy/effectiveness. This approach can include both descriptions of the health burden as well as capacity-to-benefit. It is referred to by Coast and various UK authors as "Total Needs Assessment" (Mooney, Gerard et al. 1992; Coast, Bevan et al. 1996) and was given a pivotal role in the NHS internal market reforms, as noted previously. During the 1990s needs were assessed for many conditions in the UK (Stevens and Raftery 1994) and the notion of assessing need was also applied in the development of clinical guidelines and health care targets[122]. Early enthusiasm for needs assessment by purchasers in the UK waned however, largely because of the enormity of the research task and its limited relevance for specific purchasing decisions. Purchasers soon realised that if information on need is to provide a means of setting priorities, then there must

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concept to assist in their health service planning activities (US Department of Health and Human Services: Public Health Service 1997; New Zealand Ministry of Health 1999; Europe 2000).

[121] See, for example, (DHSS 1976; Birch, Eyles et al. 1993; Peacock and Segal 1999; Wagstaff and Van Doorslaer 2000).

[122] In the report "The health of the nation", for example, targets were based on three criteria, viz: that the area of health targeted should involve a large burden of illness; that effective interventions should be available; and that targets should be quantifiable (Department of Health 1992).

be some basis for deciding between different forms of need – between different forms of effective care. As various economists[123] in the UK pointed out, without cost data and the decision rules offered by marginal analysis, there are formidable difficulties in trying to set priorities from needs data. While disease epidemiology is useful to establish *when* a need exists (or when a potential benefit exists), it is less helpful to establish *how much* health care is required. Within a priority setting basis of equal access for equal need, for example, the precise equity criterion will differ depending upon the way in which funds are allocated between those with greater and lesser needs. The allocation could involve meeting all the greatest needs and none of the lesser ones or it could involve some provision for all needs, but lesser provision for lesser needs.

Mooney discusses three possible options, for example, in using capacity-to-benefit as a basis for priority setting (Mooney 1994), none of which are very satisfactory. First, he suggests that resources could be allocated pro rata with needs (but this requires a suitable metric). Second, he suggests the possibility of using needs assessment to provide an ordinal ranking of the resources to be allocated to each area (i.e. conditions with greater needs should get greater resources than conditions with lesser needs). In this case, however, there is no basis for deciding how much to spend on each need (i.e. no decision rules). Third, he suggests the option of using cardinal weights to reflect the relative importance of the needs of different conditions. This is similar to the severity categories adopted by several countries reviewed in Chapter Six (eg Oregon stage two and the Nordic countries). This technique still requires, however, an appropriate method to allocate resources within each needs/severity category (particularly if priority setting is not to slip back into implicit mode).

Table 8.1 provides an assessment of needs-based approaches against the checklist. It is concluded that the poor performance of needs-based models on key criteria (particularly marginal analysis and decision rules) explain their poor performance in prioritising purchasing solutions. Needs-based models could prove useful, however, in RAF for distributing regional budgets, in devising severity classification systems and as an input to economic models (see Chapter 10).

The difficulty needs-based approaches have in informing purchasing decisions provides for a natural coalition between needs-based concepts of equity, and efficiency-based decision rules employing marginal analysis. It is also the reason that the definition of need is sometimes linked to expenditure. Culyer and Wagstaff, for example, defined need as "the expenditure required to effect the maximum possible health improvement, or equivalently, the expenditure required to reduce the individual's capacity-to-benefit to zero" (Culyer and Wagstaff 1993).

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[123] See, for example, (Mooney, Gerard et al. 1992; Donaldson and Farrar 1993; Mooney 1994).

Table 8.3: Summary of performance of needs-based models against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	Clarity in research question varies between methods and from study to study. Some models take a broad-based societal perspective (such as the GBD and associated national DALY or "avoidable mortality/morbidity" studies) while others focus on specific diseases and particular health service sectors. Well-designed research question is achievable within context of model objectives.
Clear concept of benefit	Few of the needs-based approaches explicitly consider priority setting objectives and what this means for the concept of benefit. Equity is a complex concept and few studies define it clearly. Needs-based models do not have an in-built mechanism to discuss and clarify concept of benefit with stakeholders. Most assume disease/health is the distribuendum. Broader objectives, such as procedural justice, affordability or feasibility, are rarely canvassed.
Process for generating options for change	"Health needs" studies focus on a description of the size and distribution of disease problem, rather than health gain or interventions. "Health care needs" studies take into account whether efficacious interventions exist, but rarely provide advice on option generation/selection matched to specific decision contexts.
Marginal Analysis	Needs-based models are not based on economic principles and do not involve marginal analysis or opportunity cost principles.
Clear decision rules	Fail to incorporate decision rules for priority setting in situation of resource scarcity. Needs-based models contain no mechanism to adjust health service mix towards the optimal (such as the MB = MC rule of economics).
Role of judgement noted and clearly specified	Performance would vary between models and studies. The better studies would make explicit the role of judgement in specification, application and interpretation of the technical analysis.
Data needs made tractable	Like most forms of technical priority setting, needs-based approaches can involve large requirements for data that often pose considerable problems. Existence of the requisite data on disease incidence/prevalence, duration, mortality and disease burden varies by disease and from country to country. Integration of quality of life weights involves further detailed data and ethical issues. Modeling and simplifying assumptions often employed.
Due process	Needs-based models, like most technical approaches, rarely give consideration to issues of procedural justice. Most studies endevour to make their methods explicit. Involvement of stakeholders varies between models.
Rigorous approach to measurement	Performance varies from study to study. Rigorous and balanced approach to measurement is achievable.
Reporting issues of concern to decision-makers	Some issues of concern to decision-makers not covered by approach (i.e. financial cost; allocative and technical efficiency). Coverage of other issues (ethical values; feasibility; acceptability to stakeholders) would vary from study to study.
Overall assessment	**Needs-based models have been useful to in distributing regional budgets (RAFs), in prioritising problems, and in estimating potential benefits. Failure to provide mechanism to address choice between different needs/ interventions, compromises ability to guide individual purchasing decisions. Best utilised to provide need/severity classification systems and as an input to decision-making where decision rules are introduced from efficiency-based models.**

8.2.2 Age-based models from philosophy

Approaches to health service planning incorporating age-based rationing have been put forward both by philosophers[124], reflecting various moral justifications, as well as by economists[125] seeking to reconcile efficiency and equity objectives. The focus here will be on the philosophers, particularly the writings of Daniel Callahan and Norman Daniel, who offer the most developed arguments for age-based rationing. It is noticeable that the justifications for rationing by age from these philosophers are not related to the use of age as a proxy for the assessment of outcome or need, although much of the criticism of their ideas invokes these issues (Coast, Bevan et al. 1996).

Interestingly, the concept of a "fair innings" began with Harris, a fervent critic of QALYs[126]. Harris criticised QALYs for discriminating against the elderly (and those with pre-existing disabilities), because a "full" recovery from a life threatening condition will be smaller for these groups in terms of QALYs gained than a full recovery for the young or the able-bodied. This has been referred to as "utilitarian ageism" (Nord, Richardson et al. 1996). On the other hand, Harris acknowledged the idea that under certain circumstances the old should give way to the young in the name of fairness, because by definition the former have lived more than the latter. Harris appreciated that this idea had intuitive appeal to many[127] and gave the idea a form and the name "the fair innings argument" (Tsuchiya 2001).

The main point of the argument under this initial Harris formulation (what Tsuchiya calls the "Original Fair Innings Argument" or OFIA) is that society may be prepared to specify some amount of life years as a "fair innings". If then presented with a situation where a choice must be made between someone above this age and someone below it, the younger person is to be saved (as they otherwise would not be able to enjoy a "fair innings"). Harris argues strongly for saving lives in his writings (not life years), which amounts to assigning an equal weight to what remains of one's life after the cut-off, irrespective of the expected quantity or quality[128]. Thus if patients competing for access are above the specified age, the OFIA is irrelevant, and a coin should be tossed (providing both patients wish to live).

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[124] Key contributors are Harris (Harris 1985; Harris 1988); Callahan (Callahan 1987; Callahan 1990); Daniels (Daniels 1988); and Lockwood (Lockwood 1988).

[125] Alan Williams, for example, has proposed a variant of the "fair innings" approach (Williams 1997; Williams 1998) while Chris Murray has incorporated age weights in the GBD DALYs based on a notion of welfare interdependence (i.e. that healthy people contribute to social value at different rates, and this can be captured in age weights).

[126] See, for example, (Harris 1985; Harris 1987; Harris 1988).

[127] Such preferences have been elicited from the general public. See for example (Busschbach, Hessing et al. 1993; Cropper, Aydede et al. 1994; Nord, Richardson et al. 1996; Tsuchiya 1996; Johannesson and Johansson 1997; Tsuchiya 1999).

[128] Note that in this regard the OFIA is not compatible with the utilitarian ageist aspects of QALY maximisation (which would, for example, discriminate between patients over the cut-off on the basis of their respective QALYs; as well as save the older patient, if the QALY gain was larger than the younger patient). Harris also discussed a "Relative Fair Innings Argument" where the age cut-off was allowed to

Daniel Callahan proposed a different concept of age-based rationing[129], which while similar to the OFIA of Harris in that a specified age is set as the cut-off point, reflects quite different reasoning. Callahan stresses that because of the nature of both health care and life, there will always be difficult choices to make about access to care at an affordable cost to society. Medical technology is likely to constantly expand the frontier of possible interventions, but reasonable limits have to be set and there are ways of living a better life that don't include access to the latest technologies. Callahan proposes that the "Biographical Life Span" (BLS), assumed to be the late 70s or early 80s, is a strong candidate for setting that reasonable limit. For Callahan the central aim of medicine should be to avoid premature death for those under the BLS, and to avoid pain and suffering for those over the BLS. On a practical level, Callahan was concerned with the lack of decent provision of long-term care for the elderly, while on the ethical level, he wanted the US society to re-think the meaning of ageing and death.

Callahan's BLS proposal implies that all life-saving treatment goes to those below the specified cut-off age, while those above it will not gain access as a general rule, irrespective of expected QALYs[130]. Note that the primary concern for Callahan is the sustainability and affordability of health care in society, and the value of living a good life as an individual. Fairness across different individuals with regard to age of death is of secondary importance, if any (Tsuchiya 2001).

Norman Daniels proposed another rationale for age-based rationing, which for some commentators (Hoopes 1988), rests on a stronger philosophical base than Callahan's proposal. In his Prudential Lifetime Account (PLA), Daniels proposed a re-framing of the inter-personal and inter-generational issues of access into an intra-personal and inter-temporal resource allocation issue, by adopting a "lifespan approach" (Tsuchiya 2001). This transformation of perspective means the allocation of scarce resources between different age groups, is transformed into one between different stages of our own lifespan. The obvious condition, however, is that whatever allocation pattern is chosen remains constant over our lifespan. Daniels presents his approach in the form of prudential reasoning, whereby a fixed share of resources is to be allocated to each life stage so as to maximise lifetime well-being. For Daniels, the purpose of health care is to secure a fair equality of opportunity, and this implies that resources ought to be allocated so that each can achieve a normal lifespan (Daniels 1988). Daniels extends his argument from the individual, who would prefer to use resources earlier rather than later, to age cohorts. He does this by viewing health insurance as a saving scheme whereby resources are deferred from one point in time to another in

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vary and the younger patient was always favoured. Harris rejected this formulation, although others have favoured it, such as (Lockwood 1988).

[129] See, for example, (Callahan 1987; Callahan 1988; Callahan 1990; Callahan 1993).

accordance with the relative weight given to care at different ages. Daniels argues that when faced with a particular resource constraint, prudential decision-makers will choose to give priority to enabling as many people as possible reach a normal life span, and to impose age-based rationing beyond it. He employs the veil of ignorance to argue that giving emphasis to living a normal lifespan is prudent because it gives the best chance for all to live out their life plans.

Daniels makes clear, however, that his approach is not meant to provide a general sanction for rationing by age. For Daniels PLA is only applicable when resources are limited and when it is part of a scheme whereby resources are distributed over the lifetime of individuals. Further, PLA is restricted (or framed) to individuals, and should not cross the boundaries between persons in order to deal with distributive justice[131]. This is a major difference to schemes offered by economists (eg the Williams "fair innings" proposal (Williams 1997) or the DALY age weights of Chris Murray (Murray 1996)) which involve age weighted QALYs summed across individuals.

In Table 8.2 these three age-based schemes (OFIA; BLS; PLA) are assessed against the checklist. It is concluded that age-based models have largely remained a theoretical option and are incomplete as full models of priority setting. Important aspects of an applied model have not been addressed; such as a process for generating options for change; decision rules to guide purchasing decisions (as opposed to access decisions); what constitutes "due process" in decision-making; and guidance on measurement issues associated with purchasing. The age-based models presented by philosophers have mainly focussed on the micro level of decision-making, and even then, on intra-personal choice associated with access and utilisation. Extrapolation to other levels of decision-making and to inter-personal comparisons may not be appropriate using these models.

It is interesting to note that while some authors - such as (Coast, Bevan et al. 1996) - see the PLA and BLS schemes very much as equity-based approaches to priority setting; others - such as (Tsuchiya 2001) - perceive an efficiency element to them. This stems from the fact that both Callahan and Daniels aimed at maximising the achievement of a given objective; namely, to maximise people's chances of obtaining a threshold age so as to allow them the best chance of living out their plans and aspirations. While clearly not the same objective as QALY maximisation, it does have a broad-based efficiency element to it and again illustrates that decision-makers have choices as to what arguments are included in the social welfare function.

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[130] Note that in the Harris version, people would not be denied life-saving intervention if they wish access to it and if resources were available (OFIA only operates where choices *have* to be made and candidates are either side of the specified cut-off age).

[131] Note, however, that a concern for distributive equity would arise during any implementation of PLA, because it would inevitably involve treating people differently depending on the cohort they belonged to.

8.2.3 Acceptance of models based on equity

It is important to note that while well argued at the conceptual level, particularly in relation to the concept of benefit and its moral underpinnings, age-based models of priority setting have not proven popular. All three models considered here are untried as practical approaches to priority setting. Some countries have openly announced their opposition to any form of rationing based on age (eg Sweden (The Swedish Parliamentary Priorities Commission 1995)), while many influential organisations have adopted a similar position (eg (British Medical Association 1993)). For some this reflects a preference for prioritising interventions rather than individuals, while for others it reflects practical considerations (such as the heterogeneous nature of individuals and their lifespans) and the disregard of outcomes for those above the cut-off age[132].

Needs-based models, on the other hand, appear to have gained widespread acceptance and application. Whereas age-based rationing requires the identification of a particular population group who would be denied access to cure interventions (but not care interventions); rationing by need allows all individuals the possibility of access to all interventions, dependent only on their particular "needs". Setting priorities on the basis of personal characteristics, rather than on the basis of the characteristics of the treatment, is offensive to many. As a consequence needs-based rationing, even though its conceptual rationale is less developed, has proven far more acceptable than age-based rationing.

8.3 Consensus as the basis for priority setting

Interesting endevours at explicit priority setting in health care have also been undertaken by behavioural scientists in Australia, focused on the achievement of consensus. As discussed in Chapter Six (refer Sections 6.3.2 to 6.3.4), an important example of this consensus approach was developed in 1992 by researchers in the Hunter Region of NSW in response to the need to identify priority areas for health promotion for women. What they termed a "three-stage model" (Brown and Redman 1995) enabled epidemiological data on disease incidence and distribution, together with views from the community, to be synthesised and integrated with those of experts from health and social services (key informants) using a nominal group process (Delbecq and Van der Ven 1971). While focussed on goals and targets, its proponents believe the method appropriate to inform resource allocation decisions, and their consensus-based approach has certainly influenced several other attempts at explicit priority setting (Redman, et al. 1997; NCCI 1998). For this reason their "three-stage model" was selected for inclusion in Part C.

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[132] Cassel, for example, argues that decisions should be based on prognosis rather than on the basis of age (Cassel 1992). Seigler is concerned with limiting care to the elderly because it threatens to

Table 8.2: Summary of performance of age-based models against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	The age-based models put forward by philosophers all address the issue of choice in the face of resource scarcity, but do so at an in-principle level, rather than in the context of practical decision-making. Discussion focussed on the micro level and on intra-personal choice. Extrapolation to other levels of decision-making and to inter-personal comparisons may not be appropriate.
Clear concept of benefit	The age-based models give very careful consideration to the appropriate objective of health care and to the associated concept of benefit. They demonstrate subtle and complex arguments, with detailed philosophical underpinnings.
Process for generating options for change	There is no process for generating or selecting options for chance. The focus of these models is on the concept of benefit.
Marginal Analysis	Not utilised
Clear decision rules	OFIA and PLA are based on the specification of an age cut-off as to what constitutes a "fair innings" and associated moral arguments that govern its application. PLA based on prudential reasoning over individual's life span. These approaches are not consistent with QALY maximisation or distributive equity between individuals.
Role of judgement	Clearly specified in relation to concept of benefit.
Data needs tractable	Not considered, as these models have remained theoretical models argued at the conceptual level. Is likely to require much less data than other technical approaches.
Due process	Offer explicit reasoning for objective and concept of benefit. Other aspects of due process not addressed.
Rigorous approach to measurement	This issue has not arisen, as models have not been applied or moved beyond conceptual level. May need to be combined with measurement techniques from other disciplines to be operationalised.
Reporting issues of concern to decision-makers	Models not applied in practical context. Treatment of cost and practical feasibility/acceptability issues remains to be demonstrated.
Overall assessment	**These models are well thought out in relation to the concept of benefit, but have not proven popular in practice. Applied priority setting has focused on interventions that should be given priority, rather than individuals who should be given priority. The age-based rationing models assessed have not been developed into full models of priority setting for practical application.**

The first step of the model involved the review of epidemiological data on women's health available for the local population. In the second step a community survey of women's perceptions of their health and health care needs was carried out. The third step involved the use of the nominal group process with two parallel groups of key informants. The two expert

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undermine traditions of clinical medicine, based upon medical need and patient preferences (Seigler 1984).

committees were recruited from a range of professional and community groups, which were each asked to nominate two representatives. One from each pair of nominees was then randomly allocated to each committee. At the first meeting each committee was given an explanation of the target-setting process, examples of targets previously set and principles of target selection[133]. A nominal group process was then used to identify high-priority women's health issues. The nominal group process was selected as it offered "nominal opportunity" for discussion and for achieving consensus in circumstances where opinion-based processes were needed to complement quantitative data (Brown and Redman 1995). This involved each person being asked, in turn, to offer and defend one priority area; this was repeated around the group until no further priorities were generated. The investigators then undertook to review the nominated priorities and to group them to remove repetition.

At their second meeting each committee ranked the priorities, aided by information supplied on available epidemiological data and the community survey. This was done by asking each person to select five priorities and to allocate five, four, three, two or one point(s) to each, in order of importance. Before the third and final meeting of each committee, the investigators undertook a literature review relating to each of the ten targets identified as having highest priority. Existing data was then used to brief the committees on possible interventions and performance indicators.

At the final meetings of the two groups, informants were given the information on the top ten priorities and reminded that the targets needed to be amenable to health promotion action that could be evaluated to determine its impact on health status. At the end of the meeting the groups were again asked to rank the proposed targets using the five-point voting system.

The nominal group process adopted thus ensured that each committee member had an opportunity to propose his or her perceived priority, and that each received discussion. The reliability of the method was investigated by comparing the results for the two committees. The group of targets chosen by the two committees was remarkably similar, although the ranking of each target certainly differed. The investigators were impressed with their results, concluding:

> *"The model used in this approach to setting targets for women's health could now be adopted for use in a wide variety of health and health care settings. In addition to its potential use in health promotion, it might also find application in determining health care priorities in local areas, where there would be advantages in having broader community input into the determination of resource allocation for health care." (p. 269) (Brown and Redman 1995)*

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[133] The target setting principles were: i) targets should reflect the prevalence and severity of the problem in the Hunter Region; ii) targets should be amenable to health promotion action using existing local resources, expertise and interest (plus there should be strong evidence that these interventions are effective and cost-effective); and iii) targets must be defined in such a way that they can be evaluated.

The three-stage model presented clearly has some advantages in terms of its potential to achieve consensus; to synthesise important data sets; to involve community input; and to achieve legitimacy for the results in the eyes of stakeholders. Aspects of its operation are, in fact, quite similar to the way the economic approach of PBMA can be carried out (Peacock, Richardson et al. 1997b; Carter, Stone et al. 2000). These include the reliance on a working group of key informants to assess information and to make judgements about the merit of various options before it; the use of a research team to assist the working group by assembling key data sets; and a set of criteria to guide the working group in its deliberations.

There are, however, also some important differences that from an economic perspective would compromise the role of the three-stage model as a guide for resource allocation decisions. These relate principally to the type of information provided to guide decision-making (eg. omission of cost data); the omission of marginal analysis; the lack of precision in how criteria were to be used in ranking options; and the primary focus on size of the problem rather than on health gain. While the principles for target selection included a generic reference to effectiveness and cost-effectiveness, it is by no means clear how these judgements were informed or their intended weight in the ranking process. Note also, that interventions were chosen by the supporting research team, not by the Working Party, and did not appear to cover both increments and decrements.

Table 8.3 provides an assessment of this consensus-based approach against the checklist. It is concluded that while the three-stage model clearly has potential, it is another illustration of where inter-disciplinary cooperation would have yielded a superior approach. Inclusion of marginal analysis and economic data, for example, could have achieved a form of PBMA where the behavioural scientists' strength in achieving consensus and stakeholder satisfaction, was blended with the technical strength of economic evaluation in guiding resource allocation decisions.

8.4 Concluding comments on models proposed by non-economists

While the models reviewed have innovative aspects and demonstrate merit in relation to some of the criteria in the checklist, none perform well against all the criteria. All the models proposed by non-economists have serious weaknesses that compromise their credentials as stand-alone guides for resource allocation, particularly as guides to purchasing decisions. They are best utilised in combination with an economic approach that provides decision rules based on marginal analysis, preferably one that satisfies the ten criteria set out in the checklist. Chapter Nine addresses the question of whether an economic model currently exists that meets this challenge.

Table 8.3: Summary of performance of consensus model against checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting	Applications illustrate this is achievable with the "three-stage model". Note, however, that potential of this model to apply to purchasing decisions (as opposed to selecting targets or work programs) not yet demonstrated[134].
Clear concept of benefit	Approach to date has focused more on prioritising the problem, rather than prioritising interventions. There is a lack of precision at present in defining criteria and their relative weight in the voting process.
Process for generating options for change	Selected by research team in response to problems/targets prioritised by the Working Party. Mechanism and criteria for selection of options not specified. While "opportunity cost" implicit in voting process, compromised in option selection process.
Marginal Analysis	Not utilised.
Clear decision rules	Rules of nominal group and voting process are clearly specified. Relationship between selection criteria and vote not made explicit. Links between vote and purchasing implications not clear (i.e. no budget information provided; no cost data provided; no apparent decision rule to guide purchasing decisions).
Role of judgement	Clearly specified in relation to voting process and nominal group approach. Model well positioned to achieve consensus for opinion-based judgements, although clarity in use of decision criteria could be improved.
Data needs made tractable	Working Party assisted by research team. Data process places reliance on readily available epidemiological data and key informant judgements. Efficacy and efficiency data based on literature review. Only community survey involves substantial data collection issue.
Due process	Major strength of this model. Demonstrated effective capacity to satisfy concerns of "due process". Stakeholder participation and effective involvement encouraged by nominal group approach.
Rigorous approach to measurement	Acceptable in some aspects, but very questionable on others (such as efficacy data on interventions; economic evidence on interventions; lack of precision in decision rules).
Reporting issues of concern to decision-makers	Achievable within research question adopted. Reflects strength in achieving consensus. Note weaknesses in efficacy and efficiency may impact here.
Overall assessment	**Offers important strengths in achieving consensus and effective stakeholder participation. Role in assisting purchasing not substantiated at this time. Best utilised in combination with an economic approach, if intended as a model of priority setting to aid purchasing decisions (as opposed to selecting targets or prioritising problems).**

[134] The National Cancer Control Initiative (NCCI 1998) discussed in Chapters Six and Twelve was a consensus-based approach applied to prioritising interventions, but was different in significant ways to the three-stage model reviewed here. Key differences include: clear specification of the option generation process; utilisation of a multi-stage filtering process, rather than the nominal group technique and Delphi-style voting; provision of COI data in addition to BOD data; and active involvement of a management committee in addition to stakeholder-based working parties.

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Chapter Nine: Models of Priority Setting Proposed by Economists

9.1 Introduction

In this chapter existing economic approaches to priority setting are briefly outlined and assessed against the ten criteria of the checklist. As with Chapter Eight, it would be difficult in the available word limit to present and assess all the possible models and their various permutations. Instead, the chapter focuses on four key approaches that are the best credentialed for the specific decision context of priority setting, viz: League Tables; PBMA; the Health Benefit Group/Health Resource Group Model; and the Disease-Based Framework.

In considering these four economic approaches, it is important to appreciate that the selection of appraisal techniques (discussed in Section 4.3.3) and the selection of the decision-making process within which the results of the appraisals are brought together and ranked, are two separate but related components of priority setting. Priority setting approaches such as PBMA or League Tables are not appraisal techniques per se, but rather provide a framework for ranking, within which various techniques for assessing value (such as CBA; CEA; CUA; Options Appraisal; etc) can be placed. The level of attention given to appraising individual interventions in these approaches, together with the source of those appraisals (i.e. whether based on a review of the literature or carried out as part of the model) are important distinguishing characteristics.

9.2 League Tables

In recent years it has become common practice for the results of economic evaluations to be brought together to provide a "league table", in which the interventions are ranked in order of their cost per life year or cost per QALY results. Decision rules for achieving economic efficiency using cost-effectiveness analysis are well-established (Dasputa and Pearce 1972; Johannesson and Weinstein 1993; Weinstein 1995), although not without dispute in relation to their practical application (see below). Drummond et al. (Drummond, O'Brien et al. 1997) report that the first published ranking or "league table" for the UK was that derived by Alan Williams (Williams 1985), but many others have followed in a number of countries and in a variety of decision contexts[136].

There are two separate reasons evident in the literature behind the league table approach. First, analysts undertaking an appraisal of an individual intervention may wish to look for some indication of the opportunity cost of their intervention in the relative cost-effectiveness of

[136] See, for example, (Torrance and Zipursky 1984; Australian Health Ministers' Advisory Council 1990; Australian Health Ministers' Advisory Council 1991; Maynard 1991; Schulman and al. 1991; Tengs and Adams et al 1995; George, Harris et al. 1999).

other programs. Comparing the result of an individual appraisal against other results can help analysts and decision-makers develop a sense of what constitutes reasonable value-for-money, by seeing how resources are currently being utilised. As discussed in Chapter Four, this stems directly from the fact that CEA/CUA provide rankings rather than absolute assessments of worth. To assess worth from CEA/CUA requires a social judgement as to willingness-to-pay for a health outcome. Use of such a shadow price, however, raises the important issue of whether the outcome measure satisfactorily captures all relevant benefits of the health care program (as well as the broader question of whether it reflects all arguments in the social welfare function).

Second, some analysts develop league tables in order to inform decisions about the allocation of health care resources between various options for change – that is, to guide priority setting involving multiple interventions. Alan Williams, for example, in his 1985 study divided various health care interventions into strong candidates for expansion and less strong candidates on the basis of their cost per QALY results (Williams 1985). Laupacis and colleagues took a slightly different track in arguing that health technologies could be classified into five grades of recommendation based on their cost per QALY result (Laupacis, Feeny et al. 1992).

Provided programs display constant returns to scale, the league table can, in theory, be used to allocate a budget across programs efficiently. In the presence of a fixed budget, programs can be implemented in sequence from the top to the bottom until the budget is exhausted. The last program chosen determines the cut-off value or shadow price of the health gain. The simple case of a decision-maker presented with a fixed budget and a complete set of divisible program choices is rare however. The more usual approach is to use a critical or cut-off value of the cost-effectiveness ratio derived from other than the true shadow price of the marginal intervention. Weinstein, for example, identifies a number of approaches used to derive this shadow price, of which the most common are comparisons with other programs, rules of thumb, and inference from past decisions (Weinstein 1995).

Economists have urged caution, however, in the use of league tables, particularly to inform priority setting. Four reasons are discussed in the literature, viz:

- First, for the information in league tables to be of use to decision-makers, they need to be confident that the methodology of the source studies is sound and that it is relatively homogeneous across the various studies (Gerard and Mooney 1992; Drummond, Torrance et al. 1993; Mason 1994). The aim is to ensure that the economic merit of interventions evaluated is not confounded by differences in the evaluation approach and associated assumptions.

- Second, those league tables compiled from a review of the literature often include studies from a range of settings and economic data may not be easily transferable from one setting to another (Gerard and Mooney 1992; Drummond, O'Brien et al. 1997).
- Third, there are issues associated with the practical application of decision rules in the presence of indivisibilities and a budget constraint which warrant caution against simplistic interpretation[137] (Birch and Gafni 1992; Birch and Gafni 1993; Johannesson and Weinstein 1993; Drummond, O'Brien et al. 1997).
- Fourth, there are also concerns as to whether the adoption of a cost-effectiveness threshold (or shadow price) is wise, given that the shadow price would not be independent of the size of the health program being considered (Laupacis, Feeny et al. 1992; Gafni and Birch 1993; Naylor, Williams et al. 1993).

Economists who have assessed the source studies combined in well-known league tables have found considerable variation the methodologies used (Drummond, Torrance et al. 1993). Drummond reports that the key methodological features where consistency is important are: i) choice of discount rate; ii) the method for estimating health state preferences; iii) the range of costs and consequences considered; and particularly iv) the choice of comparison program (Drummond, O'Brien et al. 1997). The validity of any attempt to incorporate a league table into priority setting is contingent upon consistency in the methodology used. This is an important qualification that will clearly vary from table to table. Priority setting approaches that are reliant on reviews of the literature for their CEA/CUA results will be much more vulnerable to confounding through methodological variation, than approaches (like MEEM) that conduct their own CEA/CUA as part of the priority setting process.

Notwithstanding the challenges of achieving methodological validity and consistency, a number of authors have challenged whether cost-effectiveness decision rules are workable in practice using league tables. Birch and Gafni, for example, argue that issues of program divisibility and returns to scale will compromise the decision rules in real life (Birch and Gafni 1992; Birch and Gafni 1993). Others, like Johannesson and Weinstein (Johannesson and Weinstein 1993) are satisfied that the decision rules give close enough approximations. Drummond argues that:

> *"[T]heoretically a cost per QALY league table can provide comprehensive and valid information to inform resource allocation decisions",*

but also acknowledges that

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[137] Such as moving from the top of the table down the list of possible interventions until the entire budget is exhausted. Selection on the basis of average CEA/CUA results ignores the importance of marginal analysis (variation with patient needs; population sub-group; program size and design; health service setting; etc); and non constant returns to scale and indivisibilities also means that selection is not independent of financial cost (i.e. share of the budget utilised and its opportunity cost).

"Such a table would require listing all existing and potential treatments, for all patient groups, at all feasible levels of program scale or intensity, calculated using standardised comparable methods". (Drummond, Torrance et al. 1993).

Analysts and decision-makers cannot possibly, of course, imagine and compute all possible combinations of interventions or programs, and judgement is clearly required to determine key design elements in order to make decisions in an incremental fashion. Ultimately, in the absence of a fixed budget, the league table is not decisive in determining whether an intervention should be implemented. The decision on what value is attached to programs requires an independent judgement about the willingness-to-pay for health gains. As mentioned above, this not only involves society's willingness-to-pay for a QALY, but also broader issues involving what society wants from its health care system.

A summary of the performance of league tables assessed against the checklist is provided in Table 9.1. It is concluded that the concept of ranking interventions on the basis of their economic merit is inherent in most models proposed by economists and league tables are potentially important in this role. League tables need to be handled with caution, however, both in terms of their technical validity and the weight placed on ratios based on a narrow interpretation of benefit and implicit value judgements. League tables are more likely to make a positive contribution if utilised within a broader approach to priority setting that involves distributive equity, procedural justice and macro economic evaluation based on a protocol specifically designed for a multiple intervention decision context.

Table 9.1: Summary of performance of league tables against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	Clarity in research question, together with scope, perspective and context varies from table to table. League tables are adaptable to problem setting and context, and are sometimes incorporated into other broad-based approaches to priority setting (such as PBMA). Well-designed research question is potentially achievable with league table approach to priority setting.
Clear concept of benefit	Few league tables explicitly consider priority setting objectives and what this means for the concept of benefit. Most league tables simply assume a "health gain" definition of benefit, with no attention to broader issues such as distributive equity or procedural justice.
Process for generating options for change	There is no in-built mechanism in league tables for option generation and selection. Selection process varies from analyst discretion (literature review based league table) to dictates of problem context (PBAC league table). Rationale for option selection is rarely well documented.
Marginal Analysis	Most league tables report average CEA/CUA results, rather than marginal analysis. Decisions based on averages, especially when condition/treatment pairs involve disparate patient groups, are unlikely to maximise community benefit. This is more a criticism of current practice than intrinsic to method.
Clear decision rules	Incorporates decision rules for priority setting in situation of resource scarcity. Not decisive in absence of budget constraint, without pre-defined

	shadow price. Opinion varies about appropriateness and practicality of using shadow price of societal willingness-to-pay for health gains.
Role of judgement noted and clearly specified	Performance varies between tables. The better studies would make explicit the role of judgement in specification, application and interpretation of the technical analysis. Many league tables have substantive implicit elements, as evidenced by PBAC and Oregon. Ethical issues rarely made explicit
Data needs made tractable	Many league tables simply rely on reviewing the economic literature as the source of studies. There is no other mechanism to make data needs tractable, unless league table is incorporated into broader approach where such mechanisms exist (such as MEEM).
Due process	There is no consideration of "due process" or discussion mechanism inherent in the league table approach, unless it is combined with a broader approach to priority setting.
Rigorous approach to measurement	Performance varies from table to table. League tables based on a literature review would be susceptible to confounding due to variation in methods and setting of source studies. Rigorous and balanced approach to measurement is potentially achievable, however, particularly if appraisal is part of the priority setting approach. This in turn raises issue of data tractability.
Reporting issues of concern to decision-makers	Some issues of concern to decision-makers not covered by basic league table approach, unless part of broader approach (i.e. financial cost; distributive equity; feasibility; acceptability to stakeholders).
Overall assessment	**League tables need to be handled with caution, both in terms of their technical validity and the weight placed on ratios based on a narrow interpretation of benefit and implicit value judgements. League tables are more likely to make a positive contribution if utilised within a broader approach to priority setting that involves distributive equity, procedural justice and a macro economic evaluation protocol specifically designed for a multiple intervention decision context.**

9.3 Program Budgeting and Marginal Analysis (PBMA)

Program Budgeting and Marginal Analysis (PBMA) is an approach to priority setting specifically designed as a practical guide for decision-makers in the planning and provision of health services. The starting point for most PBMA studies has been to examine how resources are currently spent before focusing on incremental gains and costs of changes in that spend, through comparison across or within programs (Donaldson and Farrar 1993). As John Deeble comments:

> *"It is in many ways a formalisation of some similar bureaucratic methods but with additional rigour, a concentration on resource allocation at the margin rather than on whole programs, and, sometimes, an extension beyond provider preferences to include those of consumers and the community as well." (p. 17) (Deeble 1999)*

The basic PBMA methodology involves (after (Deeble 1999)):

- Establishment of a Working Party (and possibly Steering Committee) to undertake the study;
- Defining programs and sub-programs (services) within them;
- Defining program and sub-program objectives;

- Establishing some indicators of achievement that reflect the objectives;
- Establishing program and sub-program costs;
- Identifying options for marginal change, i.e. increases and decreases in program/ sub-program activity, including new options;
- Identifying marginal costs (or savings) of increased (decreased) activity;
- Identifying the benefits to be gained or lost from each of the options for change; and
- Choosing the combination of changes (both increments and decrements) which is expected to yield the greatest benefit with available resources.

In practice the question of whether current resources are being used optimally is generally formulated in terms of how to allocate relatively small increases or decreases in expenditure – of say 5% to 10% around the current level. This is of course the process nominally followed by most bureaucracies, but without the clarity and marginal analysis that PBMA offers.

It is clear from a growing literature on PBMA, both domestic and overseas, that substantially different evaluation approaches have emerged within this overarching framework. While the steps in conducting a PBMA are broadly similar between studies, rigour in the selection of options, in the consultation/bargaining process[138], in the measurement of costs and benefits, and in the level of evidence demanded, all vary substantially. While PBMA was first mooted[139] in the 1970s (Pole 1974; Mooney 1977), it must still be regarded as a developing technique whose credentials are yet to be firmly established. During the 1980s, PBMA received little attention (Craig, Parkin et al. 1995; Donaldson, Walker et al. 1995), and its resurgence in the 1990s can be attributed to health system reforms in the UK. The purchaser/provider split initiative created the incentive for UK health economists to provide regional health authorities with an economic approach to purchasing that was tractable and user-friendly[140]. Advocates of PBMA believe it provides a practical way of applying the economic principles behind the achievement of allocative and technical efficiency, by utilising best available evidence in an open and systematic planning process. Studies have been undertaken to address both vertical and horizontal priority setting, although the former (called vertical or micro PBMAs) are far more common and easier to undertake (Mitton and Donaldson 2000). This experience supports the international experience reported in Chapter Six (particularly New Zealand, The Netherlands and the Nordic countries) where economic evaluation was increasingly focussed on interventions dealing with the same disease or problem, often within the context of developing guidelines or technology assessment.

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[138] The Working Party, for example, plays a central role in PBMA, yet there is little guidance available on appropriate membership, how discussion should be conducted or consensus achieved.
[139] The origins of PBMA can in fact be traced back to the Planning, Programming, Budgeting Systems (PPBS) of the 1960s, which was popular in the US bureaucracy until its demise (Hilleboe, Berkhuus et al. 1972; Cutt 1974; Lockett, Raftery et al. 1995; Hollinghurst, Bevan et al. 1999).
[140] See, for example, (Donaldson and Mooney 1991; Mooney, Gerard et al. 1992; Sheill, Hall et al. 1993; Madden, Hussey et al. 1995; Radcliffe, Donaldson et al. 1996).

Most attempts at PBMA have relied on local subjective judgements for assessing the effectiveness of options for change, and for some observers this, together with the possibility of "gaming"[141] and/or reinforcement of the status quo[142], has undermined their credibility (Coast and Donovan 1996; Posnett and Street 1996; Peacock and Edwards 1997c). The pragmatic origins of PBMA have contributed to the view by some of its advocates that those sources of information readily available be used in any given study (Scott, Donaldson et al. 1999). This evidence may be taken from the literature, but is more likely to involve local expert opinion. Other researchers, however, have sought to improve the evidence base (Carter, Stone et al. 2000) in line with the growing acceptance of the evidence-based medicine movement. Similarly, attempts have also been made to improve the methods by which multiple objectives are specified and brought together into a single benefit score, in order to increase the rigour of the PBMA methodology (Peacock, Richardson et al. 1997b; Edwards, Peacock et al. 1998). More objective information on options, costs and their benefits also reduces the potential for gaming. Gaming works best in situations where power and knowledge are unevenly distributed and more formalised processes would help diffuse them (Deeble 1999).

It needs to be acknowledged, however, that these improvements require a research capacity (i.e. a research team assisting the Working Party) and may detract from PBMAs user-friendliness. Irrespective of its evidence base, it is argued by advocates that PBMA allows the concept of benefit to be related to program objectives and local context, and for the key economic principles of marginal analysis and opportunity cost to be applied in a practical way (Mooney, Gerard et al. 1992). In reality, what quality of evidence is deemed acceptable, will depend largely on the research question, the setting and the stakeholders for whom the results need to have legitimacy.

Given this background, it should come as no surprise that the PBMA technique is regarded as having important potential, but that there is as yet no large-scale commitment for its application. While there are certainly advocates of PBMA (including the present author), much remains to be done before PBMA could be recommended as an established and effective priority setting technique. There are, for example, no critical appraisal guidelines published anywhere that prescribe what constitutes an acceptable or rigorous PBMA study (let alone widely accepted guidelines, such as those published on conventional economic evaluation techniques (Drummond, O'Brien et al. 1997)). There are very few published assessments of the impact of PBMA studies on decision-making or of the various factors that influence that

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[141] Deeble suggests, for example, that when proposals for additional funding are sought, currently popular or professionally interesting issues are likely to dominate; whereas when reductions are in prospect, the most strategic behaviour is to put forward those which are most likely to be refused on equity grounds, or if accepted, are the easiest to manage (Deeble 1999).

[142] Coast has noted that a strong reliance on "expert group" processes runs the risk of reinforcing the status quo and reflecting the views of the most articulate or those with most status. (Coast and Donovan 1996)

impact (Mitton and Donaldson 2000). Nonetheless, PBMA is an important part of the economic toolkit and its development deserves ongoing attention. The key issues that emerge from a growing literature on Australian and international experience are:

- A variety of approaches have been used under the general PBMA framework, particularly in regard to the source and quality of data on efficacy/effectiveness, and the way in which benefit is defined and measured;
- Most PBMA studies have focussed on vertical priority setting (i.e. within programs), rather than addressing the more challenging horizontal priority setting across different programs;
- Regardless of its pragmatic origins, successful implementation of PBMA requires resources and commitment, both from the auspicing organisation and from health economists involved in its trial. Where PBMA activity has commenced and fallen away, either in Australia or overseas, it has reflected the movement of key personnel, expertise or a PBMA "champion";
- There must be a recognition from health economists that in order for PBMA to be integrated into the management culture, the approach adopted must recognise and cater for managerial needs; including multiple objectives that go beyond health gain and its integration with ongoing management information systems. Links to the decision-making approach described in Chapter Four are apparent;
- Both overseas and Australian experience confirms that options for change that involve decreased expenditure are inherently harder to generate, assess and implement than increments. The involvement of personnel providing programs in the Working Party in order to draw on their expertise can contribute to this problem of taking the "tough decisions";
- Greater attention to the type and quality of information provided to the Working Party charged with making judgements (either by the provision of a small research team and/or option advocates) can increase the rigor of the decision-making process as well as participant satisfaction; and
- The process by which judgements are taken warrants further research, including the contribution which could be made by other disciplines (such as the nominal group technique of the behavioural scientists) and encouraging deliberative judgements through consensus and discussion, rather than the simple averaging of individual scores.

Table 9.2 presents a summary of the PBMA approach to priority setting assessed in terms of the checklist. It is concluded that the PBMA technique is capable of providing both a valid and practical approach to priority setting. Many of the criticisms of PBMA reflect more the "growing pains" of an evolving technique, than fatal flaws in its underlying structure or rationale. As with any evaluation approach, there is no simple "cookbook recipe" of how PBMA should be

applied in any given setting, and expertise in the selection of appropriate methods takes time and practical experience. PBMA is capable of performing well against most of the criteria in the checklist, with only the data tractability criterion standing out as an important reservation, once the current reliance on expert opinion is removed to achieve a more rigorous methodology. Other criticisms, such as lack of measurement rigour, inadequacies in option selection, narrow perspective and poorly developed marginal analysis (Segal and Chen 2001); are all resolvable within the PBMA approach, as evidenced by recent developments (Peacock, Richardson et al. 1997b; Carter, Stone et al. 2000). In this regard, it is important to bear in mind the important distinction between the logic and potential of an evaluation framework, and how well researchers have used it. The most rigorous of frameworks can be invalidated if employed in a very sloppy way.

A solution is also possible with the data tractability criterion. As with the League Table approach, PBMA also lends itself to combination with other approaches that do provide a means of resolving the data tractability issue. This is illustrated in Chapter Twelve, where the major case study application of MEEM incorporates the PBMA framework.

Table 9.2: Summary of performance of PBMA against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	Most PBMA studies have been undertaken at a regional or organisational level, but studies at the national level are also feasible. The horizontal/ vertical design options for PBMA provide flexibility for adaptation to various decision contexts and settings; although horizontal (or macro) studies have proven difficult to achieve in practice. PBMA can be undertaken as once-off study or institutionalised as ongoing planning process. Study perspective will vary between applications in accordance with context and setting.
Clear concept of benefit	Achieving a clear concept of benefit is a major strength of the PBMA approach, with clarification of objectives a basic step in the PBMA process. The Working Party provides the vehicle for discussion and clarification of the concept of benefit and underlying values with stakeholders. Broader objectives can be canvassed, and integrated using decision theory; options appraisal; or a two-stage approach.
Process for generating options for change	Discussion of option generation/selection is an important matter for the Working Party to discuss and decide. A more formalised process, involving a research team assisting the Working Party, is an important way of improving the comprehensiveness and rigour of the option selection process and controlling "gaming" or domination of Working Party discussion. PBMA can be undertaken as an iterative and ongoing process to increase coverage of current activities and options for change.
Marginal Analysis	PBMA is based on the fundamental economic principles of marginal analysis; opportunity cost; and clear concept of benefit. The level to which marginal analysis is achieved will vary from study to study. Simplifying assumptions (eg that equate average and marginal changes for sub-groups) are not uncommon, but this is true for most applied economic evaluation work. PBMA can embody the full range of economic evaluation techniques.
Clear decision rules	PBMA applies standard optomisation rules of economics, although they maybe subject to adjustment to reflect broader objectives. Particular rules will depend on evaluation technique utilised (i.e. CEA; CUA; CBA; options appraisal). Any modification of standard decision rules should be clearly

	specified.
Role of judgement noted and clearly specified	Performance on this criterion would vary between studies. The better studies would make explicit the role of judgement in specification, application and interpretation of the technical analysis and any broader issues taken into consideration. Scope exists for the clarification of ethical values in Working Party discussion, but such discussion would not be commonplace at present.
Data needs made tractable	Data needs are made tractable at present through undue reliance on opinions of Working Party, but this practice may compromise validity of conclusions and confidence in PBMA approach (Peacock and Edwards 1997c; Segal and Chen 2000). Undertaking an evidence-based approach will require research support for Working Party and may require linking PBMA with other approaches (such as MEEM) that incorporate a macro evaluation protocol and in-built mechanism for resolving data needs. Institutionalising PBMA at organisational level will require linkage with existing financial and statistical collections.
Due process	PBMA provides a mechanism, through the Working Party, to give consideration to issues of procedural justice. Most studies endevour to make their methods explicit. Nature and degree of involvement of stakeholders (including community representation) varies between studies.
Rigorous approach to measurement	Performance varies from study to study. Has been a point of major criticism of early PBMA studies, which relied on judgement rather than evidence for assessing intervention performance (Peacock and Edwards 1997c; Segal and Chen 2000). Rigorous and balanced approach to measurement is achievable, however, with PBMA approach. Merit of the PBMA framework needs to be distinguished from how some researchers have chosen to employ it.
Reporting issues of concern to decision-makers	All issues of concern to decision-makers are potentially covered by PBMA approach, although performance would inevitably vary from study to study. Evidence to date suggests addressing organisational and managerial issues will be central to successful implementation (Mitton and Donaldson 2000).
Overall assessment	**The PBMA technique is capable of providing both a valid and practical approach to priority setting in many contexts. The criticisms of PBMA reflect more the "growing pains" of an evolving technique, than fatal flaws in its underlying structure or rationale. Criticisms such as lack of measurement rigour, inadequacies in option selection, narrow perspective and poorly developed marginal analysis; are all resolvable within the PBMA approach, as evidenced by recent developments (Peacock, Richardson et al. 1997b; Carter, Stone et al. 2000). Important to distinguish between merit of the evaluative framework and how well the framework has been utilised.** **Data tractability, however, will be a problem once the current reliance on expert opinion is removed to achieve a more rigorous methodology. Evidence to date suggests addressing organisational and managerial issues will be central to successful implementation.**

9.4 The Health Benefit Group/Health Resource Group Approach

As with PBMA, the Health Benefit Group (HBG)/Health Resource Group (HRG) approach was one of a range of tools established by UK economists to help inform resource allocation decisions in the new internal market (Sanderson 1996; Sanderson and Mountney 1998; Mountney 1999). The HBGs are designed to categorise the population on the basis of their need for healthcare. HBG categories, for example, would normally cover the following:

"population not at risk"; "population at risk"; "population with symptoms"; "population with confirmed disease"; and "population with ongoing consequences" (Beaver, Williams et al. 1999; Deeble 1999; Northern Territory Health Services 1999).

The HRGs (similar to casemix) are treatment/ intervention groups that are clinically similar and use similar amounts of resources (i.e. interventions within each group are resource homogeneous). The general approach is to select a disease and to map HRGs onto the HBGs as a matrix so that health care needs and their resource consequences can be planned. The rows describe the types of service available and the cell entries are the cost of resources used at each level of care (see Figure 9.1). Thus for the "population not at risk" health promotion interventions are available; for the "population at risk" illness prevention/screening interventions are available; for the "population with symptoms" investigation and diagnosis procedures are available; for the "population with confirmed disease" clinical management procedures and services are available; and for the "population with ongoing consequences" continuing care services are available.

Figure 9.1: Health Benefit Group (HBA)/ Health Resource Group (HRG) approach

Services	Not At Risk	At Risk	Symptomatic	Acute Illness	Chronic Illness/ disability
Promotion Prevention Investigation & Diagnosis Acute treatment Continuing care Palliation					

Source: Based on (Beaver, Williams et al. 1999; Deeble 1999)

The UK NHS has conducted pilot studies in which multi-disciplinary teams have worked through major conditions such as cancer, CHD and stroke (Mountney 1999). The Northern Territory Health Service has developed a computer-based HBG/HRG model with an illustrative application in diabetes (Beaver, Williams et al. 1999; Northern Territory Health Services 1999). Based on a descriptive mapping of current health status and management patterns, the future call on health care resources can be investigated. The aim is to investigate where health care resources could be invested in the disease pathway from prevention through to palliation for greatest return in terms of health gain and cost per DALY (or other nominated objectives). There seems to be an assumption in these models that doubling or halving expenditure will in turn double or halve outcomes. Assuming such a linear

relationship focuses particular attention on how homogeneous the HBGs and HRGs really are.

While a model that matches packages of services with the needs of consumers is conceptually appealing as a planning aid, the "devil is in the detail" in terms of its use as a realistic aid to priority setting. The key problem for the NT model at this stage of its development is the heroic assumptions about homogeneity of the broad benefit and resource categories. The model does not yet incorporate specific interventions, but rather makes very broad-brush assumptions about cost, efficacy, and health gain for population groups receiving a broad category of care. In the illustrative diabetes study, for example, the following baseline average estimates were used as cost of care per head per year:

- Population not at risk (i.e. health promotion): **$4**;
- Population at risk (i.e. illness prevention): **$7**
- Population with symptoms (i.e. investigation): **$1,707**;
- Population with confirmed disease (i.e. acute care): **$12,426**; and
- Population with ongoing consequences (i.e. chronic care): **$559**.

The efficacy/benefit assumptions are similarly broad-brush, based on the judgement of medical providers/advisors. Evidence to support the nominated impacts is not provided. While this is acceptable in an illustrative study to demonstrate the potential capacity of the model to explore investment scenarios, it would be strongly challenged, as with the early PBMA work, as the basis for applied decision-making. In terms of its analysis of allocative and technical efficiency, the challenge for the HBG/HRG approach is to define the HRG categories (and hence the options for change) in a way that makes marginal analysis meaningful. HRG categories that are too broad will sacrifice validity for ease of data collection. On the other hand, HRGs that are too finely grained may suffer the same problems as Oregon[143] in being able to find meaningful data sets to calibrate the model. While an approach that covers all diseases simultaneously is conceptually appealing, the heroic nature of that task will mean that in reality diseases will be covered one-by-one. In practice, the HRG/HBG approach has some similarities to the disease-based models discussed below.

Some commentators believe data availability is likely to remain a problem for the HBG/HRG approach in Australia for some time to come (Deeble 1999; Segal and Chen 2000). John Deeble notes, for example, that there are significant differences in the way in which conditions are perceived and recorded at the various levels of the Australian health care system. Much of the health promotion effort in Australia is not particularly disease specific, while in other

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[143] The Oregon experience discussed in Chapter Six demonstrated that more detailed classification systems that have hundreds of condition/treatment pairs suffer criticism because of data paucity in the face of the heterogeneity of patients and their needs/outcomes.

services diagnostic refinement ranges from broad systemic classification of presenting problems in primary care, to the detailed records of teaching hospitals (Deeble 1999). The HBG/HRG model has large data needs and the information content is likely to be limited for some time to come.

Moving from the technical analysis, there are also important issues like the capacity of the HBG/HRG model to include distributive equity and other objectives of concern to the community. From the information available, it is not clear at this stage how broader concepts of benefit might be handled. One possibility for distributive equity is to consider segmentation of the population to identify target groups, but this would need to occur at all stages of the pathway and would require significant data to implement.

Table 9.3 presents a summary of the HBG/HRG approach to priority setting assessed in terms of the checklist. It is concluded that the main contribution of the approach to date, like the Irrawarregon discussed in Section 6.3.5, is as a planning tool to investigate the likely impacts of various scenarios. The approach has potential as an approach to priority setting, but would need to demonstrate its credentials in this role. More specifically, it would need to demonstrate its capacity to operationalise the HRGs in a way that allowed meaningful analysis of technical and allocative efficiency issues. Thought will need to be given to how to bridge the gap between broad brush HRGs and meaningful options for change at the intervention level. As with the league table and PBMA approaches discussed previously, significant scope exists for the HBG/HRG model to be coordinated with other approaches to priority setting that provide some of the missing elements. Coordination with MEEM, for example, would provide a mechanism to make the data needs more tractable, as well as help provide clarity in generation/selection of options for change and in the concept of benefit. Application of the HBG/HRG approach is ongoing in the Northern Territory. Whether implementation can be carried out in a way that encourages confidence in the assumptions and data inputs, and thus results of the model, is yet to be established.

In sum, as Segal and Chen have concluded:

> *"[T]he Northern Territory Health Service Model may provide a structure within which a health agency could explore alternative health strategies across an entire health sector. The capacity to develop the model to encompass data inputs of sufficient quality is yet to be established.... With a developed computerised system, it may be able to serve as a decision support system for health planners, especially in identifying the implied future resource requirements of addressing current health problems" (p. 54) (Segal and Chen 2000)*

Table 9.3: Summary of performance of HBG/HRG model against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	The research question is described broadly and allows various perspectives to be taken – societal; third party funder; or provider. Major contribution at present is as a financial planning tool rather than as a priority setting approach to guide purchasing decisions.
Clear concept of benefit	There is no in-built mechanism in the HBG/HRG approach to discuss and clarify concept of benefit with stakeholders. Current applications assume health gain as the primary benefit (NT project using the DALY). Broader objectives not canvassed, although the HBGs potentially allow distributive equity to be explored through targeting population sub-groups.
Process for generating options for change	Current models do not operate at the level of individual interventions, which compromises their credentials to guide specific purchasing decisions. This, together with data tractability, is an important reservation. Rationale for scenario development should also be documented with assumptions made explicit.
Marginal Analysis	The model adopts incremental analysis (in that scenarios are compared to the status quo) and the health needs of the population can be compared in terms of the stages of the disease pathway. The HBGs and HRGs assume homogeneity, however, and thus they need to be operationalised at a level where this is a meaningful assumption (as for DRGs). It is difficult for the approach at present to address technical efficiency, when it is not even operating at an intervention specific level. This is a key weakness at present.
Clear decision rules	Model would utilise the standard optomisation rules to the extent this was feasible. Model offers choice of what to optomise (i.e. health gains; cost savings; cost per DALY). The assumptions behind the cost and outcome estimates, however, may compromise their meaning.
Role of judgement noted and clearly specified	Judgement plays a major role in the specification, application and interpretation of the technical analysis. It is important that this is clearly specified. This has not yet been achieved.
Data needs made tractable	The HBG/HRG approach has large requirements for data that poses considerable problems. Data needs solved at present through broadly-based HRGs, reliance on provider judgement, modeling and simplifying assumptions. There is no in-built mechanism to make data needs tractable. As rigour in specification of the model improves this will prove to be an important problem.
Due process	Like most purely technical approaches, no consideration is given to issues of procedural justice. Nature of involvement of key stakeholders needs to be made explicit. Provider opinion seems to dominate current approaches.
Rigorous approach to measurement	Rigorous and balanced approach to measurement is achievable, but closely linked to the data tractability and marginal analysis issues.
Reporting issues of concern to decision-makers	Some issues of concern to decision-makers not covered by approach (i.e. particularly allocative and technical efficiency at the level of specific interventions). Coverage of broader issues (ethical values; feasibility; procedural justice; acceptability to stakeholders) not part of technical analysis.
Overall assessment	**The main contribution of the approach to date is as a planning tool to investigate the likely impacts of various scenarios. The approach has potential as an approach to priority setting, but would need to demonstrate its credentials in this role. More specifically, it would need to demonstrate its capacity to operationalise the HRGs in a way that allowed meaningful analysis of technical and allocative efficiency issues. Valid technical analysis should then be placed in a framework**

	that avoids a narrow definition of benefit and implicit value judgements (a problem that has compromised other approaches to priority setting). Significant scope exists for the HBG/HRG model to be coordinated with other approaches to priority setting that provide some of the missing elements.

9.5 The Disease-Based Framework (DBF)

The Disease-Based Framework (DBF) was developed by Segal and Richardson[144] (Segal and Richardson 1994; Segal 2000) as a specific attempt to meet the requirements of an ideal economic approach to priority setting. It is an ambitious model that seeks to establish desirable resource shifts that would minimise morbidity and mortality for all diseases and health problems, given current total resource allocation to the health sector. Moving sequentially through each disease/health problem, the goal is to establish priorities and desirable resource shifts for the whole health sector. Desirable resource shifts are based on marginal analysis, commencing with a selected disease, and working through each stage of the disease pathway and then across stages for identifiable population sub-groups (Segal 1997). It has been applied in detail to Non-insulin Dependent Diabetes Mellitus (Segal 2000) and at a broader level to colorectal cancer and hypertension (Segal, Robertson et al. 1997).

The key features of the DBF are:

- Its comprehensive scope (targeting all stages of all diseases – prevention through to palliation; all health delivery settings; all providers and funders; the whole population plus targeted sub-population groups);
- A systematic framework for an innovative staged approach and selection of options for change (staged by disease; by disease pathway; by identifying marginal interventions through quick CEA-based literature reviews; and focusing detailed CUA analysis only on marginal interventions);
- An endevour to be evidence-based and minimise reliance on opinion;
- A purely technical approach with clear decision rules but no in-built mechanism for discussion/consultation with stakeholders or recognition of "due process" issues; and
- Heavy data demands with no in-built mechanism (apart from staging the research task and focus on marginal interventions) to make these data needs tractable.

The DBF has similarities with the HBG/HRG approach in that it focuses on patient needs structured via the disease pathway, but the analysis is centred on specific health care

[144] Professor Richardson was Ms Segal's Ph.D. supervisor and is co-author on several publications.

interventions, rather than broad health resource groups. Figure 9.2 illustrates the approach with population sub-groups at key stages of the disease pathway (vertical axis) classified against health problems/disease groups (horizontal axis), and with individual health services (actual and potential) to be listed in the cells. Each column is intended to encompass all the potential interventions that may address the health problem or disease of interest.

Broadly, the model proposes each disease/health problem is studied separately (i.e. vertical priority setting); with the final phase involving comparison across all the diseases/health problems (i.e. horizontal priority setting) to eventually cover the entire health sector. The analysis of each disease/health problem involves a two-stage process whereby; first, the most marginal interventions (best and worst) within each pathway stage are found from an exhaustive list of options using best available information and quick CEA studies; and second, a more thorough evaluation using CUA is undertaken of the marginal interventions. Desirable resource shifts are established based on the detailed marginal analysis, first within each stage of the pathway; then between pathway stages; and finally across diseases. A consideration of equity is raised as an important element of the recommendation stage,

Figure 9.2: Disease-Based Framework (DFA) approach to priority setting

Disease Stage *Population or patient target*	Endocrine Disorders *Type 2 Diabetes, Type 1 Diabetes, etc*	Cancers *Breast, lung, etc*	Mental Health *Anxiety disorders; etc*	Cardiovascular *CHD, Stroke etc*	Other ICD-9 Diseases	Total Resource Use
Primary Prevention *Population at risk*						
Early identification *Persons with undiagnosed disease*						
Disease management and prevention of complication *Persons with established disease*						
Treatment of end-stage disease, palliative care *Persons with advanced disease*						
Total Resource Use						

Source: After (Segal and Chen 2000); p. 34

possibly through population sub-group analysis, but no clear process is provided for its clarification or implementation (either through QALY weights; hand adjustment as per Oregon; staged filters as per the Netherlands; or options appraisal; etc). Similarly, recognition is given to the importance of the community's view of "benefit" – that benefit is broader than simply health gain – but no process is discussed or provided on how these views would be obtained or integrated into the model.

Considerable attention is paid in the DBF to the development of a comprehensive list of intervention options and the importance of taking a societal perspective. A major objective of the model is to avoid the limitations that arise from a focus restricted by the viewpoint of a particular agency or third-party funder, or one that is restricted by existing health system funding and delivery arrangements. While laudable from an academic viewpoint, this may restrict the number of decision-makers for whom the model would have practical relevance. Government decision-makers may be well be prepared to adopt a truly societal perspective on occasions, but there are also other instances where they will seek advice from a more narrow perspective – such as a health sector perspective or a third-party payer perspective. While it can be argued that it is the economist's responsibility to argue for the societal perspective in all cases, there is also a strong case for supporting the needs of the decision-maker. Economic models need to be a little flexible on study viewpoint, preferably adopting a layered approach that provides results from a range of perspectives, thereby highlighting the trade-offs involved.

Use of literature reviews and provider consultations to help generate the comprehensive list of interventions is normal practice across a number of the priority setting approaches. Use of quick CEA analyses to select the most marginal interventions for detailed appraisal is an insightful and innovative aspect of the DFA, but does raise some issues for consideration. First, it means the interventions selected for detailed CUA appraisal on based on crude CEA appraisal (rather than the preferred CUA technique) and it is well known that different techniques may yield different rankings. This reservation would be overcome by iterative analysis at the detailed CUA stage, and while this is intended, it may be difficult to achieve and still make progress with the huge research task involved in covering all diseases. Second, the quick CEA analysis is literature-based and would be subject to same methodological confounding between the source studies that has plagued league tables. Third, the selection of options is researcher-based (albeit based on sound economic reasons) and may omit options for change of importance to decision-makers. The lack of a mechanism for stakeholder consultation (such as the Working Party of the PBMA approach) makes this a real possibility.

Framing the research question to encompass the entire health and community services sector and ensuring comprehensiveness in the selection of interventions were considered important

in the development of this model. Empirical experience in a variety of countries has shown this to be a very daunting task, however, in which economic evaluation has not fared well (refer Chapter Six). While the model, has some innovative aspects to stage the research task, there is no in-built data mechanism to make its potentially huge data needs more tractable. There are no databases, for example, that provide a common base case (i.e. status quo comparator) that can be used in all the quick CEA analyses required or in the detailed CUA analyses. There is no database of QALY weights established for the ICD-9 framework based on a common instrument (analogous to the DALY). If the huge research task involved in the DBF approach is to be made tractable, there must be some way of gaining massive economies of scale.

It needs to be acknowledged, however, that an important aspect of the quick "back of the envelope" CEAs to rank each stage and to find the marginal interventions, followed by data intensive CUAs only on the marginals, was to solve the data tractability problem. Unfortunately, this innovative approach has not generated the anticipated economies. The authors have found in their work to date that limitations in the available cost effectiveness literature has limited the effectiveness of this approach, as well as restricting the sensitivity of their marginal analysis. The data requirements of such ambitious technical approaches will remain a fundamental problem for some time to come.

Table 9.4 presents a summary of the DBF approach assessed against the checklist. It is concluded that the model represents a significant contribution as a technical approach to priority setting, with important innovative aspects worthy of careful consideration. Clarification of the theoretical foundation would be a useful refinement, together with confirmation of how confounding is avoided in the quick CEA analyses undertaken to find the marginal interventions. The DBF performs well against those criteria that relate to technical analysis, with the exception of providing a means to make its data needs tractable. As Deeble notes, this is "an ambitious proposal with large data needs" (p. 21) (Deeble 1999). As with the earlier economic models, this suggests the DBF may work well with an approach such as MEEM that provides such a mechanism through the establishment/use of standing databases. Further empirical experience with the model will help to clarify the importance of the data needs reservation, and possibly, the scope for collaboration with other approaches.

On those criteria that broaden the ideal features of a priority setting model beyond a purely technical approach, the DBF performs poorly. There is no surprise here, as these criteria were not taken into account in the model's development. There is, for example, no mechanism in the current DBF to discuss and clearly establish the concept of benefit. While a Working Party of stakeholders could help at the individual disease/health problem level, it is recognised that the broad scope of the model makes this a very challenging undertaking if consistency in benefit definition is to be achieved across the entire health sector. The

importance of distributive equity is recognised in the model, but there is no specific mechanism offered to integrate equity into the results of the marginal analysis. This is an important task for future development of the approach to clarify. There is no consideration given to the importance of "due process" or how procedural justice and ethical values might be integrated into the decision process. The lack of any Working Party or mechanism for stakeholder consultations leaves the model a heavily researcher-based approach, with little apparent weight given to decision-maker needs. This may create problems for the DBF in achieving relevance to decision-makers and impacting upon policy.

Table 9.4: Summary of performance of disease-based framework against the checklist

Criterion	Performance
Well-defined research question. Adaptable to decision context and setting.	The DBF has a well-defined (albeit very ambitious) research question. The model is designed for implementation at the national/state levels and takes a societal perspective. The model is not intended for use at an organisational level and consciously avoids adhering to institutional budgets or study viewpoints other than a societal perspective. Within the confines of its intended use, the model is adaptable to context and setting. Clear criteria exist for selection of disease sequence and staging of analysis.
Clear concept of benefit	The model focuses on health gain (life years in CEA; QALYs where CUA undertaken), but recognises the importance of equity and community values. There is no in-built mechanism for discussion with stakeholders on the objectives and concept of benefit. If community values not available recommends research be undertaken. Specific process proposed for combining elements of benefit not clear.
Process for generating options for change	Comprehensive and well-developed process for option generation and selection. While this is undoubtedly a real strength of this model, aspects of the quick CEAs undertaken to select the most marginal interventions are questionable (such as scope for methodological confounding due to reliance on the literature; possible neglect of options for change considered important by decision-makers).
Marginal Analysis	Strongly based on economic principles with heavy focus on marginal analysis and opportunity cost. Strength of marginal analysis may be constrained in practice by reliance on the literature and lack of in-built mechanism to make data needs tractable.
Clear decision rules	Clear decision rules for priority setting based on marginal analysis. Mechanism for inclusion of equity in decision rules not clarified (whether by QALY weights or some other mechanism).
Role of judgement noted and clearly specified	Intention is clearly to make explicit the role of judgement in specification, application and interpretation of the technical analysis. No mechanism for exploration with stakeholders of ethical values or broader aspects of benefit.
Data needs made tractable	DBF approach has huge data requirements because of its comprehensive scope and technical approach. There is a well-defined framework for staging the research task. Data tractability was to be achieved through innovation of "back of the envelope" CEAs to find marginal interventions at each stage; restricting data intensive CUAs to the margins. In case studies so far, however, approach has not generated expected economies. Heavy reliance on the literature remains a serious problem. There are no in-built databases as DBF is currently practiced to make the data needs more tractable, but this remains an option. Satisfying the data needs criterion is an important issue for the model as currently developed.
Due process	Like most purely technical approaches there is no consideration given to issues of due process. Nonetheless care is taken to make methods as explicit as possible and recognition is given to importance of community values. There is no in-built mechanism for stakeholder involvement.

Rigorous approach to measurement	Rigorous and balanced approach to measurement is potentially achievable with the DBF. Emphasis is given to evidence-based approaches and minimal reliance on expert opinion. Selection of evaluation techniques is appropriate. However, heavy reliance on literature, lack of effective mechanism to make data needs tractable and size of the task, may compromise rigor in practice. No evidence in the published literature of the specification of a macro evaluation protocol (as distinct from conventional micro evaluation protocols) to make evaluation task tractable and ensure standardised approach.
Reporting issues of concern to decision-makers	DBF as currently formulated is a heavily researcher-oriented model. Weight given to decision-maker needs is not clear. This may create problems for the DBF in achieving relevance to decision-makers and impacting upon policy. Some issues of concern to decision-makers not covered by approach at present (i.e. budget implications for affected organisations; procedural justice; ethical values; feasibility; acceptability to stakeholders). Specific process for integrating equity and community values warrants clarification.
Overall assessment	**The DBF represents a significant contribution to the economic toolkit as a technical approach to priority setting, with important innovative aspects worthy of careful consideration. Clarification of the theoretical foundation would be a useful refinement. The DBF performs well against those criteria that relate to technical validity, with the exception of providing an effective means to make its data needs tractable. Further empirical experience with the model will help to clarify the importance of this data reservation, and possibly, of the scope for collaboration with other approaches.** **On those criteria that broaden the ideal features of a priority setting model beyond a purely technical approach, the DBF performs poorly. There is no surprise here, as these criteria were not taken into account in the model's development. The DBF as currently formulated is a heavily researcher-oriented model with little apparent weight given to decision-maker needs. This may create problems for the DBF in achieving relevance to decision-makers and impacting upon policy.**

9.6 Concluding comments on the economic models

The four economic models reviewed all demonstrate merit in relation to some of the criteria in the checklist, particularly those criteria oriented around technical analysis, but none perform well against all the criteria. Economic models currently available have not given adequate consideration to the concept of "benefit", nor to the important issues raised by the notion of "due process" in priority setting.

Table 9.5 summarises the performance of the four economic models reviewed in this chapter and is based on Tables 9.1 to 9.4. Some of the models presented have innovative aspects that merit recognition and careful consideration. If used carefully, with due regard for their strengths and limitations, all could make useful contributions to decisions about health service planning and/or resource allocation. Some are better credentialed than others at this point in their development to assist with purchasing decisions. All the models would benefit from further development and/or refinement along the lines suggested above. The models have been assessed in their "original" published form in order to assess this literature and identify any deficiencies that need to be overcome. It becomes quickly apparent, however, that the

models are not mutually exclusive and that innovative aspects can be mixed and matched to provide the best solution to any given research problem. All these models have at least one serious reservation, which suggests they might usefully be used in combination with each other, or with another economic approach, that provides the missing ingredient.

The challenge thus remains to develop and trial an economic model that performs well against all the ten criteria in the checklist. This challenge is taken up in Part D of the thesis.

Table 9.5: Overview of performance of major economic approaches to priority setting

Criterion	League Tables	PBMA	HBG/HRG Approach	Disease-Based Framework
Well-defined research question.	X	XX	X	XX
Clear and acceptable concept of benefit	X	XXX	X	X
Process for generating options for change	-	X (usually) XX (sometimes)	- (not intervention based)	XXX
Marginal Analysis	-	X	-	XX
Clear decision rules	X	XX	XX	XX
Role of judgement noted and clearly specified	-	X	-	-
Data needs made tractable	X	X	X	X
Due process	-	X	-	-
Rigorous approach to measurement	X	- (usually) X (sometimes)	-	XX
Reporting issues of concern to decision-makers	X	XXX	X	X
Overall assessment	X Handle with caution.	X Has potential. Requires development.	- Not suitable for priority setting. OK for planning.	X Strong on most technical aspects. Weak on other criteria.

Key:

- Blank: performs poorly with respect to criterion
- X: partially meets this criterion
- XX: fully meets this criterion
- XXX: key strength of this approach

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PART D: THE MACRO ECONOMIC EVALUATION MODEL

Chapter Ten: The Development of MEEM

"The point is to let the question drive the analyses rather than simply imposing a pre-determined framework and making the question fit the framework in procrustean fashion." (p.391) (Hurley 1998)

10.1 Introduction

In Part C of the thesis existing models of priority setting were assessed against the checklist developed in Part B. It was concluded that while there are models with considerable merit in relation to some or most of the criteria, none of the current models of priority setting perform well across all the criteria. This assessment confirmed the significance of the task attempted in Part D of this thesis, viz the presentation and trialing of an approach to priority setting that attempts to meet all the criteria. As Part D presents my own research, a first person account will on occasions be more appropriate to reflect the development of MEEM, than the third person format utilised until now.

Part D consists of four chapters. In this chapter a description of the Macro Economic Evaluation Model (MEEM) is provided, together with an overview of its development. Extracts from the early case studies are provided to illustrate the purely technical approach adopted in the early stages of MEEM's development. A dominant theme in the empirical evidence (Chapter Six) was how the information needs of technical approaches have restricted their relevance and usefulness. Chapter Eleven focuses on how the information needs of MEEM were made tractable through the creation of a database on health care expenditure and the utilisation of summary measures of population health. In Chapter Twelve the major case study of MEEM is presented, supplemented by material provided in the Appendices. Finally, in Chapter Thirteen MEEM is assessed against the checklist developed in Part B, drawing primarily on the major case study.

10.2 The Origins of MEEM

MEEM was conceived in response to an unresolved priority setting problem I encountered in the early 1990's involving an assessment of periodic health checks in general practice. At that time the Australian National Health and Medical Research Council (NH&MRC) had appointed a Working Party to develop guidelines on the relative effectiveness, efficiency and acceptability of different periodic health checks, covering the fields of screening, immunisation, counselling and chemopropylaxis. It was not feasible for the NH&MRC Working

Party to undertake detailed micro economic evaluations of a large number of possible interventions. Equally, there was a widely held view that an appropriate form of economic appraisal was necessary to provide guidance on the merit and likely impact of the various measures.

Two key problems arose that made it difficult to integrate economic evidence into the priority setting process – even a broad-brush approach. First, many of the 150 or so interventions under consideration had not at that time been evaluated from an economic perspective. Trolling the available cost-effectiveness literature provided some help, but that still left many gaps, together with a range of issues involved in utilising the "League Table" approach to priority setting (refer Chapter Nine) – particularly comparability of study methods, setting and context. The available evaluation literature was focussed more on efficacy/effectiveness than efficiency, and where cost-effectiveness studies were available, very few involved the Australian setting.

Second, economic analysis requires a comparator, with the most meaningful from a policy perspective being "current practice". While the economic data on the options for change was quite patchy, the economic data on current practice in Australia was virtually non-existent. What was required was comprehensive information on health care expenditure patterns in Australia in a form that could be related to current care patterns and the options for change. Unfortunately, the health expenditure information then available was not in this form. The Australian Institute of Health and Welfare (AIHW) published information on health care expenditure, but it was classified by institutional setting (hospitals; nursing homes; etc) and by broad non-institutional categories (medical services; pharmaceuticals; etc), with no linkage to the diseases/conditions to which the expenditure was related (AIH 1970-1984; AIHW 1992-2000). The inability to describe expenditure on current practice, even in general terms, made it virtually impossible to provide the economic advice that the Working Party needed in the time available with any level of rigour.

What was required, it seemed to me, was a new approach to evaluation that was based on economic principles, but which worked with multiple options for change, rather than being focused on detailed assessment of an individual project. This would still require a clear evaluation protocol, but the evaluation methods would involve simplifying assumptions geared to the decision context of priority setting. Thus the assumption might be made (as in the major case study) that interventions would be compared in "steady-state operation" over one year to achieve comparability across all interventions. Detailed project specific evaluation, on the other hand, would involve comparison over a 10-20 year period with full phase-in and learning curve assumptions applied. The challenge was to develop a theoretically sound framework, which was feasible in terms of its data requirements and associated research effort. Solving this challenge gave rise to MEEM – i.e. an approach to evaluation developed specifically for

the priority setting context where multiple interventions were being assessed and ranked in merit order.

Apart from this specific challenge of economic evaluation in a multi-intervention decision context, there were also a number of broader considerations that encouraged my interest in what might be called "macro evaluation" and in particular, its use as a method of priority setting. These included:

- the sheer scale of the economic evaluation task required to make a real impact on resource allocation;
- the importance of matching economic evaluation techniques to the decision context; and
- the frequent need of decision-makers for economic information that goes beyond the capacity of project specific evaluations to provide, no matter how well they are carried out.

While it is hard to provide any precise estimates, few economists would dispute the vast scale of the evaluation task required to make a serious impact upon resource allocation decisions. Only a small percentage of medical procedures have been evaluated to establish their efficacy/effectiveness credentials (through randomised control trials, cohort studies, demonstration projects, etc), with even fewer assessed to establish efficiency. Quite apart from the immense backlog of interventions without rigorous evaluation – clinical and/or economic -- it is not difficult to construct realistic scenarios that see health expenditure demands doubling over the next 30 years (Richardson 1993). There is thus an important need to ensure an appropriate capacity is developed to evaluate such additional expenditure demands. Viable methods of macro evaluation could have an important role to play in this regard, particularly in triaging interventions in to three groups, viz: those interventions which are clearly cost-effective; those which are clearly cost-ineffective; and those requiring further detailed assessment before even broad judgements could be made.

The second general consideration involved the desirability of having techniques in the evaluation toolkit that facilitate a closer match between evaluation methods and decision context. Priority setting decisions have to be taken across a broad variety of settings and problem contexts at the macro, meso and micro levels of the health care system (refer Chapter Two). Conventional project specific evaluation is undoubtedly important and suitable for many decision contexts, such as assessment of major technologies. Its role, however, may have been overplayed and this may have contributed to the limited impact that economic evaluation has had on policy decisions – a problem which economists around the world have bemoaned (Ludbrook and Mooney 1984; Drummond, Brandt et al. 1993; Hall 1993).

In a recent Australian study (Ross 1995) of senior decision-makers, for example, almost half of the sample pointed to the nature of the decision-making process and to the need to make

fast decisions in the absence of relevant existing studies (with no time to commission one), as major barriers to the greater use of economic evaluation[145]. If economists are to pay heed to such feedback from decision-makers (Mooney and Wiseman 1999), then we will need to consider innovative evaluation approaches where various options for change (sometimes large in nature) can be evaluated quickly using consistent methodologies that reflect economic principles. As Hurley argues quite cogently in his article:

> *"The point is to let the question drive the analyses rather than simply imposing a pre-determined framework and making the question fit the framework in procrustean fashion." (p.391) (Hurley 1998)*
>
> *"One immediate consequence of such an approach would be room for less rigid analytical frameworks...A more pluralistic approach might also force researchers to think more carefully about taxonomic principles that can provide guidance in choosing methods and in determining which factors are most important in a given analysis."(p.390) (Hurley 1998)*

The third general consideration is really related to the second, and concerns the need of many decision-makers for economic information that goes beyond the capacity of conventional project specific evaluations to provide. My involvement with the then National Better Health Program, for example, raised questions like: "If this program, which is working well in Sydney or Adelaide, were to be applied on a national basis, what would be its likely impact on health status and health care expenditures?" In other words, an approach to priority setting that facilitated a move from internal validity of individual studies to considerations involving external validity and broader-based policy consequences.

Related to this issue of policy relevance, was also the desirability of encouraging an economic way of thinking in policy formulation. By this I mean incorporating notions of "opportunity cost", "marginal analysis" and a "clear concept of benefit" into the various "what if?" questions that inevitably arise in the policy process. This includes speculation about potential cost offsets from various health promotion strategies; through to the possible health status gains from achieving nominated health goals and targets. Decision-makers constantly have to make choices between various strategies and options for change, usually in a multi-disciplinary environment with a range of stakeholder interests and perspectives. The challenge for economists is to develop methods that will assist them in the most meaningful way – and this will mean developing methods that have appeal to a broader range of disciplinary perspectives, together with a much greater sensitivity to the pragmatic constraints of the policy process.

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[145] This same result was recorded by students of mine in a follow-up survey conducted during 1998 of senior Commonwealth Department of Health officials.

10.3 The Initial Concept (MEEM Mark I)

There are two broad approaches to establishing priorities in a multi-intervention decision context that seek to incorporate scientific evidence. The first is based on a subjective assessment of a range of independently assembled databases (such as disease incidence/prevalence trends; risk factors; hospital beddays; GP visits; Medicare utilisation; intervention costs; etc). An Australian report entitled "Health Assessment for Adults: A Health Screening Manual for Doctors, Nurses and Health Care Workers" (Couch 1989) is an excellent example of this "profile" approach. The key problem with this approach is the lack of explicit decision criteria on the basis for the rankings and decisions taken. It is very much a "trust us" approach that is based on the credentials of the participants. There is no information provided on what weight is given to the various data components or on how the implicit criteria employed relate to the goals of the exercise.

Another Australian example, the National Cancer Control Initiative (NCCI 1998) discussed in Chapter Twelve, at least specifies ranking criteria in addition to the profile data, but provides no guidance on how the various criteria are to be brought together to arrive at the final decisions. There are obvious implications in terms of the difficulty of replication and inter-judge variation. Subsequent differences in rankings might be due to differences in the databases; and/or differences in the weights implicitly given the criteria; and/or simply because different people are involved. Without a clear rationale for why differences arise, this first approach fails to provide a policy tool or comprehensive overview that can be applied usefully on an ongoing basis.

10.3.1 Description of MEEM Mark I

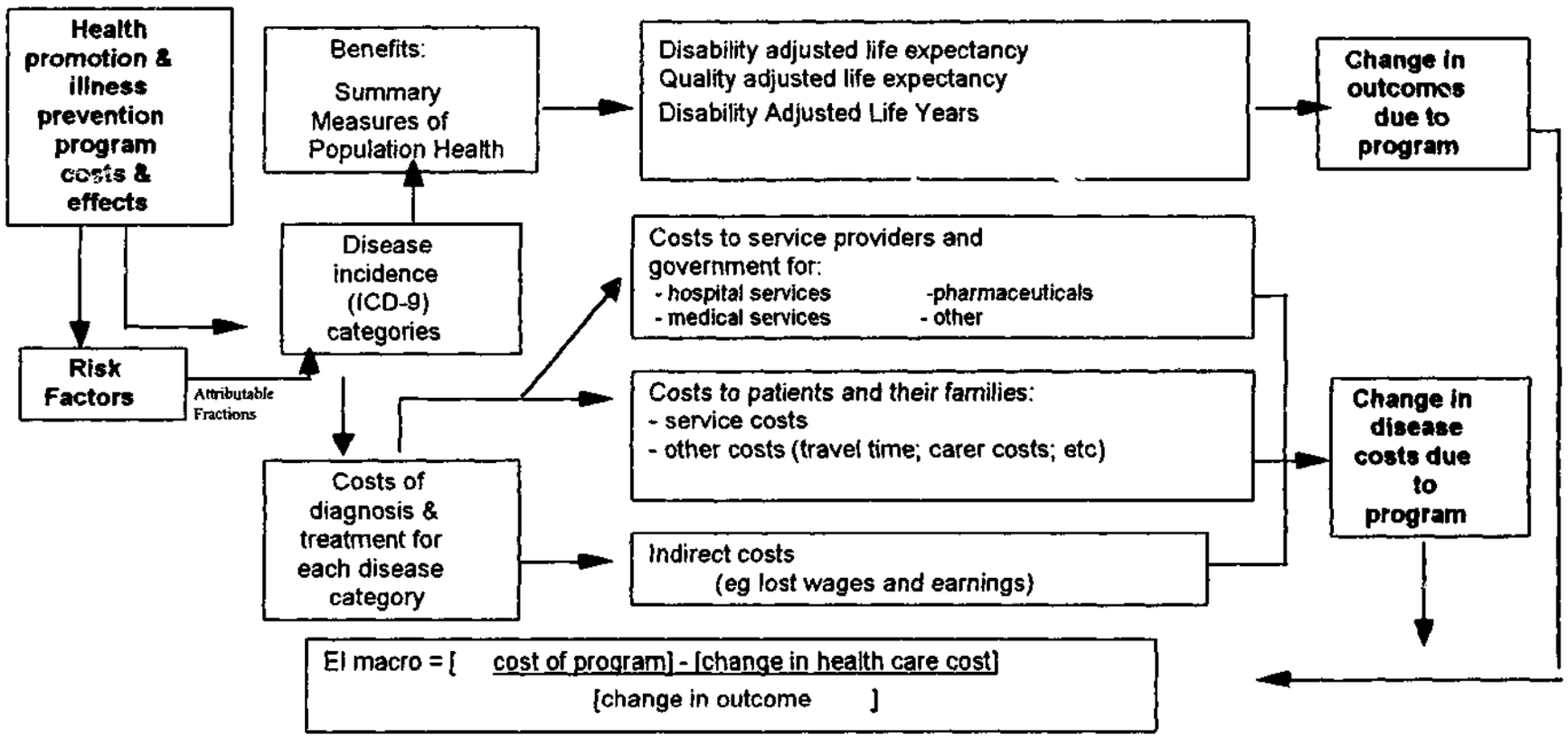
The second approach to what I term "macro evaluation", is to try and develop a systematic model that makes explicit the decision rules, together with the principles and assumptions utilised in putting the databases together. MEEM falls into this second category and is illustrated in Figure 10.1. MEEM is a "model" in the sense that the ranking index it provides is a construct using a specified economic methodology and assumptions that make best use of available and specifically developed databases. It is not an econometric model that purports to predict or simulate behaviour.

Starting on the left-hand side of Figure 10.1, MEEM uses best available information on the efficacy/effectiveness of interventions to select options for change and to assess the change in disease incidence and associated sequelae that individual options may realise. Interventions may focus directly on reducing disease incidence and associated sequelae (eg screening for early stages of cancer) or impact indirectly by modifying risk factor exposure (eg exercise, nutrition, sun exposure, etc). Note that in its early stages MEEM was focused specifically on health promotion/illness prevention activities (reflecting its origins) but has

since been broadened to include interventions from across the disease pathway (refer 10.5 below).

Moving to the middle lower portion of Figure 10.1, MEEM involves cost-of-illness (COI) estimates of the utilisation/cost impact on the health care system of disease incidence classified using the International Classification of Disease No 9 – Clinical Modification (ICD 9-CM). A description of the utilisation/cost impact has been developed for each Chapter of the ICD 9-CM, together with more detailed results at the three-digit code level for selected chapters (eg cancer; cardiovascular disease; injury) and disease groupings. The utilisation/cost data is estimated on a sex and age group specific basis (10-year age groups) by area of expenditure in the health care system (i.e. hospitals, nursing homes, medical services, pharmaceuticals and allied health care professionals). The cost estimates reflect a National Accounts orientation, so that certain cost impacts are not included (such as carer costs and travel time). The coverage of costs falling on health care providers is quite comprehensive (i.e. "C^1" costs in the Drummond et al. typology (Drummond, O'Brien et al. 1997)), but only partial for costs falling on patients and their families (i.e. "C^2" costs). Production costs have been estimated in the early COI work using the human capital approach, but these estimates are now a little dated (i.e. 1989/90). A fuller explanation of the COI component of MEEM is set out in Chapter Eleven. Its use within the major case study is set out in Chapter Twelve. It should be noted that the COI work was not undertaken for its own sake (although various researchers have found this information useful) but rather as an input to the macro evaluation model. The role and usefulness of COI studies is discussed further below.

Figure 10.1: Conceptual Overview of Macro Economic Evaluation Model Mark I



Each disease is also matched to health status outcome data similarly structured around the ICD 9-CM (middle upper portion of Figure 10.1). Early case study application of MEEM used life expectancy data (and derivatives like Potential Years of Life Saved [PYLS]) calculated from ABS cause-deleted life tables. The major case study (Chapter Twelve) adds a quality of life dimension to the mortality outcomes, by utilising the emerging work on Disability Adjusted Life Years (DALYs). Issues surrounding the selection of outcome measures and use of the DALY are taken up in Chapter Eleven, with relevant discussion also in Chapter Four (theoretical foundations) and Chapter Twelve (case study).

The burden of illness databases, both COI and health status, may then be used as an input to the evaluation of specific interventions as shown on the right-hand side of Figure 10.1. The COI component of MEEM is used as a description of current practice and enables changes in health care resource use from reducing disease incidence or modifying care patterns to be estimated. In the case of illness prevention and health promotion interventions, for example, the cost offset is calculated by assuming that the percentage reduction in new cases will yield a proportionate reduction in the cost of health care for the specified diseases. This can be estimated on an age/sex specific basis, with lag times incorporated to reflect both the year when incidence reduction is anticipated and when health gains are achieved. This calculation assumes that the current average cost of care for the specified target groups is representative of the marginal[146] costs of care when the cost offsets are experienced. The cost offset is then expressed in present value terms utilising the chosen discount rate. Simple or two-step discounting is used, depending on the lag factors involved. Further detail is provided in the economic protocol in Section 12.6 and in Appendix Two.

The health gain is calculated in a similar way, using the intervention efficacy data to compute the change in the health status databases. When DALYs are used as the outcome measure, for example, the health gain is measured as the difference in DALYs with and without the intervention. The change can be recorded in the years of life lost (YLL) component of the DALY and/or in the years of life lived with disability component (YLD), according to the mortality/morbidity effects of the interventions involved. This enables both cost effectiveness ratios (cost per YLL prevented) and cost utility ratios (cost per DALY recovered) to be calculated. In the case of illness prevention and health promotion interventions, for example, the YLL prevented is calculated by assuming that the percentage reduction in new cases (by age/sex) will yield a proportionate reduction in the YLL for the specified diseases (by age/sex). As for the cost offset, this assumes that current disease etiology and prognosis (averaged for the relevant target groups and care pathways) are representative of marginal

[146] The validity of assuming that average cost is a reasonable proximate for marginal cost will depend on the size of the fixed cost component of total costs (which tends to be a minor component in most health care interventions, as they are dominated by labour costs) as well as the extent to which average costs can be calculated for target client/patient groups.

changes for the time period over which the benefit stream applies[147]. Lag factors and discount rates are applied in a similar manner to the costs. For changes to the YLD component, the disease specific disability weights are modified to reflect the anticipated impact of the interventions using the "Dismod" worksheets[148] in the DALY database (refer Section 12.6.7 for further detail).

The resulting net cost can then be compared with changes in health status to produce a macro economic index. The conceptual model thus incorporates the two basic principles of economic appraisal: first, that both costs and outcomes are identified and measured; and second, that a comparison between alternatives is made, particularly between current practice and interventions for change (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997). These two principles are embodied in the basic expression for the macro economic index (EI^{m}), viz:

$$EI^{m}: \quad \frac{\text{[Cost of project } ^{\text{plus/minus}} \text{ Change in health care costs attributable to project]}}{\text{[Change in outcomes attributable to project]}}$$

This expression includes the 'current practice' verses the 'options for change' comparison by measuring the change in health care costs and health status attributable to the interventions. In principle, the expression can be written as cost-effectiveness, cost-utility or cost-benefit indices by varying the way health outcomes are measured and incorporated. The early work on MEEM focused on the simpler cost-effectiveness form of appraisal, using 'cost per case prevented' (Carter 1993) (Carter 1994) or 'cost per PYLS' (Carter, Marks et al. 1999) (Carter and Scollo 1999). In the major case study (Chapter Twelve) the cost-utility form of appraisal was utilised with the DALY as the outcome measure.

The cost-benefit form of appraisal has not yet been applied, as the MEEM approach requires a health status database on which to draw. There is at present no willingness-to-pay (WTP) database on the scale required for MEEM and as discussed in Chapter Four (Section 4.3.3), uncertainties remain over the validity, reliability and sensitivity of the survey methods and associated results. While human capital databases exist by ICD 9 chapters (albeit somewhat dated) there are substantive methodological issues associated with using this approach or the frictional cost modification within an evaluation[149]. The change in non-health sector costs

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[147] It should be noted that the use of averages in the measurement of changes in costs and outcomes for selected target groups is also common practice in conventional micro economic evaluation. In the QALY methodology, for example, it is common practice for individual scores to be averaged to work out the change in health status, as well as in the development of weights for the various dimensions of health gain.

[148] DISMOD is a software program developed by the Burden of Disease Unit at the Centre for Health and Population Studies, Harvard, to assist disease experts to arrive at internally consistent epidemiological estimates of incidence, duration and case fatality rates (Mathers, Vos et al. 1999).

[149] See, for example, context (Koopmanschap and Rutten 1993; Olsen 1993; Weinstein and Manning 1997; Olsen and Richardson 1999; Brouwer and Koopmanschap 2000) and discussion in Chapter Four.

(other than production costs) could be incorporated into MEEM, but this would be done on an application specific basis and would not involve routine data sets. It is anticipated that MEEM applications will focus on cost-utility analysis in the foreseeable future, exploring issues associated with using DALYs in an evaluation context.

10.3.2 Possible Uses of MEEM Mark I

Section 10.3.1 provided an overview of MEEM Mark I. In this section three possible uses for the MEEM (i.e. description; broad-based policy analysis; and priority setting) are presented, together with illustrative examples taken from the early case study work.

Description:

The COI component of MEEM is ideally suited for identifying how resources are currently allocated between different types of costs; between different age/gender groups; between different types of services; between different diseases; and between different risk factors. Table 10.1 shows illustrative information for selected disease categories for 1989-90, taken from the work I undertook[150] while at the AIHW (refer Chapter Eleven for development of the cost and utilisation database). Table 10.2 illustrates the service utilisation data that could similarly be derived from the COI database (i.e. beddays, medical consults, scripts, etc). The MEEM COI database could provide this information on a 10-year age and gender-specific basis. Such detail could provide an excellent starting point for examining the descriptive economics of a specific disease, for understanding what diseases dominate in what type of health service, for examining the impact of disease by age and gender and for teasing out equity implications of current health care financing arrangements. The knowledge of diseases with a strong 'Allied Professionals' component, for example, would provide useful information for describing the equity implications of services not covered by Medicare.

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[150] Note, that as set out in the Acknowledgements to this thesis, the size and scope of this early cost-of-illness work meant that I had assistance from a small group of researchers. While the personnel varied, the team usually included two statisticians and one junior economist.

Table 10.4: Cost [a] of Selected Diseases, by Sector of Expenditure, Australia, 1989-90

Sector of Health expenditure ($'000)	Circulatory System ($'000)	Neoplasms ($'000)	Injury ($'000)	Mental Disorders ($'000)	Digestive System ($'000)
Hospitals [b]	925,349	648,188	691,815	261,811	764,485
Nursing Homes	529,298	121,334	262,907	422,991	86,026
Medical Services [c]	299,389	105,645	251,268	225,700	147,583
Allied Health Professionals	3,673	1,054	14,944	8,021	6,248
Pharmaceuticals	412,543	19,747	99,209	171,389	105,282
Total	2,170,252	895,970	1,320,143	1,089,912	1,109,624

Source: Table I from (Carter 1994)
Notes:

(a) These estimates are based on direct costs only. Indirect costs (forgone earnings due to illness and premature death) are not included in these estimates
(b) Includes public and private hospitals, but not psychiatric hospitals.
(c) Includes consultations and procedures under Medicare by GPs and Specialists

Table 10.2: Utilisation Statistics for Selected Diseases, by Sector of Expenditure, Australia, 1989-90

Sector of Health expenditure	Circulatory System	Neoplasms
Hospital Admissions		
Public	238,108	173,168
Private	45,634	65,405
Total	283,741	238,573
Hospital Beddays		
Public	2,398,232	1,393,799
Private	370,406	366,306
Total	2,768,637	1,760,105
Nursing Home Admissions	2,768,406	1,942
Medical Services [a]	9,694,498	3,116,155
Allied Health Professionals: Referrals	123,327	1,247,815
Pharmaceutical Scripts	25,946,382	30,203

Source: Table 2 from (Carter 1993)
Notes:

(a) Refers to number of visits to GPs and Specialists

The health status component of the MEEM can be used in an analogous fashion to describe the mortality and morbidity impact of disease by age and gender. Table 10.3 provides an example for PYLL lost due to diet-related disease.

In the early phase of MEEMs development, descriptive economic papers were prepared and released for a number of diseases and/or ICD-9 chapters, including:

- diet-related disease (Crowley, Antioch et al. 1992; Segal, Carter et al. 1994);
- HIV/AIDS (Antioch, Waters et al. 1992);
- drug and alcohol abuse (Conway, Pinyopusarerk et al. 1993; Waters, Jelfs et al. 1996);
- injury (Carter and Penm 1993; Mathers, Vos et al. 1999);
- cancer (Carter and Penm 1993; Mathers, Penm et al. 1998);
- cardiovascular disease (Carter, Pinyopusarerk et al. 1993; Waters, Mathers et al. 1998);
- diseases amenable to GP preventive activities (Carter, Pinyopusarerk et al. 1993);
- hepatitis B (Antioch, Waters et al. 1995);
- tuberculosis and syphilis (Antioch, Waters et al. 1995); and
- diabetes mellitus (Segal and Carter 1995).

Table 10.3: Potential Years of Life Lost (PYLL) Due To Premature Death in Australia in 1989-90 Attributed to Poor Diet

Diet-Related Diseases	PYLL with High Estimate of the Population Attributable Fraction	PYLL with Medium Estimate of the Population Attributable Fraction	PYLL with Low Estimate of the Population Attributable Fraction
Coronary Heart Disease			
To age 65	25,847	17,190	8,575
To age 75	75,237	49,814	24,738
Stroke			
To age 65	9,256	6,168	3,083
To age 75	24,229	16,126	8,050
Hypertension deaths			
To age 65	865	569	285
To age 75	2,369	1,579	789
Diabetes (non insulin dependent)			
To age 65	5,217	3,476	1,737
To age 75	17,061	11,358	5,671
Neoplasms			
To age 65	39,187	8,433	2,787
To age 75	83,760	18,064	5,984
Total PYLL			
To age 65	79,808	36,604	16,961
To age 75	205,358	100,055	46,716

Source: Table 3 from (Crowley, Antioch et al. 1992)

Policy development:

Based on this economic and epidemiological database, the MEEM can also be used at a higher level of analysis. Here the issues might relate to the likely costs and implications of applying a demonstration project on a national or state wide basis, to the 'cost offsets' achievable by health promotion, to the health sector and life expectancy implications of achieving different national health goals or targets, or to a consideration of the balance between primary, secondary, or tertiary prevention strategies in a particular context. Illustrative examples of the annual benefit from the achievement of selected health promotion targets are given in Table 10.4. Note that the concept of benefit can be varied to cover both health status (eg. PYLS, DALY, etc) and cost offsets. There are undoubtedly a large number of 'what if' questions that confront policy makers, which the MEEM, calibrated with the best available information, could make a useful contribution.

Table 10.4: Annual Benefits Potentially Available from Achieving National Health Targets for Selected Risk Factors

Risk Factor	National Health Targets	Annual Saving in Health Care Expenditure ($ millions)
Smoking	Prevalence of 22 % for men & women	54.1 (CVD) 5.1 (Cancer)
Diet	Assume dietary fat and salt goals reduce health care costs by 10%	67.1 (CVD)
Obesity	Obesity prevalence of 9.5% for men and women	42.1 (CVD)
Physical Inactivity	Physical inactivity prevalence of 15% for men & women	30.3 (CVD)
Falls	Reduce morbidity from falls in men & women aged 65 and over by 15% and 20% respectively	57.5 (Injury)

Source: Table 2 from (Carter 1994). Goals and targets taken from (Nutbeam, Wise et al. 1993).

MEEM has also been used to assist with policy judgements about whether existing or potential interventions are value-for-money. In an article published in the journal "Health Promotion International", for example, MEEM was utilised in an assessment of whether a national skin cancer primary prevention campaign in Australia would be worthwhile from an economic perspective (Carter, Marks et al. 1999). More specifically, MEEM was utilised to assess the potential health care offsets and health gains in the manner described in Section 10.3.1 above. Thus for the cost offsets, the percentage reductions in the incidence of melanoma and Non Melanomic Skin Cancer (NMSC) attributed to the national campaign were multiplied by the MEEM estimates of total recurrent expenditure on these diseases (shown in Table 10.5).

Table 10.5: Burden of Suffering from Skin Cancer [a] in Australia, 1993/94

Cost and Activity Data	Number	Cost per Year ($millions)
Mortality		
Deaths	1067	
PYLL to age 75	11,567	
Morbidity		
Hospital Admissions	38,007	80.64
Hospital Beddays	101,913	
Outpatients	225,510	14.98
Medical Consults	2,141,156	63.26
Prescriptions	68,689	3.37
Referrals to Allied Health Professionals	124,621	2.16
Nursing Home Admissions	196	5.64
Direct Health Service Costs		**170.05**
Melanoma		18.74
NMSC		95.73
Other Benign Skin Cancers		55.58
Total		**170.05**

Source: Table 1 from (Carter, Marks et al. 1999)
Notes:

(a) Skin cancer is defined to include: Non Melanomocytic Skin Cancer (NMSC) (ICD9+ 173; Melanoma (ICD9: 172) and Other Benign Skin Cancers (ICD9: 214, 216, 232). Other Benign Skin Cancers are not included in the cost offsets as are not related to sunlight. The exception is Solar Keratoses, which is costed separately to MEEM and involved an estimated expenditure of AUD$ 48.46 in 1993/94.

The lag periods before the reduced cancer incidence is realised had been set at 5 years for melanoma and at 15 years for NMSC and solar keratoses (with variations tested in sensitivity analysis). The net cost of the proposed national program (i.e. its estimated cost minus the offsets) over its 20 year assumed life was presented in present value terms using a 5% discount rate. The health outcomes were measured in terms of premature deaths deferred and potential years of life saved (PYLS). The PYLS was estimated by analysis linking predicted changes in sunburn to corresponding reductions in total lifetime ultraviolet radiation (UVR) exposure, and hence to anticipated outcomes in terms of reduced incidence of melanoma and NMSC. The percentage reductions in disease incidence were applied to the PYLL database in a similar manner to the cost offsets and discounting applied.

MEEM has also been used to assist with the evaluation of Australia's National Tobacco Campaign (NTC) "Every Cigarette Is Doing You Damage" (Carter and Scollo 1999). The federal government committed approximately $7 million to the first phase of the NTC, while 'in kind' support provided by the State/Territory Quit campaigns and partner organisations

equaled this amount. The appraisal was undertaken from the perspective of the Commonwealth government, as well as from a broader perspective that included the State/Territory Quit campaigns and their partner organisations. The impact of costs falling on individuals on the cost-effectiveness of the NTC was approximated in the sensitivity analysis.

Using the NTC benchmark and follow-up surveys (Hassard 2000), estimates were made of the reduction in the number of smokers that could be attributed to the NTC. This reduction in the prevalence of smoking (approximately 190,000 people) was then translated into a reduction in the number of new cases of selected diseases that could be anticipated (refer Table 10.6) using population attributable fractions (sometimes called etiological fractions). Tobacco-related diseases were chosen on the basis of the size of impact they have on the community, together with the strength of the causal linkage between smoking and disease incidence. The delay between a fall in the prevalence of the risk factor and a reduction in disease incidence was built into the analysis, together with the relative risks for "smokers," "ex smokers" and "non smokers." The time lags incorporated were based on the literature, but erred on the side of caution (eg 20 years for lung cancer; 10 years for COPD; and 5 years for CVD). A discount rate of 5% was used to express key variables in present value (PV) terms.

Benefits from the estimated reduction in disease incidence were measured in a number of ways using the MEEM databases (refer Table 10.7). Firstly, as the number of premature deaths that would be prevented; secondly, as the potential years of life saved to age 75 ($PYLS^{75}$); and thirdly, as the cost offsets in terms of the direct health care costs associated with these preventable diseases.

Table 10.6: Population Attributable Fractions (before and after change in smoking prevalence due to NTC); Reduction in New Cases; $PYLS^{75}$; and Time Lags:

Diseases	PAF (before)	PAF (after)	% change in PAF	Reduction in new cases	$PYLS^{75}$ (discounted)	Time Lags
Lung cancer	80.1 %	79.7 %	0.50 %	1.76 %	738 (278)	20 years
COPD	78.6 %	78.4 %	0.25 %	0.93 %	163 (100)	10 years
CVD Group						
CHD et al	37.9 %	37.0 %	2.37 %	1.40 %	1874 (1469)	5 years
PVD	37.3 %	36.8 %	1.34 %	0.63 %	42 (33)	5 years
Stroke	36.8 %	35.8 %	2.72 %	1.61 %	521 (408)	5 years
Total					3,338 (2,228)	

Source: Table 6 from (Carter and Scollo 1999)

Table 10.7: Deaths and PYLL[75] due to Specified Tobacco-related Diseases, 1989/90

Cause of death	ICD-9-CM Codes	Deaths	PYLL[75]
Lung Cancer	162	6,309	41,930
COPD	490-492; 496	5,645	17,550
Coronary Heart Disease	410-414	32,825	127,156
Stroke	430-438	12,740	32,359
Peripheral Vascular Disease	441-444; 440	3,139	6,592
Heart Failure	428-429	4,216	3,976
Cardiac Dysrhythmias	426-427	807	2,718

Source: After Table 3 and Table 6 from (Carter and Scollo 1999)

As with the estimates for the PYLS[75], the calculation of the cost offsets was based on the percentage reduction in disease incidence (by age/gender) predicted from the fall in smoking prevalence (by age/gender). The same percentage fall in new cases was used (refer Table 10.6) and applied on this occasion to the estimated health care costs attributed to the seven selected diseases. Table 10.8 summarises the relevant data.

Table 10.8: Percentage changes in incident cases due to NTC; disease costs attributed to these diseases in 1989/90; and cost offsets adjusted to PV 1997/98

Disease	% fall in new cases	Disease related health care costs ($M 1989/90)	Disease costs inflated to ($M1997/98)	Cost offsets ($1997/98) No time lags	Time lags	PV of Cost offsets (5% discount) $
Lung Cancer	1.76 %	82.19	98.05	1,725,727	20 yrs	650,427
COPD	0.93 %	224.57	267.91	2,491,537	10 yrs	1,529,555
CVD group						
Coronary heart disease; heart failure; cardiac dysrhythmias	1.40 %	1014.0	1209.71	16,935,828	5 yrs	13,269,222
Peripheral vascular disease	0.63 %	166.52	198.78	1,252,299	5 yrs	981,176
Stroke	1.61 %	515.29	614.74	9,897,330	5 yrs	7,754,558
1.10 Total		2002.67	2389.19	32,302,721		24,184,937

Source: Table 7 in (Carter and Scollo 1999)

Priority setting:

Undoubtedly the most complex and challenging use for MEEM, was the prime reason for its development – that is, to rank a large number of projects in the context of priority setting. Two early case studies that illustrated the potential of MEEM in this role are presented in tables 10.9.and 10.10 (the major case study is presented in Chapter Twelve). The first case study of MEEM in a priority setting context (as opposed to the potential cost effectiveness of single interventions) involved an assessment of strategies to prevent coronary heart disease. Table 10.9 summarises the macro CEA index for four interventions, together with the associated

effectiveness assumptions based on an article by Hall and colleagues (Hall, Heller et al. 1988). The measure of outcome chosen in this early case study was "cases of coronary heart disease prevented". Effectiveness rates are also identified (that is, for the interventions chosen, the number of cases prevented as a percentage of the number of cases which would otherwise have occurred). The cost offset estimates are based on the percentage reduction in new cases applied to the MEEM COI database as explained above.

Table 10.9: Example of the Macro Cost Effectiveness Indices [a] Used in Priority Setting Context, Coronary Heart Disease Case Study

Components of index and effectiveness rates	Strategy One [b] Whole Population	Strategy Two High Risk Individuals	Strategy Three Combination of One and Two	Strategy Four High Risk Group Identified
A. Cost [a] of the Intervention [c]	7,703	116,428	144,468	75,095
B. Reductions in the cost [a] of illness attributed to intervention	11,178	7,154	14,755	5,701
C. Number of cases prevented by intervention	8,303	5,315	10,945	4,246
D. Macro CEA ratio (A-B)/C	Net saving of 3,475	Cost per case prevented = 20.56	Cost per case prevented = 11.85	Cost per case prevented = 5.1
Effectiveness rate[d]	10.0	6.4	13.2	5.1

Source: Table 3 from (Carter 1994)
Notes:
(a) Costs in $A'000
(b) Strategy One demonstrates a net saving as well as cases prevented, i.e. it is "dominant".
(c) Costs of interventions and effectiveness rates adapted from (Hall, Heller et al. 1988).
(d) Effectiveness rates of these interventions have been modeled on the basis of a population of 500,000 people, with a target group of all males aged 40-59 (N=60,000). Estimates of benefits of risk factor reduction are based on the findings of the large European Multifactorial Prevention Trial (World Health Organisation European Collaborative Group 1983). Effectiveness rates measure the proportion of cases prevented by the intervention as a percentage of the number of cases of myocardial infarction that would otherwise have occurred.

The interventions selected for analysis target whole populations (Strategy I: Media campaigns); high-risk individuals (Strategy 2: population screening including cholesterol check and counselling); high-risk groups (Strategy 4: opportunistic screening by GPs based on epidemiological criteria and counselling); and a combination of the above (Strategy 3). Strategy 1, the media campaign, not only produces net health cost savings ($3.5 million), but also results in the second highest number of predicted cases prevented (8303) and would be the preferred strategy on the basis of economic analysis (focused on a health gain concept of benefit). Issues of social justice may, however, lead to a different consideration of the effectiveness of strategies for different groups. There remains, for example, the question of whether whole population strategies are sufficient, given that the number of cases prevented remains a small proportion of the total number of myocardial infarctions occurring. Further,

there is the issue of whether media campaigns are effective for socially disadvantaged groups. It could be argued, for example, that the combined approach has an acceptable cost effectiveness result, together with other significant attributes (eg. it is the most effective in terms of the total number of cases prevented and offers a more equitable solution in terms of reach to disadvantaged groups). It was considerations such as this (explored more fully in Chapters Four to Six) that led to my trialing of methods such as PBMA that can place technical analysis within a broader framework, and eventually to MEEM Mark II.

The second early case study of priority setting (shown in Table 10.10) involved typical smoking cessation strategies, viz: brief counselling advice; extended counselling advice; extended counselling advice plus nicotine gum; and taxation changes. The cost offsets and life year saved estimates were calculated[151] by estimating the population attributable fractions (PAF) between smoking and smoking-related diseases before and after the anticipated falls in smoking prevalence for the various interventions. The assumed intervention effectiveness rates are used (via the PAFs) to work out the percentage fall in disease incidence, which is multiplied by the MEEM databases on health sector expenditure and PYLL attributable to smoking. Again the assumption is made that the average and marginal benefits are the same for the age/gender cohorts (i.e. the benefit of an intervention which prevents 'x' percent of new cases in each age/gender cell is 'x' percent of the burden of disease in each corresponding age/gender cell). As Richardson notes in a recent paper in which he comments on BOD work utilised in an evaluation role, "this assumption is not unreasonable and commonly made in single intervention studies." (p. 5) (Richardson 2001)

Table 10.10: Example of the Macro Cost Effectiveness Indices Used in Priority Setting Context, Smoking Cessation Case Study

Components of index	Strategy One [b] Brief Advice	Strategy Two Extended Advice	Strategy Three Extended Advice plus Gum	Strategy Four Tax Options
A. Cost of the Intervention	8.1m	$21.6m	$98.3m	Nil
B. Reductions in the cost of illness attributed [a] to intervention	24.0m	$37.5m	$50.3m	$25.5m
C. Years of Life Saved attributed to intervention	3,923 yrs	6,130 yrs	8,215	4,169 yrs
D. Macro CEA ratio (A-B)/C	$4,055 per life year saved	$2,596 per life year saved	$5,846 per life year saved	Dominant

Source: Table 3 from (Carter 1992)
Notes:
(a) The efficacy rates for smoking cessation of the interventions are based on the literature, viz: (Goss 1990; Victorian Office of Prices 1990; Clark 1991)

[151] As smoking prevalence falls, the PAF falls, the estimated number of new cases falls and hence health gains/cost offsets are experienced.

Conclusion

In summary, the early case studies overviewed above demonstrated that MEEM Mark I was potentially useful for health care decision-makers at three levels:

- First, in providing a comprehensive description on an age and gender specific basis of health status and health resource utilisation patterns. This "stocktake" role (Richardson 1993) is similar to the use made of GDP estimates in monitoring the nation's performance.

- Second, based on this knowledge, MEEM could be useful in identifying/clarifying policy issues and asking 'what if' questions about potential health gain, cost offsets, and value-for-money of one-off interventions.

- Third, and most important in the context of this thesis, MEEM could be useful in providing an economic ranking of a large number of projects using the macro CEA index.

The essential contribution of MEEM Mark I is thus about empirical tractability; about achieving efficiency in an applied microeconomics research task; and about increasing the relevance of economic evaluation for decision-makers. MEEM was never intended to, nor does it, attempt to develop a new body of economic theory. Rather, MEEM has been located within an economic foundation (refer Chapter Four) and the accepted principles of economic evaluation have been adhered to. Through the MEEM approach, evaluation of multiple options for change becomes a feasible and timely task, because much of the necessary data is available as ongoing databases. In MEEM Mark I, new data is limited to two items: the efficacy/effectiveness of the proposed options for change; and the activity pathways from which costs can be calculated. This requires two quite reasonable assumptions, viz: i) that the options for change can be specified in a concrete way; and ii) that there is evidence to sustain the underlying claim that the proposed options for change actually work. Other attempts to develop macro evaluation (critiqued in Chapter Nine) have consistently encountered significant data problems through over-reliance on literature appraisal for all of the requisite data[152].

It is important to note that MEEM is not being put forward as a replacement for conventional micro economic evaluation. When the decision-making context suggests detailed micro evaluation is appropriate to the research question, then micro evaluation should be the

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[152] Reliance on the literature for the incremental cost-effectiveness indices, for example, assumes both the availability of relevant studies (which is often not the case) and the absence of methodological confounding. Over and above the efficacy/effectiveness data required by MEEM, a full reliance on the literature also assumes the costs and benefits of the "current practice" comparators in the source studies are appropriate, as well as the unit costs of the options for change.

method of choice. In this context MEEM might only have a supplementary role in relation to policy implications and broader health system effects. It is in the situation where the decision context involves multiple projects (i.e. the normal context for priority setting) that MEEM is being put forward as a primary evaluation method. It should be noted in this regard that MEEM does help overcome the key documented problems in utilising league tables in a priority setting context (refer Chapter Nine). The problems, for example, of ensuring consistent methods and relevance to local setting and context, are addressed through the development of a macro evaluation protocol, together with the use of ongoing databases specific to Australia.

10.3.3 Burden of Disease and Cost-of-Illness Studies

Finally, before closing this overview of MEEM Mark I, it is worth pausing to comment briefly on the desirability of conducting cost-of-illness (COI) and/or disease burden studies (BOD). This question has been an issue of some controversy in the literature, particularly since the WHO Global Burden of Disease Study (Murray and Lopez 1996), with some economists and commentators very skeptical of their usefulness[153]. The main danger with COI/BOD studies is that policy makers may see them as a pragmatic alternative to economic appraisal. It is important that COI/BOD studies not be used to justify further expenditures simply because money is currently devoted to a disease and similarly, that BOD not be used to justify expenditures simply on the size of the health problem. While these considerations may form part of a broader concept of benefit (see discussion in Chapter Four and Five), they are unlikely on their own to lead to resources being directed to their most efficient use. From an economic perspective, future decisions on the allocation of scarce health resources should be focussed on the development of a comprehensive set of interventions, together with a clear assessment of their relative costs, risks and benefits (a position which many COI/BOD researchers fully support).

While I fully endorse this caution, I have difficulty in accepting[154] the position of the more fervent critics who see COI/BOD work as a waste of scarce research capacity. Other economists[155], however, accept that COI/BOD can be sensibly utilised in the priority setting process by providing relevant cost and outcome data for subsequent economic appraisal. As Drummond acknowledges, the description of current practice follows naturally from separately

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[153] See for example, (Sheill, Gerard et al. 1987; Wiseman and Mooney 1998; Williams 1999; Mooney and Wiseman 2000). While I have focussed on the use of BOD/COI to assist economic evaluation and priority setting, its use for other purposes has been acknowledged by some of these critics. Mooney and Creese (Mooney and Creese 1990) acknowledge, for example, that BOD/COI can be useful for setting the research agenda, as such data documents the maximum achievable benefit. They see this as useful if we know little or nothing about the probability of research success.

[154] For reasons articulated in various parts of this thesis, I see this position as simplistic and counter-productive to the task of increasing the role of economic evaluation in policy-making. One could be forgiven for seeing a form of religious fervor in some of this criticism that has more of an ideological than theoretical basis.

[155] See for example, (Drummond 1992; Davey and Leeder 1993; Carter 1994; Murray and Lopez 1996; Murray and Acharya 1997; Richardson 2001)

identifying the components of current care activity and associated costs (such as hospitals, medical services, pharmaceuticals, nursing home, allied health, etc). The data tractability advantage of utilising COI/BOD is clearer when account is taken of the data complexity involved for interventions that focus on major risk factors. Tobacco cessation, for example, involves linkages between smoking and over 30 diseases; while alcohol involves 38; nutrition over 20; obesity 6, etc. Similarly, when interventions focus on diseases that involve major co-morbidities, such as diabetes with 10 related conditions, a practical means of estimating the change in BOD/COI is very helpful. This is particularly so, when an ongoing policy tool is sought that incorporates an ability to vary key assumptions over a plausible range of values.

Another less obvious advantage of comprehensive BOD/COI databases, is that they allow options for change to be generated with a far more complete understanding of current practice, disease management pathways and health system effects. This is rather akin to the program budget stage of PBMA, where the description of current activities and current resource usage provides the framework on which the potential reallocation of resources is based.

Over and above their use in estimating health benefit and options for change, COI studies are also useful in coming to grips with the potential scale and scope of interventions. As noted by Birch and Donaldson (Birch and Donaldson 1987), Birch and Gafni (Birch and Gafni 1992) and the World Bank Development Report (World Bank 1993), the simple application of CEA ratios to choose between programs need not lead to the maximisation of the benefits from a fixed resource pool. If the alternative programs under consideration have differing resource requirements (and indivisibility characteristics) then the evaluation cannot be restricted simply to these two programs if it is to be used to pursue allocative efficiency. The evaluation must also consider the opportunity cost of reducing the size of other programs impacted by the budget constraint[156]. Information on project scale, indivisibilities and the resource pool is thus important.

The World Bank report also makes a different but related point that spending on interventions that are very cost-effective, but resolve very small disease burdens, could waste resources by making it difficult to deal with diseases that impose much larger burdens. This argument reflects the level of fixed costs involved in infrastructure and program administration that World Bank projects impose, together with the limited availability of administrative capacity and project funding.

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[156] For example, a new program 'B' which costs $2 million may produce a greater rate of return (or smaller C/B ratio) than the current program 'A' costing $0.5 million. But that does not mean necessarily mean substituting 'B' for 'A' would be efficient, because 'B' not only consumes the resources presently going to 'A', but also the resources of other programs. This of course is an old issue raised in earlier texts on cost benefit analysis (see for example Dasgupta and Pearce, 1972).

10.4 Evolution of the Initial Concept

It is clear from Section 10.3 that MEEM started life as a technical approach (see Chapter Two) focussed on evaluating multiple interventions for health promotion and/or illness prevention in accordance with proscribed economic decision rules. The concept of benefit was based on health gain only, measured using changes in cases detected and/or mortality (using cause-deleted life tables). Since this initial focus in the early 1990's, MEEM has evolved in a number of ways, reflecting my continual involvement in priority setting tasks – in particular PBMA (Peacock, Richardson et al. 1997b; Carter, Mihalopoulos et al. 2000; Carter, Stone et al. 2000) and disease specific modeling (Mihalopoulos, Carter et al. 1999) – together with ongoing study of the theoretical and empirical priority setting literature. The development of MEEM was also aided by the helpful feedback I received at various conferences I presented MEEM (and the early case studies) over the years of my candidature[157].

More specifically, MEEM evolved in four key ways, which is reflected in the major case study presented in Chapter Twelve. First, the technical specification of decision rules and the associated arithmetic was tempered by an appreciation of the importance of due process – that legitimacy comes from both an acceptance of the logic behind the decision rules, together with the decision-making process by which the outcomes were derived (refer Chapters Seven and Five). As a consequence the PBMA framework was adopted as the way of incorporating consensus processes (that Coast calls pluralistic bargaining (Coast and Donovan 1996)), together with the participation of stakeholders in the decision-making process.

Second, and related to the first point, empirical evidence from a variety of sources (refer Chapter Six), together with my own work, highlighted the important role played by judgement in arriving at sensible priority decisions, as opposed to decisions based on the automatic application of rules. Again, the PBMA process provided a potential vehicle through which judgement could be incorporated in an explicit way (so as not to default back to implicit priority setting), and clarity achieved about the ethical values that underpinned the judgements (refer Chapter Five). Achievement of this aim also involved the development of

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[157] These conferences included the following:

- Carter, R. (1992) "Macro economic evaluation model for health policy", Proceedings of the Annual Conference of the Australian Evaluation Society. Melbourne.
- Carter, R et al. (1992) "Macro economic evaluation model for health policy", Proceedings of the 24ht Annual Conference of the Public Health Association of Australia, Canberra.
- Carter, R. (1993) "Macro Economic Evaluation Model", Proceedings of the Second European Conference of Health Economists, Paris.
- Carter, R (1993) "Economic Approach to Health Promotion: A Macro Approach to Assist Health Policy", Economic Planning Advisory Council Seminar "Investing In Health – A Challenging Future", Canberra.
- Carter, R (2000) "Priority Setting in Cancer Control: Using DALYs in an Evidence-based Approach to PBMA". Proceedings of the Third International Conference on Priorities in Health Care, Amsterdam.

the PBMA process (as it was then being applied) to develop the evidence base and achieve greater clarity in the measurement of benefit.

Third, and related to due process and judgement, the narrow definition of benefit which focussed only on health gain was broadened to reflect broader considerations that are important to decision-makers and the general community. It was clear from the empirical and ethical literature, and consistent with economic theory, that the arguments in the social welfare function needed to include distributive equity and other legitimate concerns of decision-makers (feasibility, acceptability, size of the problem, severity and health potentials; affordability, evidence base, etc). Again, the PBMA approach provided an appropriate framework to broaden the concept of benefit and to clearly relate "benefit" to health system objectives.

Fourth, the initial focus in MEEM on health promotion and illness prevention was broadened to encompass the complete disease pathway from prevention through to palliation. The broadening has both a theoretical rationale (in that the pursuit of allocative efficiency is contingent on the generation of a meaningful range of comparators) as well as a pragmatic rationale of usefulness for decision-makers (in that the decision contexts I was encountering increasingly involved priority setting across the full disease pathway).

The result of this evolution is a more robust and practical macro evaluation model that has been applied in one major case study. This study, presented in Chapter Twelve, had as one of its essential tasks to examine the acceptability of the MEEM Mark II approach to the participants. This assessment was considered important to support claims that MEEM was likely to be acceptable to decision-makers and demonstrated potential to make a real contribution to priority setting.

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Chapter Eleven: Solving the Data Problem

" [W]ithin any resource constraint, there may be a direct conflict for technical priority-setting schemes. This conflict is between assumptions about heterogeneity and the acquisition of good quality data." (p.53) (Coast 1996)

"A third defence of comprehensive POD studies is that results may, in fact, be used to estimate the benefits from interventions once the efficacy of the intervention is known. If it is assumed that the marginal and average benefits are the same then the QALY/DALY benefit of an intervention which cures x percent of the population affected by the illness will be x percent of the BOD." (p.5) (Richardson 2001)

11.1 Introduction

Chapter Eleven focuses on how the information needs of MEEM were made tractable through the development of a database on health care expenditure and the utilisation of DALYs as the preferred summary measure of population health.

An overview is provided of the cost-of-illness (COI) research undertaken as an input to MEEM. The Acknowledgments to the thesis contain a brief history of this research in order to document my contribution. The description in this chapter is based on a joint AIHW/CHPE publication (which I co-authored with the AIHW research team[158]) released to document the methodology (Mathers, Stevenson et al. 1998). As the focus of the thesis is on priority setting, rather than COI analysis, no attempt is made to present the COI methodology in detail or to trace its development from my initial approach. References are provided, however, where the detail is available (particularly in (Mathers, Stevenson et al. 1998)), but also in various working papers and publications released by the MEEM/DCIS collaboration (see footnote).

A similar approach is taken in relation to the Burden of Disease (BOD) database, where the focus is placed on the appropriateness of the chosen health status measure (i.e. DALYs), rather than detailed explanations of the various summary measures of population health available.

11.2 Cost Information

As explained in Chapter Ten, the development of the COI database was undertaken to make the data needs of macro evaluation tractable. The COI database helps to do this by providing

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[158] The initial COI research work at the AIHW was called the Macro Economic Evaluation Model (MEEM), reflecting my interest in using the estimates as input to MEEM. When I left the AIHW and joined the Centre for Health Program Evaluation (CHPE) the COI research continued under the leadership of Dr Colin Mathers. The COI research at the AIHW was re-named the Disease Costs and Impact Study (DCIS) to reflect my focus on MEEM, which I took with me to the CHPE. I continued my involvement in the COI work through collaboration with the DCIS research team.

consistent and comprehensive descriptions of current expenditure patterns (i.e. current practice) as well as potential cost offsets, once the efficacy of options for change is known. This role for COI in economic evaluation/priority setting requires acceptance of the simplifying assumption that average costs by age/sex disease groups can be used as reasonable estimates of marginal costs. As Richardson comments:

> *"The assumption is not unreasonable and commonly made in single intervention studies." (Richardson 2001).*

This simplification is commonly made and may be justified in the long run if services may be expanded at average cost and if complexity of cases treated does not increase substantially.

11.2.1 Overview

The basic approach in estimating the direct costs of health service provision has been to take known aggregate expenditures on health care (published in the AIHW Health Expenditure Bulletins (AIHW 1992-2000)) and develop attribution formulae to apportion these to disease categories using Australian data[159] on disease prevalence and health service utilisation. The disease costing methodology aims to disaggregate the total recurrent health expenditure ($31.4 billion in 1993/94) by the following dimensions:

- disease (defined by ICD-9 code groups (World Health Organisation 1977));
- service provider sector (hospital inpatient; hospital outpatient; medical services; nursing home; allied health services; pharmaceuticals; etc);
- program (treatment; prevention);
- gender (male; female); and
- age group (0-4; 5-14; 15-24; 25-34; 35-44; 45-54; 55-64; 65- 74; 75+).

A prevalence-based costing approach is used, reflecting the available data sets. The prevalence-based approach provides estimates of the direct costs of heath services for preventing, diagnosing and treating illness incurred as a consequence of the prevalence of illness (i.e. all existing cases) during a specified period, usually one year. An incidence-based approach on the other hand, would estimate the present value of total expenditure – in the reference year and beyond – for complete care of all *new* cases in the reference period. The incidence/prevalence distinction is relevant because some options for change relate to health promotion, which can only prevent new cases from occurring, while other options might be applicable to all existing cases. In terms of total expenditure per disease group, this raises issues both in relation to the

number of cases included in the analysis and the cost per case. By and large, economists prefer to work with incidence-based costs in economic evaluations[160], while COI analysts prefer prevalence-based costs[161] (Rice, Kelman et al. 1991). To the extent that disease episodes are of a short duration, prevalence-based costings give similar estimates to incidence-based costings, and the net effect of this distinction will thus vary from disease to disease.

One way of resolving the lack of data on the number of incident cases (as opposed to cost per case) has been made available through the DALY research program (Murray and Lopez 1996; Mathers, Vos et al. 1999; Vos and Begg 1999a; Vos and Begg 1999b). In order to assist disease experts to arrive at internally consistent estimates of incidence, duration and case fatality rates for the Global Burden of Disease Study, the Burden of Disease Unit at the Centre for Health and Population Studies, Harvard, developed the DISMOD software program. DISMOD enables incidence and duration to be modeled from estimates of disease prevalence, remission, case fatality and background fatality. As a consequence, a by-product of the Australian DALY study is a detailed mapping between disease incidence and disease prevalence (refer Annex Table D (Mathers, Vos et al. 1999)). While DISMOD has been employed in the DALY database utilised by MEEM in the major case study (refer Section 11.3), it has not yet been utilised to produce incidence-based COI estimates. Given the number of component databases involved in the COI work (see below) and the National Accounts orientation, this may take a little time to achieve. The impact of the incidence /prevalence issue is discussed further in Chapter Twelve in the context of the case study.

An important feature of the MEEM/DCIS disease costing work (refer footnote) is its coverage of the complete ICD-9 framework which makes it possible to ensure that the attributed disease costs sum to the totals in the AIHW Health Expenditure Database. A known problem with one-off COI studies is their tendency to over-estimate the costs attributed to individual diseases, with no reliable independent mechanism available for validation (other than reviewing their own assumptions and costing methods, and/or cross-checking against other one-off COI studies). When the cost of diet-related diseases was estimated using the MEEM/DCIS approach, for example (Crowley, Antioch et al. 1992), the results were approximately half those of earlier estimates.

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[159] The key attribution databases are the hospital morbidity database held at the AIHW; casemix data; the 1990-91 Survey of Morbidity and Treatment in General Practice; and the ABS National Health Survey. Refer Table 11.2 for further detail.

[160] As the pathways of care are tracked through time, which incorporates the full effects of an intervention (both the health status and cost effects, together with the timing of those effects) for the chosen reference population.

[161] Due to the data issues posed by the incidence-based approach – i.e. tracking patients through time – and the ready availability of prevalence data sets associated with administrative data collections.

11.2.2 Identifying the direct costs to be included

The areas of health expenditure included in the MEEM/DCIS approach (based on the AIHW Health Expenditure Database) are shown in Table 11.1. It should be noted that MEEM/DCIS reorganises some areas of expenditure in the AIHW Health Expenditure Database to split hospital

Table 11.1: Total recurrent health expenditure 1993-94, by MEEM/DCIS area of expenditure

MEEM/DCIS area of expenditure	Expenditure $ millions	As per cent of the total expenditure
Hospital inpatients		
Recognised public hospitals	7,652	22.4
Private hospitals	3,221	9.4
Repatriation hospitals	295	0.9
Public psychiatric hospitals	473	1.4
Hospital non-inpatients	2,421	7.1
Nursing homes	2,647	7.8
Out-of-hospital medical services	5,640	16.5
Dental services	1,831	5.4
Allied health services	1,244	3.6
Pharmaceuticals		
Prescription drugs	2,972	8.7
Over-the-counter drugs	1,070	3.1
Cancer-related public health programs[a]	69	0.2
Research	534	1.6
Other institutional (nec)	121	0.4
Administration	1,099	3.2
Other non-institutional	109	0.3
Total included in the MEEM/DCIS costings	**31,397**	**92**
Not included in the MEEM/DCIS costings		
Ambulance	484	1.4
Community/public health[b]	1,490	4.4
Aids and appliances	770	2.3
	34,141	**100**
Total recurrent health expenditure	**1,852**	
Capital expenditure		

Source: Based on (Mathers, Stevenson et al. 1998) Table 1.2 on page 6.
Notes:
(a) Includes costs of breast, cervix, lung and skin cancer screening/prevention programs (Richardson, Segal et al. 1996; Carter, Marks et al. 1999).
(b) Community health services and public health services other than breast, cervical, lung and skin cancer programs in (a).

expenditure into inpatient and outpatient costs; to include in-hospital private medical costs with inpatient costs (rather than as out-of-hospital medical services); and to split pharmaceuticals

into prescription drugs and over-the-counter medicines. The current MEEM/DCIS methodology has increased the proportion of direct health expenditure included in the disease costings from around 70% (in the initial1989/90 estimates) to 92% (in the 1993/94 estimates). Recurrent expenditure on health care which has not yet been attributed includes expenditure on ambulance services, community health services, health promotion and illness prevention services (apart from selected public health programs in cancer control) and aids and appliances. Other types of direct costs not yet attributed to disease categories are capital expenditure ($1.85 billion in 1993/94) and costs not counted within the National Accounts context of the AIHW Health Expenditure Database. These include costs incurred by families and friends in caring for patients, travel costs of patients and welfare services.

The current estimates of direct costs are therefore conservative. Detailed "bottom-up" costing of the treatment costs of a specific disease[162], calculated by adding up actual costs for a cohort of patients, may in some cases give more accurate estimates than the "top-down" approach of MEEM/DCIS (as well as incident-based estimates). Important advantages of the MEEM/DCIS approach, however, is that it ensures consistency of costing method, complete coverage of all diseases, and provides the validation check that cost estimates for individual diseases and age-gender groups add to the known total health recurrent expenditures.

11.2.3 Attribution of cost categories to disease groups

The health sector expenditures shown in Table 11.1 are attributed to disease, age and sex groups using available data on the distribution of service utilisation and the relative cost of services (where available). The data sets used and the basic method of attribution is summarised in Table 11.2 and overviewed below. More detailed information is available in Chapters 2 to 8 of (Mathers, Stevenson et al. 1998) published separately by the AIHW as part of the AIHW/NCHPE collaboration.

Hospital inpatient services

This sector includes inpatient (admitted patient) costs for recognised public hospitals (including public psychiatric hospitals), repatriation hospitals (Department of Veterans' Affairs) and private hospitals. The proportions of total public acute hospital expenditure that relate to inpatients are given by the inpatient fractions estimated for each State/Territory by the National Health Ministers' Benchmarking Working Group (National Health Ministers' Benchmarking Working Group 1996).

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[162] Such as the MORUCOS model for Stroke ! developed with a colleague, which utilises an NHMRC funded cohort study of stroke cases in the North East Metropolitan area of Melbourne (Mihalopoulos, Carter et al. 1999).

Table 11.2: Summary of MEEM/DCIS methodology, 1993-94

Health Sector	Basis of cost attribution to age-sex disease groups	Data sources
Hospitals		
Acute hospital inpatients	Separations weighted by DRG cost weight and length of stay.	AIHW National Hospital Morbidity Database 1993-94.
Repatriation hospital inpatients	Beddays.	AIHW National Hospital Morbidity Database 1993-94.
Public psychiatric hospital inpatients		
Hospital non-inpatients	At chapter level: number of visits in last two weeks. Sub-chapter level according to inpatient separation by site.	1989-90 ABS National health Survey. AIHW National Morbidity Database 1993-94.
Medical services		
In-hospital medical services for private, compensable and other patients	Separations weighted by DRG-based estimated medical service cost weights.	AIHW National Hospital Morbidity Database 1993-94. Medicare data on fees charged for eligible in-hospital medical services 1993-94.
Out-of-hospital medical services	GP encounters weighted by Medicare data on fees charged. Specialist referrals by GPs, weighted by Medicare data on fees charged.	Medicare data on fees charged for eligible out-of-hospital medical services 1993-94. 1990-91 Survey of Morbidity and Treatment in General Practice.
Pharmaceuticals		
Prescription drugs	Prescriptions weighted by relative utilisation and average prescription cost for therapeutic drug group	Pharmaceutical Benefits Scheme Utilisation & Cost data for 1993-4 1990-91 Survey of Morbidity and General Practice.
Over-the-counter medicines	Use of non-prescription medications in the last two weeks	1989-90 ABS National Health Survey.
Allied health services		
	Reported visits in the last two weeks, together with GP referrals	1989-90 ABS National Health Survey. 1990-91 Survey of Morbidity and treatment in General Practice.
Nursing homes		
	For ICD-9 chapters: number of residents by main disabling condition. Attribution to sub-chapters: on basis of distribution of transfers from acute hospitals	1993 Survey of Disability, Ageing and carers. AIHW National Hospital Morbidity Database 1993-94
Other		
Public Health (partial coverage only)	Estimated costs for breast and cervix national screening programs and for lung & skin cancer prevention programs.	(Richardson, Segal et al. 1996) (Carter, Marks et al. 1999)
Research	Estimated expenditure for major diseases from (Nichol, McNeice et al. 1994) Distributed to detailed age/sex/disease groups in proportion to NHMRC and other relevant grant distributions	(Nichol, McNeice et al. 1994) NHMRC 1996
Other institutional (nec) Administration and Other non-institutional	Allocated to age/sex/disease groups in proportion to total expenditure in other categories	n.a.

Source: Based on Table 1.3 in (Mathers, Stevenson et al. 1998) page 7.

The basic approach to estimating acute hospital inpatient costs by disease category, age and sex is to apportion total inpatient expenditure to individual episodes of hospitalisation with an adjustment for resource intensity for the specific episode (using DRGs). The AIHW National Hospital Morbidity Database contains information on all inpatient episodes for public hospitals,

repatriation hospitals and private acute hospitals in Australia in 1993-94 on a state by state basis. DRGs are coded using Version 1 or Version 2 of the Australian National DRG coding system (KPMG Peat Marwick 1993/1994). The age/sex/disease estimates are made at the State/Territory level and then aggregated to produce the national estimates. To account for patients with unusually long periods of stay, "outlier " days are costed at a lower nursing home rate. Medical costs for private, compensable and other non-public patients in public and private hospitals are estimated for age/sex/disease groups using a set of private medical weights for DRGs and age/sex specific information from the Health Insurance Commission on in-patient private medical charges for various categories of service.

Outpatient and casualty services

The total expenditure on non-inpatients is estimated using the State/Territory inpatient fractions from the National Ministers' Benchmarking Working Group (1996). The 1989-90 ABS National Health Survey (Australian Bureau of Statistics (ABS) 1989-90) is used to apportion non-inpatient costs to the ICD-9 chapters. Total visits to outpatient clinics (including casualty or accident and emergency departments) for each age/sex/disease group are estimated from the National Health Survey (NHS) data on numbers of outpatient visits in the two weeks prior to interview. Expenditure is allocated assuming that all visits have the same cost[163]. Expenditure at the sub-chapter level is apportioned using the specific codes used to record health conditions in the NHS and, where these do not provide sufficient detail, on the corresponding attribution fractions based on the DCIS inpatient expenditure fractions for acute hospitals

Recurrent expenditure for public psychiatric hospitals included in the AIHW Health Expenditure Database relate entirely to hospitals. Outpatient expenditures by public psychiatric hospitals are included with other non-inpatient psychiatric services in the "Community and Public Health" sector, which is not yet included in the MEEM/DCIS disease cost estimates.

Nursing homes

The distribution of the main disabling health condition of nursing home residents in the 1993 Australian Survey of Disability, Ageing and Carers (Australian Bureau of Statistics (ABS) 1993) is used to allocate total nursing home expenditure for 1993-94 to age/sex/disease categories at the ICD-9 chapter level[164]. This expenditure is apportioned to specific disease groups at the sub-

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[163] When the 1993-94 estimates were calculated there were no suitable outpatient DRG weights available. This has changed in recent times and it remains a task for the AIHW to update the DCIS methodology to incorporate them.

[164] This procedure includes the simplifying assumption that all beddays are of equal average cost. While an adjustment for resource intensity is clearly desirable, data are not yet available on the distribution of dependency levels of nursing homes residents by disease category. These dependency levels form the basis of Commonwealth payments to nursing homes. If and when such data becomes available the DCIS methodology will be revised.

chapter level according to the distribution of diagnoses for patients in that age/sex group who transfer from acute hospitals (around 65% of nursing home admissions).

The current methodology does not take account of co-morbidities in the elderly and assumes that all the cost is attributable to the main disabling condition. The method also assumes that disability is the principal reason for nursing home admittance. Depending on the uses to which the MEEM/DCIS data is put, it may not be appropriate to treat all nursing home expenditure as health service costs or to attribute all nursing home patients to disease categories. Co-morbidities may be too extensive in the older age groups and, for some applications, it may be sensible to exclude nursing home expenditure for the "oldest old". However, as total nursing home expenditure is included in the National Accounts and AIHW health expenditure estimates as "health expenditure", it is fully included in the base MEEM/DCIS estimates.

Medical services

This sector includes expenditure on all private medical services (GPs and specialists) apart from those for hospital inpatients. It includes consultations as well as pathology tests, screening services and diagnostic imaging services. The GP survey (Bridges-Webb, Britt et al. 1992) is used to calculate attribution factors (refer (Mathers, Stevenson et al. 1998) for details) to allocate age/sex specific out-of-hospital expenditure on medical services to disease groups. This allocation is done separately for GPs (based on patient encounter profiles) and for 17 categories of specialist (based on the GP referrals to each category of specialist in the survey).

The GP survey covered a representative sample of approximately 100,000 GP visits (encounters) in 1990-1991 and collected information on the age and sex of the patient; reasons for encounter and diagnosis made; referrals to specialists and allied health professionals; treatments and pharmaceutical scripts; and orders for tests and investigations. The MEEM/DCIS methodology assumes that the pattern of GP services by diagnosis in 1993-94 is the same as that collected in the 1990-91 survey, that the pattern of diseases managed by each type of specialist in 1993-94 reflects the pattern of referrals to that specialist type from GPs in 1990-91, and that each referral to a specialist of a given type generates services with equal cost.

Allied health services

The GP survey (Bridges-Webb, Britt et al. 1992) and the National Health Survey (Australian Bureau of Statistics (ABS, 1989-90) are also used to develop attribution formulae to allocate total Australian expenditure on allied health practitioners to age/sex disease groups. Total visits to allied health practitioners in 1994-94 for each age/sex disease group are estimated from the NHS data on visits to 14 types of allied health practitioner in the two weeks prior to interview. Annual visits to other types of allied health practitioner are estimated from referrals by GPs in the GP

survey. The expenditure allocated at the ICD-9 chapter level is apportioned to specific diseases at the sub-chapter level purely on the basis of the GP survey. Expenditure is allocated assuming that all visits of a given type have the same cost. This methodology covers all allied health professionals except pharmacists, which are covered under pharmaceutical expenditure.

Pharmaceuticals

Total pharmaceutical expenditure is divided into two components: prescription drugs and over-the-counter pharmaceuticals. Estimates of over-the-counter drug expenditure from the 1993-94 ABS Household Expenditure Database (Australian Bureau of Statistics (ABS) 1996) and of total expenditure on private prescriptions are used to split total pharmaceutical expenditure in the AIHW Health Expenditure Database.

Around 70% of non-hospital prescriptions are dispensed under two subsidisation schemes, viz: the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS). Data from the GP survey, together with 1993-94 estimates of total costs and numbers of prescriptions for 40 major categories of drugs are used to allocate total expenditure on prescription drugs to age/sex disease groups. Expenditure on over-the-counter pharmaceuticals is attributed to age/sex disease groups using information from the NHS. The level of detail on disease codes in the NHS varies with ICD-9 chapter, and where necessary the attribution formula is supplemented by recourse to other databases (such as doctor visits). This methodology addresses all pharmaceutical costs apart from the cost of pharmaceuticals dispensed in hospitals, which is included in the estimates of hospital costs.

Information for the 40 major therapeutic drug groups comes from the Pharmaceutical Benefits Pricing Authority (Pharmaceutical Benefits Pricing Authority 1994) and covers the relative distribution of prescriptions by disease, age and sex for all community prescriptions in 1993-94. This database enables the MEEM/DCIS methodology to take into account average drug costs across therapeutic categories, average number of repeats, and relative changes in utilisation and costs across drug categories through time.

Other health service expenditures

All dental services were allocated to ICD-9 chapter "Digestive system diseases". Expenditure and utilisation of these services was further allocated to treatment or prevention and screening using attribution factors calculated from the 1989/90 ABS National Health Survey (Australian Bureau of Statistics (ABS) 1989-90). Cost weights for allocating costs to occasions of service were taken from the 1993 Dental Fees Survey and total numbers of services were estimated from the 1994 National Dental Telephone Interview Survey.

Community and public health programs in general are not yet included in the estimates of disease costs due to the difficulties in obtaining comprehensive and consistent cost/utilisation data for these services[165]. However, in the context of assisting the 1997 National Cancer Control Initiative, a briefing paper on costs of cancer was prepared (Mathers, Penm et al. 1998) and estimates were included for major cancer prevention initiatives. These included breast cancer screening (Richardson, Segal et al. 1996), cervical cancer screening (Harris and Scott 1995), and programs for lung (Carter and Scollo 1999) and skin cancer prevention (Carter, Marks et al. 1999). For some programs, these source estimates were adjusted as reported in (Mathers, Stevenson et al. 1998).

Estimated total Australian expenditure on health and medical research for major disease and population groups in 1991 (Nichol, McNeice et al. 1994) was used to estimate total research spending for males and females by ICD-9 chapter. For most ICD-9 chapters, attribution at the sub-chapter level to age/sex disease groups was based on simple pro-ration in proportion to total health expenditure for all other service sectors. For two chapters (cancer and cardiovascular disease) analysis was carried out of the distribution of grants by major research councils[166] to give more accurate estimates.

Other institutional health expenditure (the Red Cross Blood Transfusion Service), other non institutional expenditure (Family Planning Services) and administration expenditure (Commonwealth and State/Territory administrations; management of Medicare; and private health insurance funds) was attributed to age/sex disease groups by simple pro-ration in proportion to total health expenditure for all other service sectors.

11.2.3 Disease categories used in MEEM/DCIS

In the MEEM/DCIS approach disease is classified using the International Classification of Diseases, Ninth Version, Clinical Modification (or ICD-9-CM). The list of diseases is based on the minimum set needed to cost each chapter of the ICD-9 in total and to cost sub-chapter level disease groups for key areas (such as cardiovascular disease, cancer and injury). Where other classifications of disease are encountered in the source data sets, such as the International Classification of Primary Care (ICPC), these are mapped across to the ICD-9-CM (using reference publications and coders at the AIHW). Table 11.3 illustrates the coding of the cancer chapter, utilised in the major case study (Chapter Twelve).

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[165] The AIHW is undertaking a project, on behalf of both Commonwealth and State/Territory health departments, to improve the reporting of expenditure on public health, and when this data is available it will enable this aspect of the DCIS database to be improved.

[166] These included the National Health and Medical Research Council, the New South Wales Cancer Council and the Victorian Anti-Cancer Council.

Table 11.3: Example of coding classification system for MEEM/DCIS: Neoplasms.

MEEM/DCIS group	ICD-9 Codes	ICPC codes	National Health Survey
Cancers			
Treatment	140-239, V58.0, V58.1, V66.1, V66.2, V67.2, V71.1, V10, V15.3	A79, B72-B75, D75-D78, F74, H75, K72, L71, N74-N76, R84-R86, S77-S82, T71-T73, U75-U79, W72, X75-X81, Y77-Y79	073
Prevention & screening	V16, V76	A26, B26, D26, L26, N26, R26, S26, T26, U26, X25, X26, Y26	074, 097

Source: Abstract from Table 1.4, page 13, (Mathers, Stevenson et al. 1998)

The term "cancer" is generally used in clinical and epidemiological parlance to refer to invasive (malignant) neoplasms and excludes in situ carcinomas, benign neoplasms and neoplasms of uncertain behaviour. In the MEEM/DCIS approach, estimates are given both including and excluding the non-malignant categories of disease. This is because their inclusion is often appropriate from an economic perspective, as much of the resource utilisation associated with health promotion and illness prevention, together with diagnostic activity, is undertaken to prevent or exclude malignancy. The categories for costing neoplasms by site and type are defined in Table 11.4. ICPC code mappings for individual cancer sites are documented in detail in Appendix A of the report on cancer costs (Mathers, Penm et al. 1998).

11.3 Outcome Information

The utilisation and role of the BOD database in making macro economic evaluation tractable is identical to that of the COI database. The BOD database is needed to provide a consistent and comprehensive description of current health status, as well as potential health gains once the efficacy of options for change is known. As with COI, this role for BOD in economic evaluation/priority setting requires acceptance of the simplifying assumption that average benefits by age/sex disease sub-groups can be used as reasonable estimates of marginal benefits. Thus if an intervention prevents 10% of an illness from occurring for men aged 50 plus, then it is assumed that 10% of the associated burden of disease in that sub-group can be prevented. This is a simplification, which is commonly made, and is justifiable if the complexity of cases treated does not alter substantially within the sub-groups – and therefore a similar pattern of treatment and recovery can be assumed.

Table 11.4: Classification of cancer sites in terms of ICD-9 codes for neoplasms

Cancer Site	Malignant neoplasms	Benign, In Situ and Uncertain	Prevention Activities
Head & neck	140-149	210, 212.0, 230.0, 235.0, 235.1	V76.42
Oesophagus	150	211.0, 230.1, 235.5, 239.0	
Stomach	151	211.1, 230.2, 235.2, 239.0	
Colorectal	153-154	211.3, 211.4, 230.3-230.6, 239.9	V76.41
Liver	155	211.5, 230.8, 235.3	
Pancreas	157	211.6-211.7, 235.5, 239.0	
Lung	162	212.2, 212.3, 231.1, 231.2, 235.7, 239.1	V16.1, V76.0
Melanoma	172	216, 232, 238.2	V76.43
Non-melanoma	173	216,232,238.2	
Breast	174	217, 233.0, 238.3, 239.3	V16.3, V76.1
Cervix	180	219.0, 219.9, 233.1-233.2, 236.6 (50%)	V76.2
Uterus	179,182	218, 219.1-219.8, 236.0 (50%)	
Ovary	183	220, 233.3, 236.2	
Prostate	185	222.2, 233.4, 236.5	
Bladder	188	223.2, 223.3, 233.7, 236.7, 236.99, 239.4	V76.3
Kidney	189.0, 189.1	223.0-223.1, 236.91	V16.5
Brain & CNS	191-192	225, 237.5,239.6	
Lymphoma	200-203	228, 229, 238.5-238.6	V16.7
Leukaemia	204-208	238.7	V16.6
Other neoplasms	Balance of 140-208	Balance 210-239	Balance V16, V76
Unspecified sites	V58.0, V58.1, V66.1, V66.2, V67.1, V67.2, V71.1, V10, V15.3		V16.9, V76.9

Source: Table 1.5, page 16 (Mathers, Stevenson et al. 1998)

Summary measures of population health (SMPH) are measures that combine information on mortality and non-fatal outcomes to represent population health in a single number (Field and Gold 1998). In the last decade there has been a marked increase in the number of SMPHs available, developed for a variety of purposes[167], including description, monitoring and evaluation.

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[167] The range of purposes include:

- comparing health conditions or overall health status between different populations (or population sub-groups), or the same population over time;
- quantifying health inequalities;
- quantifying the significance of non-fatal outcomes compared to mortality;
- measuring the magnitude of different health problems using a common metric (often to highlight the "need" for action);

To guide the selection of the most appropriate measure of disease burden from the large number of candidate statistics, three key criteria were adopted, viz:

1) Relevance of the SMPH to the question being asked (Murray, Salomon et al. 1999; Richardson 2001);
2) Validity and reliability of the SMPH, particularly in relation to the purpose and context of the research question; and
3) Availability of a relevant, valid and reliable SMPH calibrated with Australian input data (i.e. descriptive epidemiology on age/sex specific mortality and non-fatal health outcomes; as well as duration and health state weights).

In summary, the Disability Adjusted Life Year (DALY) was chosen as the best available measure for the BOD database of MEEM because; i) there are no suitable alternatives; and ii) because fortunately it performs well or adequately on each on the criteria. The rationale for this assessment is set out below, argued in terms of the three selection criteria, together with various sub-criteria and associated issues. Important questions that arise in selecting the DALY are:

- whether the person trade-off (PTO) approach adopted in the DALY is acceptable as the scaling instrument;
- whether the deliberative approach using panels of experts is acceptable as a source of values for the disability weights; and
- whether the DALY is able to accommodate the need for clarity in relation to ethical values.

11.3.1 Criterion One: Relevance to the research question

The research question for MEEM is clearly one of priority setting within the context of facilitating economic evaluation across multiple interventions along all stages of the disease pathway. This purpose in turn raises a number of sub-criteria, which are largely self-explanatory, viz: the chosen measure must provide or enable:

- measurement of the "social value" of these benefits for less orthodox economic evaluation (Richardson 2001); and
- providing information to assist in setting priorities for health planning, public health programs, and research and development (Murray, Salomon et al. 1999).

1a) a common metric for fatal and non fatal health outcomes[168];

1b) additive decomposition into age/gender sub-groups, population sub-groups, and ICD-9 disease groups to facilitate measurement of benefits in target individuals;

1c) causal attribution to risk factors (such as smoking, exercise, poor diet) using aetiological fractions; and

1d) a BOD database that is consistent with the COI database, in order to achieve reasonable symmetry between cost and outcome estimates.

Two classes of summary measures of population health (SMPH) have been developed in the literature, viz: "health expectancies" and "health gap" measures. Health expectancies are population indicators that estimate the average time in years that a person could expect to live in a defined state of health. Examples include disability-free life expectancy (DFLE), active life expectancy (ALE), disability-adjusted life expectancy (DALE), and health-adjusted life expectancy (HALE) [see, for example, (Mathers, Vos et al. 1999) (Murray and Lopez 1996)]. These measures extend the concept of life expectancy to include expectations of various states of health, not just life per se. Health gap measures, on the other hand, measure the difference between the population experience and some ideal or goal for population health. Health gap SMPHs are a natural extension of the potential years of life lost (PYLL) indicator that has been used for many years to measure premature mortality attributable to various diseases and risk factors. Health gap SMPHs extend the notion of mortality gaps to include time lived in states other than good health. Examples include disability-adjusted life years (DALYs) and healthy life years (HeaLYs) [see, for example, (Mathers, Vos et al. 1999) (Murray and Lopez 1996)]. The relationship between health expectancies and health gaps can be illustrated using a population survival curve, as shown in Figure 11.1. While both classes of SMPH use time (lived in health states or lost through premature death) as an appropriate common metric for measuring the impact of mortality and non-fatal health outcomes, there are important differences in their methodologies that guide their appropriate use.

Health expectancy SMPHs have been promoted by the International Network on Health Expectancy (REVES) and are now widely used at a national level and by the OECD to report on population health[169]. Health expectancy measures generally start with population survey data on disability in order to estimate expectations[170] of years lived in various health states (refer Figure 11.2). This ensures that all disability in the population is counted whether or not it can be attributed to specific diseases or injury. For this reason, health expectancy SMPHs are generally

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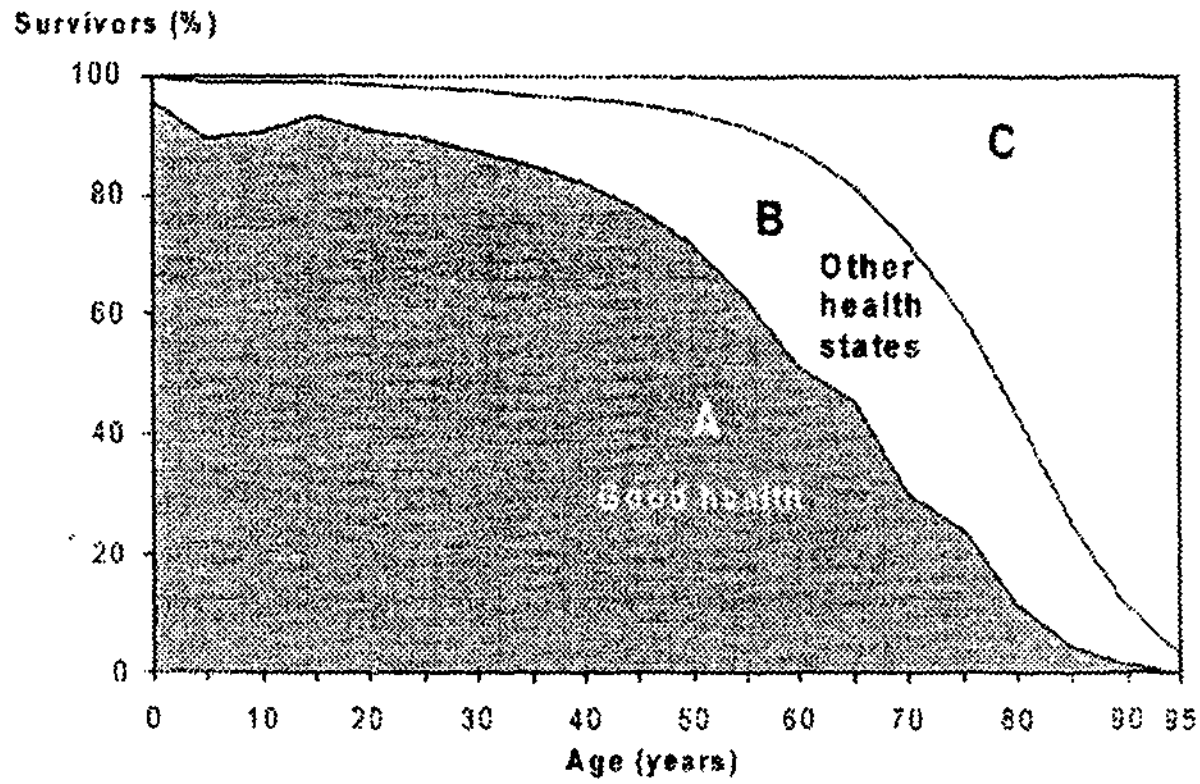
[168] Traditional mortality-based summary measures of population health, such as years of life lost (YLL) used in some of the early MEEM case studies, are no longer adequate for low mortality countries like Australia in a multi-intervention context. Non-fatal consequences of disease and injury are now of similar importance for health and well-being as premature or preventable mortality, and provide the rationale for many interventions.

[169] See for example, (Mathers and Robine 1993; Mathers 1997; OECD 1998; Mathers 1999).

regarded as superior to health gap measures for monitoring purposes, such as tracking trends in the health of populations over time or between countries[171]. The difficulty in mapping health expectancy SMPHs to individual diseases and risk factors, however, limits their usefulness for MEEM. Attempts have been made in Australia to relate health expectancies back to disease and risk factors, however there were severe problems with the quality and comparability of the

Figure 11.1: Population survival curves, health expectancies and health gaps

The relationship between health expectancies and health gaps can be illustrated using a population survival curve. The survival curves in Figure 11.1 are constructed by following a birth cohort over time and plotting for each year (age) the proportion who are still alive and the proportion who are in good health. The curve bounding area C is the usual survival curve of the type typically used to construct a lifetable and the total area (A+B) underneath it represents life expectancy at birth. Health expectancies are measures of the area underneath the survival curve that either give zero weight to years lived in the area labelled B (as in DFLE) or take some proportion of area B to represent its equivalent years of good health. Health gaps measure the difference between the population experience and some ideal or goal for population health. Thus if the ideal was taken to be 95 years of good health followed by death, then the mortality gap would be area C in Figure 11. 1. The health gap would be area C plus some proportion of area B representing the equivalent lost years of good health.



Source: Mathers, Vos et al. (1999) Burden of Disease and Injury in Australia, AIHW (p. 6).

self-reported data in the disability surveys used (Mathers 1992; Mathers 1997b; Mathers 1999b). Health expectancy measures are capable of meeting sub-criteria 1a) but fail to meet the

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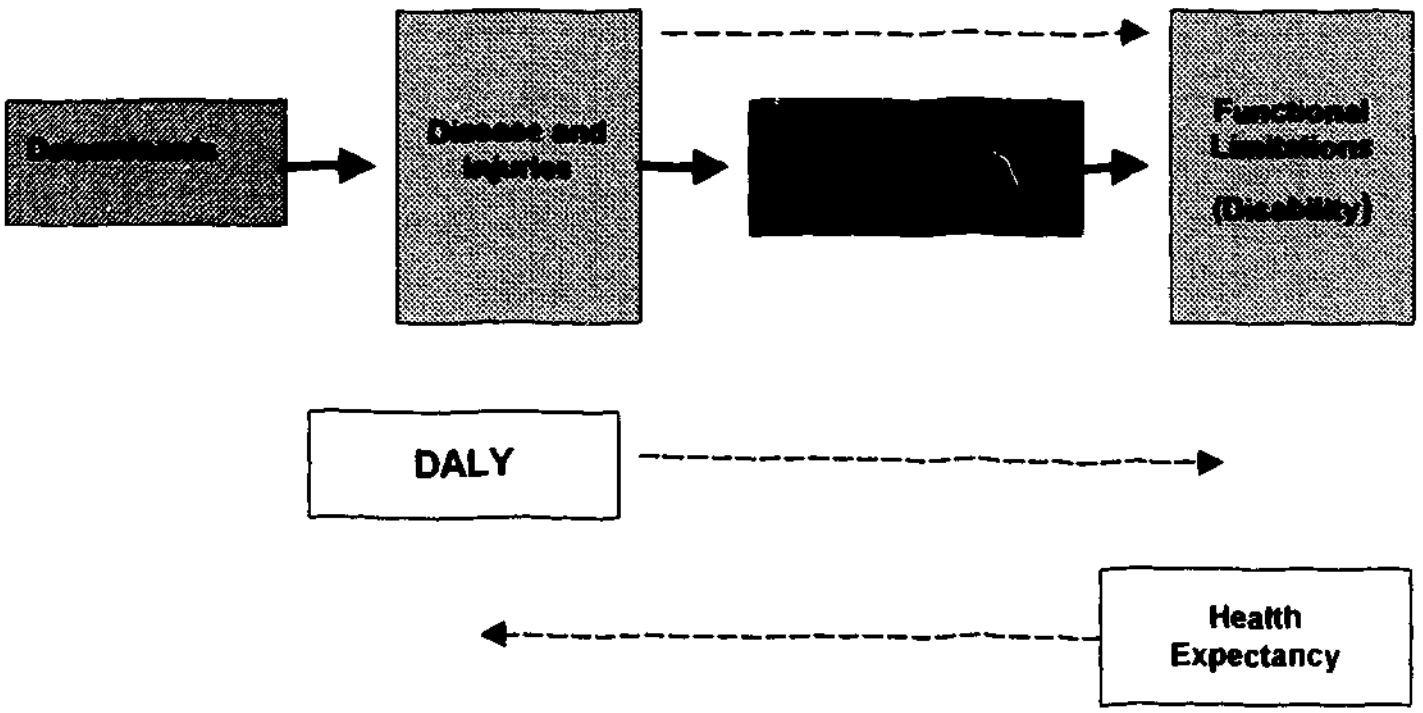
[170] The cross-sectional disability data is projected forward for a hypothetical population, as with the life table methodology.

remaining criteria. This makes their use in economic evaluation problematic and compromises the analyst's ability to carry out marginal analysis at an acceptable level of disaggregation.

Unlike health expectancy measures, health gap calculations start from information on specific diseases (incidence, duration, and prevalence) and then estimate the associated impairments and disability in order to quantify the disease burden (refer Figure 11.2). This involves multiplying the number of new cases by the average duration of the disease (to remission or death) by a derived disability weight that may have no relation to disability survey data. While less suitable for population level monitoring purposes[172], the health gap methodology is superior for quantifying the loss of good health associated with specific diseases in an objective manner across populations.

Figure 11.2: Construction of health expectancy and health gap measures - relating causes to outcomes



Source: Mathers, Vos et al. (1999) Burden of Disease and Injury in Australia, AIHW (p. 7).

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[171] Health expectancy SMPHs also have the advantage in monitoring applications that they are naturally standardised (through the life table approach) so that they are independent of the actual age distribution of a population.

[172] The health gap approach does not readily lend itself to repeated estimates over time since it relies on a synthesis of epidemiological studies which may range over considerable time periods and be repeated at irregular intervals.

Health gap measures are thus useful for analysis of the potential effects of interventions, since these are usually targeted at specific diseases and/or population sub-groups, and the outcome of a preventative or curative intervention is to prevent the stream of lost good health associated with an incident case or fatality due to the health problem. Quantifying the benefits of interventions requires an incident case perspective consistent with the health gap approach. Using population attributable risks (PAFs) it is also possible to estimate the attributable burden of specific risk factors or health determinants. Health gap measures are thus capable of meeting sub-criteria 1a) to 1d), with specific performance depending on the particular health gap measure utilised.

The most widely known of the health gap SMPHs is the disability-adjusted life year or DALY. DALYs are calculated for a disease or health condition as the sum of the years of life lost due to premature mortality (YLL) in the population and the equivalent "healthy" years lost due to disability (YLD) for incident cases of the health condition. The DALY approach has been used to guide World Bank investment policies for health (World Bank 1993; Bobadilla, Cowley et al. 1994) and to inform global priority setting for health research and international health programs (World Health Organisation (WHO) 1996; World Health Organisation (WHO) 1999). The WHO Global Burden of Disease Project (GBD) has used the DALY to provide a comprehensive assessment of the incidence, prevalence, duration, case fatality, and proportion of cases treated by disease, age/sex group and region (Murray and Lopez 1996b), together with a projection of the global burden of disease to the year 2020 (Murray and Lopez 1996). More importantly for the third criterion of selection, two Australian studies have recently been carried out (both for Australia as a whole (Mathers, Vos et al. 1999) and for the state of Victoria (Vos and Begg 1999a; Vos and Begg 1999b)) that provide comprehensive coverage of the ICD-9 framework for the reference year 1996. Other health gap measures, such as the HeaLY (Hyder, Rotlanat et al. 1998; Murray, Salomon et al. 1999) are not available for Australia and do not perform as well under criterion two (see below).

In summary, health gap measures are clearly the preferred form of SMPH for economic evaluation/priority setting and the DALY is the only health gap measure available that provides comprehensive coverage of the ICD-9 framework calibrated with Australian data. The next step was to assess whether the DALY could provide a reliable and valid input to priority setting undertaken using the macro economic evaluation approach of MEEM.

11.3.2 Criterion Two: Validity and reliability of the DALY

Useful approaches to assist with the assessment of validity and reliability of SMPHs have been provided by Richardson (Richardson 1994; Richardson 2001) and Murray, Salomon & Mathers (Murray, Salomon et al. 1999). While the purpose of the Richardson criteria is clearly specified (i.e. assessing whether metrics are appropriate in the context of economic evaluation), the precise purpose of the Murray et al. criteria is harder to ascertain. Murray, Solomon and Mathers propose five criteria for assessing SMPHs based on what they describe as "common-sense notions of population health" that appear to be focused on the monitoring/description roles of SMPHs. Their five criteria are as follows:

1) If age-specific *mortality* decreases in any age group, ceteris paribus, then the summary measure should improve. While the DALY meets this criterion, some health gap measures do not, such as the Healthy Life Years metric (HeaLYs) proposed by Hyder et al. (Hyder, Rotlanat et al. 1998; Murray, Salomon et al. 1999));

2) If age-specific *prevalence* of some health state worse than ideal health increases, ceteris paribus, a summary measure should get worse. It should be noted that incidence-based DALYs such as the GBD and the Australian DALY will not meet this prevalence criterion, but this is not serious problem for MEEM as incidence-based measures are preferable for economic evaluation/ priority setting purposes;

3) If age-specific *incidence* of some health state worse than ideal health increases, ceteris paribus, a summary measure should get worse. The DALY meets this criterion, but no existing SMPH meets both criteria 2) & 3) [173]. Clarity over the purpose for which the SMPH is to be used is therefore essential in judging the relative importance of criteria 2) and 3);

4) If age-specific *remission* for some health state worse than ideal increases, ceteris paribus, a summary measure should improve. The DALY meets this criterion as it focuses on disease-specific incidence and duration data; and

5) If *severity* of a given health state worsens, ceteris paribus, then a summary measure should get worse. This criterion is particularly important for countries like Australia where interventions may be directed at reducing severity without changing mortality, incidence or remission rates eg. psychosocial care. The DALY clearly meets this criterion when used for descriptive/evaluative purposes, but is not as strong as health expectancy measures when population monitoring is required (refer discussion above).

Application of the Murray, Solomon and Mathers criteria thus support the credentials of the DALY as an appropriate SMPH for the MEEM (particularly from an epidemiological/demographic perspective). Arguably, it is more important whether the DALY satisfies criteria posed by Richardson (Richardson 2001), which are focused on assessing whether metrics are appropriate for use in the context of economic evaluation (i.e. from an economic perspective). The Richardson criteria have a particular focus on the scaling techniques used[174] to integrate morbidity and mortality into a single metric. The criteria assess whether:

1) *More units of the summary metric are considered to be of greater social value.* Health gap metrics are simply the mirror image of QALYs in this regard, i.e. less units are considered to be of greater social value. The DALY clearly meets this criterion. Richardson (Richardson 2001) has recently extended this criterion to include additional sub-criteria, viz:

   a) *the metric should embody relevant ethical values which are consistent with stable population values and which reflect any context dependent values.* This sub-criterion raises, among other things, the issue of "double jeopardy" for the disabled commented on by many authors (Arnesen and Nord 1999; Menzel, Gold et al. 1999; Nord 1999; Nord, Pinto Prades et al. 1999)). The DALY is capable of meeting this criterion (refer discussion of ethics below);

   b) *the metric should fully measure the subject of measurement* . This sub-criterion was introduced to eliminate instruments that are insensitive to, or fail to measure, important dimensions of health gain. The modified EuroQol utilised in the calculation of the Dutch weights adopted in the Australian DALY study is acceptable under this sub-criterion, but nowhere near as strong as other QALY instruments (Brazier, Deverill et al. 1999; Richardson, Olsen et al. 1999). The DALY has the significant advantage, however, that it is the only QALY-type measure available for the whole ICD-9 framework; and

   c) *the numerical value of the metrics should not be influenced by extraneous factors.* The DALY is capable of meeting this sub-criterion, although aspects of the GBD DALY have been contentious (eg the age weights; adoption of the Japanese life expectancy) and were not adopted in the Australian studies. The Australian DALY used in MEEM is acceptable on this criterion although the GBD DALY is questionable.

2) *The summary metric should have a clear unambiguous meaning.* This criterion is important in a policy context where decision-makers need to be able to relate the measure of SMPH to

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[173] Ways of combining incidence and prevalence approaches to SMPHs are under consideration, however, in the research community (Barendregt 1999).

their objectives. The GBD DALY could be criticised under this criterion as it combines both a description of population health as well as normative aspects that place a social value on health (eg. the age weights; discounting; ideal life expectancy). Separation of positive and normative aspects is stronger in the Australian DALY, where Australian cohort life expectancy is used, with no age weights and with YLL and YLD available with and without discounting. The Australian DALY used in MEEM meets this criterion.

3) *The summary metric should exhibit appropriate "interval properties"* and in particular

   a) *The metric should have a 'weak' interval property;* viz: that incremental units should, in some easily understood sense, mean the same irrespective of units already obtained. This sub-criterion raises issues associated with severity; health potentials and the rule of rescue discussed in Chapter Five (Richardson and McKie 2000e) (Menzel, Gold et al. 1999; Nord, Pinto Prades et al. 1999)). The DALY, which incorporates the PTO, meets this criterion, but is subject to the same ethical challenges as all summary metrics; and

   b) *the metrics should have a 'strong' interval property*, viz: that an x percent increase in measured quality of life at any point along the QoL spectrum should have, in an easily understood sense, the same value as an x percent increase in the length of life. This sub-criterion raises substantial issues – particularly of an ethical nature - and this property is hard to achieve in practice. While there has been virtually no testing of this property for any instrument reported in the literature, the deliberative PTO approach of the DALY is likely to perform as well as any other approach on this test. The available evidence is very poor, but this criterion in not likely to invalidate the DALY.

4) *The scaling techniques should be sensitive to a change in a health state and be reliable and valid.* Performance of the DALY under the Murray et. al. criteria suggest the DALY is sensitive to a change in health state, and there is empirical evidence to support the reliability and validity of the deliberative PTO approach to disability weights (see below). The DALY is therefore considered acceptable on this criterion.

The Richardson criteria provide a searching litmus test and it is likely that all summary metrics will struggle to fully satisfy them (a conclusion also reached by Richardson (Richardson 2001)). In summary, the DALY (particularly the Australian DALY) was assessed as the best available SMPH for MEEM, because there are no suitable alternatives and fortunately, because it performs well or adequately on each on the criteria. In considering this conclusion, three key issues arise, viz: i) whether the PTO approach adopted in the DALY is acceptable as the scaling instrument?

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[174] The scaling techniques normally canvassed cover the rating scale (RS); magnitude estimation (ME); time trade-off (TTO); person trade-off (PTO); and the standard gamble (SG).

ii) whether the panels of experts are acceptable as a source of values for health state valuations?; and iii) how well the DALY copes with the need for clarity in ethical values?

Choice of the scaling instrument:

A number of methods have been developed for measuring preferences for health states (eg rating scales (RS)/magnitude estimation (ME); the standard gamble (SG); time trade-off (TTO) and person trade-off (PTO)). The different methods reflect different concepts of what is being measured (utility or preferences); differences in application (individual, clinical decision-making, or health service planning and priority setting); and in viewpoint (valuing one's own health state or those of others). It is important to ensure that the method used provides the appropriate type of value, is consistent with the uses to which the resulting summary information will be put, and summarises the preferences of the appropriate people.

For economic evaluation most economists[175] prefer the techniques that involve a trade-off between quantity and quality of life (i.e. TTO, PTO and SG) to the approaches that do not involve a conscious choice. Richardson argues, for example, that the RS/ME approaches do not have a clear meaning and do not satisfy his "strong" interval criterion (3b) (Richardson 2001). Putting RS and MS to one side, Richardson goes on to argue that the choice between TTO, PTO, and SG then comes down to which perspective is wanted in the analysis – personal or societal (Richardson 2001)[176]. Many analysts[177] would agree that the PTO is more suited to the measurement of health states when a societal perspective is required for health service planning decisions, rather than when a personal perspective is sought. While the selection of the preferred scaling technique to guide resource allocation decisions is likely to remain a contested issue (Anand and Hansan 1997), the choice of PTO is at least a credible position, and one that is consistent with the decision-making approach to priority setting adopted for MEEM. The DALY approach (both the GBD and Australian studies) of using the PTO method was thus considered relevant and acceptable for MEEM.

Before leaving this discussion of scaling instruments, Richardson makes an important point in his commentary on SMPHs that is worth noting (Richardson 2001). It is not uncommon in discussions of the appropriate scaling instrument, for references to be made to the "conceptual basis" of the metric, particularly by orthodox economists in defense of the standard gamble. In

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[175] See for example, (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997; Richardson and Nord 1997; Brazier, Deverill et al. 1999).

[176] In an earlier article (Richardson 1994), Richardson argued in support of the TTO/PTO techniques as being less confounded than the SG (due to the irrelevant risk context of the SG instrument), but now sees all three techniques subject to a degree of confounding (TTO by time preference; PTO by distributional considerations; and SG by the risk context).

[177] Eric Nord and Murray & Lopez for example, have argued that for evaluation of health programs at the societal level, the PTO is to be preferred to the SG or TTO. See, for example, (Nord 1994; Nord, Pinto Prades et al. 1999) (Murray and Lopez 1996).

this regard the approach exemplified by the following quote from Richardson is adopted in this thesis, viz:

> *"It is commonplace to ask for the 'conceptual basis' of a metric. This somewhat ambiguous phrase seems to suggest that a SMPH must be the outcome of an established theory. For example, it has been argued that the standard gamble is the 'theoretically correct' instrument to measure HRQoL as it is the instrument implied by the von Neumann Morgenstern axioms of Expected Utility Theory (EUT). This approach is expressly rejected here. The conceptual basis of the metric should be a statement of what it is that the metric seeks to measure and why the metric fulfils the purpose of interest." (p. 1) (Richardson 2001).*

Whose weights should be used?

There is a significant and growing literature (recently reviewed by Brazier et. al. (Brazier, Deverill et al. 1999) and Richardson et. al. (Richardson, Olsen et al. 1999)) about whose values should be incorporated into an SMPH or quality of life measure. As well as representative samples of the general population, groups asked to participate may include patients with direct experience of the health states involved, or health professionals with clinical knowledge of the health states. As with the selection of scaling instrument, much depends on the purpose for which the weights will be used. When used for the purpose of broad policy development, priority setting or resource allocation, there is a credible argument for using the values and preferences of the general population to avoid the undue influence of vested interests (Gold, Siegel et al. 1996, Ubel, Richardson et al. 2000). Support for community values is also argued on the basis that it is the community as taxpayers who pay for health programs, but this argument is less compelling and does not generally apply in other contexts (such as how funding on the armed forces or roadways should be spent) (Richardson 2001).

There is also a credible argument for the counter view that disability weights should reflect the judgements of those who have actually experienced the illness, impairment or disability. The choice is not an easy one, however, with the ethical and equity issues relating to the use of disability weights derived from people who have adapted to long-term health problems or disabilities being widely discussed (refer discussion in Chapter Five and (Murray 1996; Richardson 2001)). A number of writers have argued, nonetheless, for the inclusion of a personal perspective in judging health state improvements, while acknowledging the role of society in deciding what societal value might be attached to these personal utilities (Brazier, Deverill et al. 1999; Richardson, Olsen et al. 1999). Certainly most authors would acknowledge the important role for patients in developing techniques that better describe the health states.

In a more recent contribution, Nord and colleagues (Nord 1999; Nord, Pinto Prades et al. 1999) combined elements of both approaches in proposing a two stage procedure in which patients' perspectives and values are used to produce utility scores (using TTO), and societal representatives then assign weights to convert these into social value (using PTO). This is an

interesting approach that is still being developed and trialed by its proponents.

The GBD weighting studies for the DALY adopted the alternative of using a small group of health experts (mostly clinicians) to make judgements in a deliberative process on behalf of society and the patient. This approach was based on the judgement that a deliberative approach with small groups of people was necessary to produce weights that meaningfully reflect social preferences. Its proponents argue that the deliberative approach helps to ensure that participants fully understand and are aware of the implications of their choices (Murray 1996). Economists, with their tradition of assuming rationality and good information (refer Chapter Four) have extended this to the context of stated preferences and assumed that respondent answers are reliable and valid. Interestingly, studies that have used the deliberative approach have found little empirical support for the economic tradition of assuming rationality and good information on the part of participants (Richardson 2001).

Health experts were used in the GBD panel for convenience reasons due to the practical difficulties in ensuring that lay persons fully understood the impact and severity distribution of the illnesses being valued. In the case of the GBD the health state descriptors were poorly developed. The Australian DALY studies attempted to improve on the GBD approach by adopting disability weights developed for the Dutch BOD exercise. The Dutch disability weight study (Stouthard, Essink-Bot et al. 1997) improved on the GBD disease state descriptors, by defining the distribution of health states associated with a disease stage, sequelae or severity level using the modified EuroQol profile. The Dutch project extended the GBD small group approach from one to three panels of physicians with broad medical knowledge and added one panel of lay people with no medical knowledge. Few differences were seen in the average PTO preferences between the four panels. The Dutch study concluded that the composition of the panel was less important than accurate health state descriptions in the specification of the health problems being valued.

The choice of whose values should be used to value disability weights is not an easy one. There is an important ethical component, which as Richardson argues, lends itself to his notion of empirical ethics (Richardson 2000a) – that is, to "deliberation, systematic ethical criticism and empirical re-examination of population values after clarification of consequences" (Richardson 2001). The PTO-based deliberative approach adopted in the DALY is certainly defensible as a method for the ascertainment of social preferences for use in priority setting. This is not to argue that PTO as implemented in the DALY is necessarily the most appropriate method, but simply that it is an acceptable method that is administratively feasible and has produced sensible answers. The use of a panel constituted in a way that is acceptable to decision-makers is also consistent with the decision-making approach adopted as the theoretical foundation for MEEM.

Incorporation and specification of ethical values

Clarity about ethical values is an important issue in priority setting, as discussed in Chapters Four to Six. All summary measures of population health involve implicit or explicit social value choices. As Murray et. al. comment:

> *"In examining the properties of various summary measures, it is important to bear in mind the ultimate goal of influencing the policy process. Because of their potential influence on international and national resource allocation decisions, summary measures must be considered normative measures." (p.4) (Murray, Saloman et al. 1999)*

The mortality-based measures such as PYLL, for example, do not include non-fatal loss of health, while disability-free life expectancy indicators place no positive value on life lived with disability. Murray and Lopez (Murray and Lopez 1996) identified five key value choices that are incorporated in DALY calculations, viz:

- How long should people in good health be expected to live? (the life expectancy assumption that influences YLL);
- How should we compare years of life lost through death with years lived in poor health? (i.e. the basis of the health state valuations discussed above);
- Is a year of healthy life gained now worth more to society than a year gained in 20 years time? (time preference and the place of discounting);
- Are years of healthy life at some ages valued more than at others? (should age weights be included to reflect productivity or other social value concepts); and
- Are all people equal? (should these values be determined at a national or international level?).

The GBD and Australian DALY constructs involve explicit underlying assumptions (particularly in relation to weights for health states, discounting and age[178]). This explicitness enables the choices and values to be debated, and for the results to be presented with and without the application of these social values. This is an important characteristic of the DALY that is consistent with sub-criterion 1a) under Richardson's checklist to guide the choice of SMPH in economic evaluation.

Further, it is important to realise that the use of health state preferences and summary measures such as the DALY for priority setting does not necessarily require policy-makers to maximise

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[178] Some of the GBD choices, such as "ideal life expectancy" based on the Japanese experience and age weights to favour young adults over the aged or children, have been controversial (Anand and Hansan 1997; Murray and Acharya 1997; Williams 1999).

health outcomes. This is one option, but as discussed in Chapters Four to Six, there are other approaches involving the incorporation of additional factors which society may prefer, such as:

- Giving priority to the worst-off (Nord 1996; Olsen 1997);
- Attaching greater priority to large benefits than to the sum of many smaller ones (i.e. notion of irrelevant utility), with life-saving counting the most of all (Daniels 1994; Richardson and McKie 2000e);
- Attaching greater importance to giving everyone some benefit as opposed to larger benefits for a few (Richardson and Nord 1997); or
- Attaching less importance to life extension beyond a "fair innings" (Williams 1997; Williams 1998).

As Wolfson (Wolfson 1998) has argued, SMPHs like the DALY can assist policy-makers in making explicit the trade-offs between efficiency (defined as maximising health gains) and equity (defined as reducing inequalities in health status). They allow analysts to not only measure the burden of the problem and the potential for health gain, but also to generate measures of the distributional impacts of interventions. To quote Richardson:

> *"While there is no coercion in the way in which we construct concepts, it is coherent and potentially useful to conceptualise and define the burden of disease in units corresponding with what is (or may have been) experienced, and social value as reflecting the way in which we wish to treat this latter metric. The distinction is particularly useful if the health of different communities with different values is compared....[T]his implies the separation of the concepts of health and the value of health. This should not only apply to time and age discounting but to other dimensions of social value which might be included in 'cost value analysis' as discussed by Nord (1999) and Nord et al (1999)."(p. 2) (Richardson 2001)*

11.3.3 Criterion Three: Availability of a DALY calibrated with Australian input data

Fortuitously for the development of MEEM, two Australian studies have been carried out applying the DALY approach to Australia. Mathers and colleagues (Mathers, Vos et al. 1999) developed DALY estimates for Australia as a whole, while Vos and colleagues developed DALY estimates for the state of Victoria (Vos and Begg 1999a; Vos and Begg 1999b)). The two Australian studies provide comprehensive coverage of the ICD-9 framework, drawing on Australian demographic and epidemiological data sets for the reference year 1996. The two project teams worked closely together to adapt the GBD DALY methodology to suit the Australian context and the need for greater detail in measuring the burden of health problems that are important to Australia (such as mental health). In addition, Australian life expectancy was incorporated (rather than the "ideal life expectancy" based on the Japanese experience) and the controversial age weights were dropped.

The studies provided estimates of the BOD for 176 disease and injury categories involving the analysis of 1,260 stages, severity levels and/or sequelae. Following the classification scheme used in the GBD study, disease and injury categories were grouped in three broad cause groups:

- Group I: Communicable; maternal; neonatal and nutritional conditions;
- Group II: Noncommunicable diseases; and
- Group III: Injuries

Each of these groups was then subdivided into categories (22 in total), most of which corresponds to chapter-level groups of the ICD-9 codes (Mathers, Vos et al. 1999). These were further divided into 176 individual diseases and injury categories. Estimates of the BOD have been made for these diseases using the same age group categories as utilised in the MEEM/DCIS cost estimates. Age and gender specific BOD data is thus available on a comparable basis to the COI estimates presented in Section 11.2, available as DALY, YLL and YLD estimates.

It is important to recognise the quality of the descriptive epidemiology and disability weights that enters into SMPHs such as the DALY. Information on age and cause specific mortality, together with the epidemiology of non-fatal outcomes provides a basic input to any type of summary measure. While compared with many countries, Australia is well provided for in this department, the authors of the Australian studies were conscious that there were still limitations in this area and that further work is required, viz:

> *"This report has addressed the need for comprehensive and comparable information on the cause of loss of health in the Australian population. The study provides the first detailed and internally consistent estimates for Australia of the incidence, prevalence, duration, mortality and disease burden for an exhaustive and mutually exclusive set of disease and injury categories. It has taken the first step towards quantifying the burden associated with a range of risk factors and health determinants, including socioeconomic disadvantage.*
> *While every attempt has been made to identify the best available information in relation to each disease, injury and risk factor category, and to consult as widely as possible, it must be emphasised that the estimates published here should be seen as provisional and developmental. It is hoped that others will contribute to future improvements in data, disease models and disability weights." (p. xxvii) (Mathers, Vos et al. 1999)*

These comments by the AIHW team are an appropriate caution not to over-interpret summary measures of population health such as the DALY. The use of Dutch disability weights, while defensible in the absence of comprehensive Australian weights, suggests caution until comparable Australian weights can be developed. It is for this reason that use of the DALY estimates in the major case study that follows, was combined with detailed sensitivity analysis using the @RISK software.

11.3.4 Concluding comment

With this caution duly taken, the availability of the Australian DALY provided a unique opportunity to develop the MEEM model to include both mortality and morbidity in the outcome measure. The comprehensiveness of the BOD database across the entire ICD-9 framework, available on an age/sex disease specific basis, made an important contribution to making macro evaluation a realistic proposition.

With the COI and BOD standing databases in place, the data needs of MEEM were now quite tractable. As discussed in Chapter Ten, the data needs for assessing the net cost per DALY recovered for multiple interventions was now limited to two key items, viz: i) the efficacy/effectiveness of the options for change; and ii) the activity pathways from which costs could be calculated by adding relevant unit prices. In the context of health service planning, an expectation that proposed options for change could be specified in a concrete way and that there was some evidence to show that they worked, seemed quite reasonable. It now remained for a major case study to be undertaken to see if this was born out in reality.

It was also recognised, however, that macro evaluation using MEEM might well involve notions of benefit broader than just health gain, and that this would call for additional data (on issues such as acceptability; feasibility; importance of the problem; distributive equity; severity; etc). This additional data would to a large extent, involve the role of the PBMA Working Party in integrating issues of judgement along with the technical analysis. The additional data needs might also raise the desirability of developing additional standing databases, such as equity weights developed on a disease specific basis to reflect existing inequalities in health status. Evidence-based PBMA provided the general framework to incorporate a broader notion of benefit, but the associated data implications were also something to be assessed in the context of a major case study.

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Chapter Twelve: Major Case Study Application of MEEM

12.1 Introductory Note

The major case study of MEEM reported in this chapter was undertaken for the Cancer Strategies Group (CSG) of the National Health Priority Action Council (NHPAC) to assist with the review of Australia's cancer control strategy and to trial an economic approach to priority setting. As set out in the thesis Acknowledgements, the timing and scope of the task required that I put together a small team of researchers to assist me in implementing the approach I had proposed. The detailed results have been published separately (Carter, Stone et al. 2000; Carter, Stone et al. 2000) and are available on the CHPE website[179]. The full report runs to well over 200 pages and is presented in summary form in this chapter, supplemented by key extracts provided in the Appendix Two (Part E). The results of the case study have also been integrated into the proposed National Cancer Strategy, which has been distributed for public comment and feedback by the CSG (Cancer Strategy Working Group 2001).

As explained in Chapter Ten, MEEM evolved over the period of my candidature. The original purely technical approach, based on developing databases, applying decision rules and maximising health gain, was placed within the PBMA framework in order to embrace the importance of due process and a broader concept of benefit. This reflected several studies I had led or managed trialing the PBMA approach (Peacock, Richardson et al. 1997b; Edwards, Peacock et al. 1998; Carter, Mihalopoulos et al. 2000), together with my ongoing analysis of the literature on priority setting reported in Chapters Four (economic theory); Five (ethics) and Six (empirical experience). While the published reports of the major case study refer to it simply as PBMA, it is in fact MEEM "Mark II", or MEEM applied within a PBMA framework. I will refer to it in this chapter as MEEM/PBMA.

12.2 Background to the Case Study

In Australia there are six nominated National Health Priority Areas (NHPAs), viz: cardiovascular health; cancer control; injury prevention and control; diabetes mellitus; asthma; and mental health. Australian Health Ministers are advised on strategies to manage the six nominated priority areas by the National Health Priority Action Council (NHPAC). The Cancer Strategies Group (CSG) is a standing subcommittee of NHPAC and oversees the development of a National Cancer Strategy in Australia. A key element of CSG's approach to its task is a transparent systematic decision-making process for priority setting and strategy development.

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[179] At http://ariel.unimelb.edu.au/chpe/

In 1997 the National Cancer Control Initiative (NCCI) was launched by CSG. It was based on the conviction that it should be possible to get a better return for expenditure on cancer than was currently being obtained and that it was timely to introduce new evidence-based cancer control measures. The NCCI undertook an extensive consultation process of unprecedented breath, which included (NCCI 1998):

- The development of proposals for up to 10 options for change by expert working parties assigned to 36 topic areas;
- A winnowing process by which a broad group of stakeholders reduced (through omission or consolidation) the number of proposed actions from 276 to 147;
- Sending a questionnaire to every organisation with interests in cancer control in Australia, seeking a ranking of the 147 proposal actions[180];
- Conducting workshops in each State and Territory, attended by 242 expert participants, to discuss 30 proposed actions given priority[181] in the questionnaire responses; and
- Selection of a final set of 21 actions by the NCCI Management Committee, with 13 recommended for priority implementation. The Management Committee considered "current activities in the field, gaps in existing services, evidence of the efficacy of and benefit from the recommendations, perceived benefits for the community, costs and the potential to form strategic partnerships necessary to implement actions effectively" (p. viii) (NCCI 1998).

The NCCI achieved a set of consensus-based priorities for cancer control that would have an effect within 5 years. The findings were published in the "*Cancer Control Towards 2002*" report (National Cancer Control Initiative 1998). Most of these priorities are being addressed in the continuing work program of the National Cancer Control Initiative (Sanson-Fisher, Campbell et al. 1999). The NCCI consultation process was an important first step in CSG's attempts to adopt an explicit approach to priority setting in cancer control. Importantly, there was an attempt to relate priority judgements to the aims and objectives of cancer control in Australia. While the translation of these aims and objectives into the specific criteria to rank interventions can be criticised[182], the

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[180] Suggested criteria for ranking the proposals were "size of the problem"; "efficacy of the action within a 5-year time frame"; "likelihood of successful implementation"; "cost and cost-effectiveness"; and "equity".
[181] The proposals were ranked using a simple scoring system in which each proposal received a score based on summing the participant's response for each of the five criteria (using a 4 point scale form low to very high for each criteria). The score for each proposal by each participant (with the criteria given equal weight) was summed across all the participants to yield an average (unweighted) score.
[182] These criticisms include issues like:

- whether participants had a common understanding of the criteria;
- the lumping together of cost and cost-effectiveness, which perpetuates the ongoing confusion for many non-economists between the aims of efficiency and cost containment.
- whether participants gave the various criteria equal weight in arriving at their ratings/ judgements;
- the extent of stakeholder involvement in the development of the criteria; and
- whether the criteria were consistently applied at the various stages of the filtering process as the original 276 options were reduced to 147, then to 30, to 21 and finally to the 13 chosen for priority action.

specification of criteria was a clear signal of the intent to develop an open, transparent and accountable process where the rationale for decisions was specified.

The NCCI also made an attempt to brief participants in its survey of stakeholders and in the State/Territory workshops. This involved the provision of descriptive information on health care system costs and the health burden, which undoubtedly helped participants in assessing the "size of the problem". It is questionable, certainly from an economic perspective, whether this descriptive information was the most appropriate information to guide judgements on resource allocation issues. For economists, the more central issues for resource allocation are information on the efficacy/effectiveness of the various interventions in reducing the disease burden, the net cost of the interventions and whether the interventions represent value-for-money. Further, while "size of the problem" is one possible definition of "need", no link was made between the notions of need and equity. For criteria other than the "size of the problem", participants drew on their own knowledge in scoring the various interventions and weighted the various criteria as they saw fit in giving an overall score.

A health economist position was created on CSG during 1998 and I accepted the appointment to that position. Subsequent discussion within CSG of the strengths and weaknesses of the NCCI priority setting approach, included the issue of whether or not an economic approach could be utilised as part of the decision-making process for developing cancer control priorities in the future. In particular, the discussion focussed on the clarity of the criteria and associated decision rules, and whether the efficiency objective had been satisfactorily addressed. It was considered unlikely, for example, that participants in the NCCI consensus process assessed "benefit" attributable to the various interventions in a consistent way or were provided the type of information that would have enabled them to relate anticipated benefits to resource use in a clear and overt fashion.

As health economist on the CSG I was asked to suggest a suitable economic approach that would meet these concerns, preferably one that could be trialed in the ensuing six-twelve months period and thereby assist the cancer strategy review. I explained PBMA to CSG members, noting that a growing literature embraced a variety of approaches within its broad ambit (refer Chapter Nine). Having regard to the needs of CSG, the stated aims and objectives of the Cancer Control Strategy (see below), I recommended an evidence-based approach to PBMA that focused on marginal analysis and had a clear economic protocol based on macro evaluation (i.e. MEEM). Discussion at CSG during late1998/ early 1999 was followed by a formal submission for the trial in which I specified the broad approach and budget. In mid-1999, the CSG resolved to trial the use of MEEM/PBMA as part of its review of the priorities determined in the "*Cancer Control Towards 2000" report"* (NCCI 1998). The trial was to address whether MEEM/PBMA was an appropriate technique to include in the CSG planning process, as well as assist with what specific

options might be included in the next National Cancer Strategy. A Working Party to participate in the MEEM/PBMA trial was duly appointed, chaired by Professor Bruce Armstrong, who also chaired CSG. I led the Working Party through the MEEM/PBMA trial, assisted by a small Project Team of mostly part-time researchers (membership of the Working Party and Project Team provided at Appendix Two).

12.3 The MEEM/PBMA Approach

PBMA as a generic approach to priority setting was reviewed in Chapter Nine (Section 9.3) and is only briefly outlined here. Similarly, MEEM (both Mark I and II) was presented in Chapter Ten and that description is not reproduced in this chapter. The focus of this section is rather to explain the specific approach to PBMA taken in the case study, particularly the elements that come from MEEM Mark I.

12.3.1 Overview of key design characteristics of case study

The key characteristics of the MEEM/PBMA approach adopted in the case study are previewed below and discussed in the ensuing sections, viz.

- A nine-member Working Party was constituted to cover key stakeholder interests and take key decisions concerning conduct of the study (i.e. concerning option selection; concept of benefit; ranking of options for change; and judgements about the impact of the second-stage filters);
- A focus on the marginal analysis component of PBMA, combined with a clear rationale for the selection of options for change;
- An evidence-based approach with a small research team bringing together the best available evidence on efficacy/effectiveness and undertaking the economic analysis;
- The choice of the Disability Adjusted Life year (DALY) as the measure of health gain;
- The recognition that "benefit" is broader than just health gain;
- Adoption of a two-stage approach to the assessment of benefit involving "technical" aspects as the first stage (i.e. economic decision rule based on "cost per DALY" [preferably weighted for distributive equity]) and "judgement" aspects as the second stage filters (i.e. level of evidence; equity [if not in stage one]; size of the problem; acceptability to stakeholders; and feasibility of implementation); and
- An economic protocol specifically developed for a priority setting context, reflecting key elements of MEEM (Mark I) – refer Section 12.6.

12.3.2 Basic steps in conducting a MEEM/PBMA study

No guidelines have yet been developed or published as a standardised approach to PBMA,

similar to those that exist for conventional economic assessment (Drummond, Stoddart et al. 1987; Gold, Siegel et al. 1996). The following steps, whilst reflecting my own views on the conduct of PBMA, would generally accord with how most practitioners would see PBMA being conducted (Mooney, Gerard et al. 1992; Viney, Haas et al. 1995; Posnett and Street 1996; Scott, Donaldson et al. 1999) (Plant, Davies et al. 1995). The steps are as follows:

1. Agree on the research question and essential features of the PBMA protocol (including the macro economic evaluation protocol);
2. Decide on a program structure that matches the research question;
3. Describe the program in activity and expenditure terms (i.e. the "program budget");
4. Identify the options for change (both increments and decrements);
5. Undertake marginal analysis of the options;
    - 5.1 establish objectives of the organisation and/or program and develop the approach to measurement of benefits;
    - 5.2 assess benefit of options with the instrument and/or approach developed in 5.1;
    - 5.3 assess net costs of the options; and
    - 5.4 estimate the macro cost-effectiveness ratios using 5.2 and 5.3 (and undertake sensitivity analysis)
6. Assess and discuss the macro cost-effectiveness results, including comparison with any existing economic appraisals in the literature and/or broader dimensions of benefit included as second stage filters; and
7. Consider recommendations/design implementation strategy (if appropriate to research question).

In the case study the CSG agreed that the research question would focus on steps 5 and 6, with some attention given to step 4. This reflected the platform provided by the earlier NCCI in terms of the generation of options for change[183], together with the need for results to be available within a short time period to be useful for decision-makers. The earlier NCCI process had adopted a logical process for the generation of options that drew on best available evidence together with the expert views of a wide range of stakeholders. Starting with the NCCI 'top 20' and subjecting them to a brief review process (see below) generated a meaningful range of options for the trial that was expedient (time-wise) and policy relevant (for decision-makers).

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[183] While the options generation process was recognised as an integral part any the priority setting process, the NCCI adopted a comprehensive and rigorous process that provided a meaningful range of options to feed into the trial. The NCCI established, for example, a series of expert Working Parties in all major areas of cancer control, with broad stakeholder representation. The 36 Working Parties drew on best available evidence, together with their own expertise, to put forward a large number of options for change. It is not the

While the CSG was briefed on the important role[184] that the program budget component of PBMA usually played, it accepted that when time was short the program budget was far less significant than the marginal analysis component, particularly when option generation was not a problem. The setting and context for the National Cancer Strategy (being a national strategy involving multiple jurisdictions and organisations) also minimised the organisational advantages derived from integrating the PBMA with an organisation's financial and activity reporting systems.

The focus on marginal analysis in the case study also allowed the Working Party and CSG to assess key issues within the time available, such as:

- the potential of MEEM/PBMA to deal with quite divergent options in the disease pathway from prevention through to psychosocial care and palliation;
- the potential to measure and weight benefits involving different dimensions and different levels of evidence in a clear and understandable way;
- the potential to integrate the "technical" decision rule based approach of economics with "pluralistic bargaining" (Coast and Donovan 1996) and concerns for due process;
- whether the information provided was valued by members of the Working Party;
- the potential to break down priority setting in a complex decision context into manageable tasks with tractable data and resource requirements; and
- its acceptability to stakeholders.

12.4 Selection of the Options for Change

The options for change in this case study were identified through a three-step process. First, in accordance with the trial specifications, the starting point was the 'top 20' priority actions from the NCCI report "*Cancer Control Towards 2002*" (National Cancer Control Initiative 1998). Second, a National Cancer Strategy Development Workshop was convened in May 1999, which involved major stakeholders in cancer control (Department of Health and Aged Care 1999a). The workshop provided the opportunity to re-visit the strategy areas and to add options to the NCCI 'top 20'. This step allowed developments since completion of the NCCI report in 1998 to be taken into account, together with options that may have been excluded by the NCCI process[185]. Third, review by the Working Party of the eight NHPA priority cancers, activities of the NHPA initiative, and more recent evidence suggesting new areas of need.

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option generation process of the NCCI that economists would have trouble with, but rather the priority setting process by which options were assessed and ranked.

[184] In that the program budget provides the logical structure around which options for change are usually generated.

[185] Note that the original NCCI priority setting only considered interventions that would have an effect within five years.

The Working Party reviewed the resulting list of 21 action areas (involving over 40 individual interventions and/or activities) and classified them into one of five groups using a number of criteria, viz:

- that a clear and concrete intervention could be specified;
- that there was sufficient evidence to make an assessment of efficacy/effectiveness possible;
- that both increments (i.e. options that involve additional expenditure) and decrements (i.e. options that involve reduced expenditure) be included;
- that options from across the complete disease pathway (i.e. from prevention to palliation) be included;
- that options be included that test the assessment of both mortality and/or morbidity impacts on health status; and
- that the perceived importance of options be taken into account, as reflected in the NCCI rankings (NCCI 1998), a survey conducted of CSG members (Department of Health and Aged Care 1999b) and the National Cancer Strategy Development Workshop (Department of Health and Aged Care 1999a).

The five groups were:

1 *Options for change* – defined as interventions where sufficient evidence exists to indicate that strategies involving additional expenditure would be associated with significant health gain and strategies involving decreased expenditure would be associated with little or no reduction in health gain.

2 *Possible options for change* – defined as interventions where some evidence exists to indicate that strategies involving additional expenditure would be associated with health gain and strategies involving decreased expenditure would be associated with little or no reduction in health gain. These options may need more work to specify to a level of precision where they can be evaluated.

3 *Monitor developments/liaison* – defined as interventions that are currently being worked on and/or implemented in another context and where it is too early or inappropriate to perform an economic evaluation at present.

4 *Research strategies* - defined as possible interventions that need more research before

they can be evaluated, that is evidence does not yet exist to sustain their efficacy/effectiveness credentials and a clear intervention cannot be specified.

5 *Motherhood strategies* – defined as those ideas for action that were considered to have merit but were too broad and abstract to evaluate (and for which specific research work was not developed).

The intention was to include in the MEEM/PBMA analysis all those strategies classified as "*Options for change,*" together with some of the "*Possible options for change.*" The full list of all potential options considered by the Working Party, allocated to one of the five categories listed above, is at Appendix Two in Part E of the thesis. An abbreviated listing of the strategy areas intended for inclusion in the pilot is set out below. The option numbers given in brackets are identical to those used in the report of the National Cancer Strategy Development Workshop (Department of Health and Aged Care 1999a) and in the survey of CSG members (Department of Health and Aged Care 1999b) included in Appendix Two.

12.4.1 Options for Change

The "Options for change" were:

1 Reducing Smoking Prevalence - (option 2.2.)*
2 Reduce the risk of skin cancer - (option 4.1.)*
3 Improve skills in diagnosing skin cancer - (option 5.1.)
4 Improve efficiency of cervical screening - (option 6.2.)*
5 Improve detection of colorectal cancer - (options 7.1 & 7.2.)*
6 Rationalise prostate specific antigen testing - (option 10.1.)
7 Develop guidelines in areas of need - (option 12.2.)
8 Improve palliative care: guidelines for pain management - (new option in strategy 14.)
9 Define, implement and monitor psychosocial care – (new options in strategy 15.)*

12.4.2 Possible Options for Change

The "Possible options for change" were:

10 Increase consumption of fruit and vegetables through health promotion– (option 3.4.)*
11 Organise education and resources for those with familial cancers – (option 18.1 & 18.2.)
12 Meet urgent national needs in data collection – (option 20.2.)

Briefing papers to guide the Working Party in its assessment were prepared by the research team on six strategy areas (asterisked above), involving eight options for change[186]. The briefing papers were quite detailed assessments that summarised the available evidence on each option[187]. Appendix Two of the thesis (Part E) provides a summary of these economic evaluations and is based on the briefing papers.

12.5 The Concept of Benefit

12.5.1 Background

An important dimension of the PBMA approach is its potential to broaden the concept of benefit to reflect the underlying goals, objectives and principles of an organisation or program wishing to employ the technique. Before specifying the objectives used in the MEEM/MEEM case study, therefore, (and their translation into the proposed macro cost effectiveness ratios) it is important to briefly review the goals and objectives of the National Cancer Strategy.

In its 1998 *"Cancer Control 2002"* report the NCCI defined the goals for cancer control as:

> *"[I]mproving mortality and morbidity; reducing those risk factors which will subsequently reduce mortality/morbidity; and increasing screening which will subsequently reduce mortality/morbidity." (NCCI 1998)*

In the draft National Cancer Strategy report (Cancer Strategy Working Group 2001), the goal of cancer control in Australia is specified more simply as:

> *"[T]o reduce the impact of cancer on the community."*

This overarching goal is supported, however, by a series of objectives that add detail similar to the earlier NCCI version. The objectives are (Cancer Strategy Working Group 2001):

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[186] Evaluation of two strategies in the "options for change" list (i.e. palliative care and guidelines in areas of need) could not be commenced due to the short time scale available. Similarly, two of the three "possible options for change" could not be included (i.e. familial cancers and national data collection needs). The decision on which options to omit reflected the expertise of the research team; the anticipated time required to research the options; and the ranking of the options by the NCCI and the CSG. Two further strategies were commenced (skin cancer diagnosis skills & PSA testing) but were put on hold either due to staff availability constraints and/or data availability constraints. Data to support the evaluation of the skin cancer diagnosis intervention, for example, will become available later this year from trials being conducted in South Australia. Pending the availability of this data, it was considered sensible for the evaluation of this intervention to be put on hold.

[187] Due to the length of these briefing papers, they are listed in Appendix 3 of the Full Report (Carter, Stone et al. 2000) and are not included as part of either the Summary Report (Carter, Stone et al. 2000) or Full Report. It is intended that all the briefing papers will be published separately, however, as part of the Centre for Health Program Evaluation's (CHPE) Research Paper Series and will be made available for downloading from the CHPE web site.

- *reduce the incidence of cancer* (through prevention programs where risk factors are known; through early detection programs where evidence of efficacy/effectiveness is credible; and through timely research where causes are not known);
- *increase survival* (through screening and early diagnosis, as well as optimal treatment and management of cancer);
- *improve quality of life* (through optimal management and attention to all needs, including psychosocial needs);
- *meet community expectations* (through ensuring the system is responsive to the needs and wishes of consumers of its services);
- *identify and reduce inequities in the system* (through attention to groups within the population, process issues, and differences in outcome);
- *increase research capacity and the knowledge base for cancer control;* and
- *optimise the use of resources* (through promoting cancer control programs that represent good value for money and discouraging ineffective and/or inefficient cancer control activities).

The draft National Cancer Strategy report also argues that principles are required to underpin the goal and objectives of cancer control in Australia. The nominated principles are that the system for cancer control should be "evidence-based", "consumer focused" and "integrated and efficient." The principle of "evidence-based" is to include not only efficacy/effectiveness in its epidemiological sense, but also evidence of the practicality of implementation. The evidence base is to include ongoing monitoring of outcome and performance. The "consumer focus" is to include equity, a balance of utilitarian and humanitarian values and to feature consumer empowerment[188]. Integration is to be pursued across and within agencies and jurisdictions. Efficiency in use of resources has two key components. First, giving priority to actions that give greatest benefit for cost or reduce expenditure with little or no loss in benefit. Second, all other things being equal, priority should be given to actions with a large potential impact over those for which the potential impact is small. The Working Party endeavored to reflect the current goal, objectives and principles of the National Cancer Strategy in the approach to measurement of benefits adopted in the marginal analysis of the options for change.

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[188] This suggests solutions to priority setting that lie between the utilitarian approach of maximising health gain and the Rawlsian approach of concern for the least well-off in society (refer discussion in Chapter Five and Jan Olsen's paper (Olsen 1997)).

12.5.2 The Steps in Measuring Benefit

Step One: Determine the Criteria for Assessing "Benefit"

The Working Party adopted seven broad criteria that addressed the questions I put to them, viz: "What do we mean by benefit?" and "What are the characteristics we are looking for in a high priority intervention?" These seven criteria were:

1 Size of the problem[189] the intervention seeks to address (i.e. where can the biggest difference be made?);
2 Efficacy/effectiveness of the intervention[190] (i.e. what is the quality of the evidence that the intervention works and what health status improvement can be anticipated?);
3 Capacity of the intervention to reduce inequity[191] in health status and the health care system (a multi-factorial issue involving population groups, process and outcomes);
4 Efficiency[192] of the cancer control intervention (i.e. is the option value for money as reflected by the macro cost effectiveness ratios, supplemented by any conventional economic evaluation evidence that can be gathered from the literature?);
5 Cost[193] of the cancer control intervention (i.e. is the intervention affordable?)
6 Acceptance[194] by stakeholders, particularly the general community; and
7 Likelihood of successful implementation[195] (because of availability of relevant expertise and/or infrastructure; timing considerations; or other feasibility issues).

Step Two: Determine the MEEM/PBMA Cost Effectiveness Ratios

It was agreed by the Working Party that these seven criteria would be utilised in a two-stage approach to ranking the options in the marginal analysis. In the first stage options would be ranked by those criteria directly related to determining the resources consumed or released by the option, together with the size and distribution of the anticipated health gain (based on

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[189]Note in the principle "optimise the use of resources" outlined above, the idea that all other things being equal, priority should be given to actions with a large potential impact over those for which the potential impact is small.
[190]This criterion reflects the principle that the cancer control strategy should be "evidence-based" and the objectives relating to health gain (i.e. reduce incidence of cancer; increase survival; and improve quality of life). It also goes fundamentally to the overall goal of reducing the impact of cancer on the community.
[191]This criterion reflects the "inequities" objective directly, and the "community expectations" objective indirectly, in that community surveys report that the community values this attribute highly and will trade health gain to achieve it. It also reflects the principle of "consumer focus," particularly the notion of balancing utilitarian and humanitarian values.
[192]This criterion reflects the "optimise use of resources" objective and the "integrated and efficient" principle.
[193]This criterion reflects two objectives indirectly. First, the efficiency objective/principle, in that efficiency is fundamentally a relationship between benefits achieved and resources consumed; and second, the successful implementation objective, in that interventions need to be financed from limited budgets.

[194]This criterion directly reflects both an important objective and the principle "consumer focused."
[195]The practicality of implementation is mentioned in one of the objectives as well as the "evidence-based" criterion.

epidemiological and "technical" considerations). In the second stage the ranking of options would include the more pragmatic acceptability/feasibility issues. The first stage is characterised by aspects that lend themselves to "logical" decision-rules, drawn essentially from the health economics discipline. The second stage incorporates aspects where it is very difficult to develop decision-rules and decisions rest heavily on judgement and due process. In its initial consideration of this approach, criteria one to five were in included in the first filter, while criteria six and seven were in the second filter.

At subsequent discussions aimed at clearly defining the dimensions of benefit, at considering the data collection issues and the specific approach to calculating the macro cost effectiveness ratio, criteria were moved between the two stages. A guiding rule in identifying dimensions of benefit is that they must be "orthogonal" – that is, the dimensions must be mutually exclusive so that the elements do not overlap and are not counted more than once. After much discussion it was decided that the measure of health gain should be the Disability Adjusted Life Year (DALY)[196] and that the DALY should be weighted, if possible, to reflect equity concerns. The recent availability of the Victorian (Vos and Begg 1999a; Vos and Begg 1999b) and Australian (Mathers, Vos et al. 1999) DALY studies, meant that a common unit of measurement was potentially available that captured both morbidity and mortality effects across a wide range of diseases and intervention types. In adopting the DALY as the outcome measure, it was recognised that in addition to trialing an evidence-based approach to MEEM/PBMA, the trial was also assessing to what extent the DALY could be sensibly utilised in an evaluation context (refer discussion in Chapter Eleven).

This decision meant that criteria two (efficacy/effectiveness) and three (equity) provided the theoretical measure of "health gain" and the denominator in the macro cost effectiveness ratio. Criterion five (cost of the cancer control option) provided the numerator in the macro cost effectiveness ratio. Descriptions of the approach taken in calculating the cost estimates are provided in Section 12.6 and in further detail in Appendix Two. Criterion four (efficiency) is picked up automatically by the macro cost effectiveness ratio (i.e. efficiency is a relationship between cost and benefits). The MEEM/PBMA exercise itself is aimed at maximising benefit (as defined by the decision-makers) with the resources available.

Two dimensions of health benefit previously placed in stage one ("size of the problem" and the quality of evidence component of "efficacy/effectiveness") were transferred to the second stage of the ranking process during these discussions. In relation to "size of the problem", this reflected

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[196] A DALY is the sum of the years of life lost (YLL) and the years lived with a disability (YLD). This measure can be applied in each of the options identified by the Working Party. The model being used is based on the Burden of Disease approach used by the Australian (Mathers, Vos et al. 1999) and the Victorian studies (Vos and Begg 1999a; Vos and Begg 1999b).

the Working Party's concern that there might be overlap between this dimension and the health gain dimension (because "size of problem" would be measured in total DALYs and "health gain" measured as the reduction in DALYs). The Working Party preferred to pick up the "size of the problem" criterion more informally in stage two of the ranking process, as one of a number of broader policy considerations that may alter the ranking of projects from stage one based on the "technical" cost effectiveness ratios.

In relation to the "quality of evidence" component, the Working Party considered this to be a factor that was not part of the benefit calculation per se. Rather, it was a factor to be taken into account in considering what confidence could be placed in the cost effectiveness ratios, along with other factors in stage two. As is the custom in economic evaluation studies, sensitivity analysis would be conducted wherever feasible to tease out the implications of varying the value of key parameters.

Step Three: Develop Clear Descriptions of Each Dimension of Benefit

First stage health benefit

The principle dimension of health benefit was the estimated "*size of health gain*" associated with each option. The size of health gain is a quantitative measure, the calculation of which was evidence-based using a combination of the scientific literature and expert opinion. This dimension was calculated from the total DALYs attributed to the disease and the efficacy/effectiveness of the option in reducing that DALY burden. Calculation of the DALYs recovered for each option is presented in Appendix Two and overviewed in Section 12.6.7 below. The Working Party's intention was for the DALY score attributed to each intervention to be weighted for the distributive equity.

Moving from in-principle inclusion of equity to practical measurement, however, was not easy. It required agreement on the appropriate concept of equity; agreement on the principles to govern application of the concept; together with methods and data to enable its measurement. As discussed in Chapter Five, various views are available on the appropriate concept of equity. Definitions range from equity in the context of resource distribution, to equity in the context of access to and/or use of health services, to equity (or inequity) in health status. A second dimension relates to whether equity is being considered in the "equal treatment of equal need" context (i.e. "horizontal" equity) or whether the focus is on special treatment for disadvantaged groups (i.e. "vertical" equity). An important issue is whether the concept is based on community preferences, researcher judgement, or decision-maker judgement on behalf of the community.

In the case study, the Working Party was conscious of the equity objective specified in the draft National Cancer Strategy report (i.e. "*identify and reduce inequities in the system*") and chose to

have equity weights developed principally in terms of health status differentials. More specifically, they chose to reflect the distribution of the burden of illness from cancer in the Australian population. In particular, four relatively disadvantaged (in terms of burden of illness) sub-populations were identified: Aboriginal and Torres Strait Islander (ATSI) peoples; Non-English Speaking Background (NESB)/Migrants; rural/remote populations; and low socio-economic status (SES). Having agreed this, however, it was still recognised that since interventions were being evaluated in the case study, it was simply not possible to divorce health status effects from access/utilisation issues associated with the health interventions.

In considering how equity weights might be applied to DALYs, the Working Party agreed the following principles:

- equity weights were to reflect a vertical equity principle i.e. unequal treatment in proportion to unequal needs;
- the equity weights would be used in a positive direction only (i.e. groups with higher health status - whether target groups or non target groups - would not have their DALY scores penalised);
- all health gains in the non-target group (i.e. the general population) would receive a weight of 1; and
- where a target group was in a situation where different equity weights applied to it, the highest equity weight would be selected/used and the weights would not be summed (eg. an indigenous group might be in a remote area and be in a low SEIFA income group, with three different weights available);

While agreeing the concept of equity and principles to govern its application could (and do) give rise to heated debate, it was the third aspect (i.e. measurement methods and data) that provided the stumbling block in the case study. Three key steps are required to apply equity weights to the cost per DALY results presented in Section 12.7. These steps are:

1. disaggregation of the total DALY burden into DALYs for each population target group and the non target group;
2. estimation of the DALY reduction attributable to the interventions for each group (i.e. estimate the access/utilisation/effectiveness of the intervention for each target group and the non target group; and
3. weighting of the DALYs recovered for each group by the appropriate equity weight.

In the time available to the project team, progress was made in developing indicative equity weights (step three). These equity weights are presented in the full report published on the trial[197] (Carter, Stone et al. 2000). The project team was not able to undertake steps one and two, due to limitations in the current DALY database. Thus while the case study was able to tease out some of the issues associated with using equity weights, full application could not be finalised in the time available. It is clearly premature at this stage to offer any definitive judgement as to the practicality and acceptability of weighting cost effectiveness results for equity. It is clear, however, that if equity is to be included in an *evidence-based approach*, then there are some important implications for future research directions (particularly in relation to steps one and two). In this regard it should be noted that there are some simpler and more tractable approaches available for the inclusion of equity in the PBMA toolkit, but they may not satisfy the stipulation that the approach be evidence-based[198].

It also needs to be acknowledged that the application of equity in an evaluation/priority-setting context raises important second order effects. This arises particularly when decrements are being considered. It is one thing, for example, to consider the equity implications for current users of changing the screening interval for cervical cancer screening. It is another to consider what weight might be placed on these implications if the funds saved are available for expenditure elsewhere in the program. Thus the net effect on equity of changing the screening interval and re-directing the funds towards recruiting the hard-to-reach groups that are currently under-screened, is very different to the interval change considered in isolation. This in turn raises practical and political issues associated with whether cost savings associated with decrements are hypothecated to the relevant project/program or return to consolidated general revenue.

As a consequence of not being able to fully develop and apply equity weights in the time available for the pilot, the Working Party agreed to include equity in the second stage filters. Two dimensions of equity were considered. The first was the extent to which the intervention might redress any existing health status inequity (as reflected in the equity weights). The second was the extent to which the intervention might, through known or likely uptake or access inequalities, give greater health advantage to those who already are in a position of health advantage.

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[197] My colleague, Dr Stuart Peacock, calculated the equity weights presented in the full report.
[198] The use of decision theory combined with rating scales, for example, was used by myself and colleagues to measure equity in the South Australian and Quit PBMA studies (Peacock, Richardson et al. 1997b; Carter, Mihalopoulos et al. 2000). The scores and weights given equity, however, were based on the subjective judgement of participants with no reference to quantitative data of the sort presented in the cancer study (Carter, Stone et al. 2000).

Second stage health benefit

The second stage involved the more pragmatic issues that may impact on the implementation of an option,[199] together with those factors that influence the degree of confidence[200] that can be placed in the macro cost effectiveness ratio. These issues are discussed briefly below.

"Size of the problem":

This criterion included a consideration of the health status impact (or health burden) of the cancer addressed by the intervention, together with the health system resources devoted to its care, cure or palliation.

The health burden included consideration of indicators such as:

- the DALY contribution (Years of Life Lost: [YLL] and Years of Life Lived in Disability [YLD] by age and sex);
- cancer incidence (by age, sex, available equity data, and trends);
- mortality (by age, sex, available equity data and trends); and
- morbidity (by age, sex , available equity data and trends).

The health system resource implications (and potential cost offsets) were based on the *report "Health System Costs of Cancer in Australia, 1993-94"* (Mathers, Penm et al. 1998). As discussed in Chapters Ten and Eleven, this is one of a series of publications that owe their existence to the early development of MEEM at the AIHW. Consideration was also given to the judgement of the CSG on the "Size of the problem" criterion contained in the survey of members' views on 46 possible cancer control options (refer Appendix Two at Part E of the thesis).

"Acceptability":

This criterion refers to the acceptability of proposed interventions to the various stakeholders effected by the intervention (i.e. patients, the community, funders, providers, politicians and their advisors). By its very nature, it is a difficult criterion on which to find empirical data. It necessitated judgements being made by Working Party members and raises the issue of ensuring adequate stakeholder representation on the Working Party. Consideration was also given to the views of the CSG on the "acceptance" and "feasibility" criteria contained in the survey at Appendix Two. Intervention acceptability will be an issue that will be re-visited (appropriately) by the various groups that receive the report on the trial (Carter, Stone et al. 2000;

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[199] Such as: size of the problem; acceptability; and feasibility.
[200] Such as: level of evidence; cost effectiveness results from conventional economic evaluations.

Carter, Stone et al. 2000) during the consultation stage of finalising the National Cancer Control Strategy.

"Feasibility":

Under this criterion issues such as the availability of appropriate expertise to implement the intervention on a national scale, the time scale for implementation, and whether financial resources are available, were considered. Again it is a criterion on which the CSG survey results were consulted and on which other groups apart from the Working Party will have an important contribution to make. As with "acceptability", it is a criterion that invoives judgement rather than technical decision rules and visibility of both the process and judgements made is an important attribute of an explicit approach to priority setting.

"Level of Evidence":

The Working Party was advised[201] that the thinking of the National Health and Medical Research Council (NHMRC) about assessing evidence had moved on since publication of *"A guide to the development, implementation and evaluation of clinical practice guidelines"* (NHMRC 1999a). In particular, it has been realised that there is a single framework within which evidence on clinical, public health and social science interventions can be assessed. While the nature of the evidence for different kinds of health interventions will inevitably vary, and the evidence for public health and social science interventions will often be weaker than that for clinical interventions, the logic used to assess the evidence is the same for all of them.

This rethinking on assessing the evidence has entailed a re-categorisation of the facts that make up the evidence under three headings as follows:

1) *Strength of the evidence* – being the strength of the evidence that there is or is not an effect of the intervention[202]. The strength of the evidence depends on the degree to which chance or bias (including confounding) can be excluded as alternative explanations for the observed presence or absence of an effect and includes issues of study design;
2) *Size of the effect* – being the distance of the observed value of the effect measure from its null value[203]. The certainty about the size is represented by the width of its confidence interval; and
3) *Relevance of the effect* – being the usefulness or importance of the observed effect in clinical or public health practice[204]. Among other things it relates to the population studied, the

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[201] Professor Bruce Armstrong (personal communication).
[202] This category incorporates *Level of evidence, Quality of evidence* and parts of *Strength of evidence* as defined in Appendix A of the NHMRC guidelines (NHMRC 1999a).
[203] This category forms part of *Strength of evidence* in the NHMRC guidelines (NHMRC 1999a).

relevance of the effect measure used, and the size of the effect in comparison with what would be clinically important.

In considering these developments, the Working Party noted the approach taken by the "*best buys*" team in New South Wales.[205] The decision was taken to follow this approach, modified to reflect the classification used by the International Agency for Research in Cancer. The combined approach is illustrated in Table 12.1.

12.6 The Evaluation Protocol Adopted in the Macro Economic Evaluation of the Options for Change

12.6.1 Introduction

The results of economic evaluations can be brought together to provide a "league table" in which the interventions are ranked in order of their economic merit. This is particularly relevant where the decision context is one of priority setting. Economists, quite rightly, urge caution in simplistic use of league tables, particularly because of the dangers of methodological confounding (refer discussion Chapter Nine). These pitfalls have been avoided in the present study because the evaluations have been undertaken specifically within a priority setting context, rather than being an ad hoc collection of studies assembled from the literature. More specifically, the key features of the economic protocol in relation to these issues are:

- The rationale for the selection of interventions in the league table is clearly explained and consistently applied (refer Section 12.4);

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[204] This is the same as *Relevance of the evidence* in the NHMRC guidelines (NHMRC 1999a).

[205] Which made a distinction between the robustness of the research methodology (using the NHMRC Quality of Evidence Rating Scale) and the more important "level of evidence" conclusion. The NSW approach (NSW Health Department 1999) involved the following categories:

- "Evidence of effectiveness": Effectiveness is demonstrated by clear evidence from well-designed research.
- "Inconclusive Evidence": Effectiveness cannot be demonstrated due to insufficient or inadequate quality research.
- "Evidence of ineffectiveness": Ineffectiveness is demonstrated by clear evidence from well-designed research

Table 12.1 Classifying the Strength of the Evidence

Strength category	Strength of the evidence
"Sufficient evidence of effectiveness (or ineffectiveness)": Effectiveness (or ineffectiveness) is demonstrated by sufficient evidence from well-designed research.	• The effect is unlikely to be due to chance (eg. P is < 0.05) and • The effect is unlikely to be due to bias (eg. evidence from: ➢ a level I study design; ➢ several good quality level II studies; or ➢ several high quality level III-1 or III-2 studies from which effects of bias and confounding can be reasonably excluded on the basis of the design and analysis)
"Limited evidence of effectiveness (or ineffectiveness)": Effectiveness (or ineffectiveness) is demonstrated by limited evidence from studies of varying quality	• The effect is probably not due to chance (eg. P is < 0.05) but • Bias, while not certainly an explanation for the effect, cannot be excluded as a possible explanation (eg., evidence from: ➢ one level II study of uncertain or indifferent quality; ➢ evidence from one level III-1 or III-2 study of high quality; ➢ evidence from several level III-1 or III-2 studies of insufficiently high quality to rule out bias as a possible explanation; or ➢ evidence from a sizeable number of level III-3 studies which are of good quality and consistent in suggesting an effect).
"Inconclusive evidence of effectiveness (or ineffectiveness)": Inadequate evidence due to insufficient or inadequate quality research.	• No position could be reached on the presence or absence of an effect of the intervention (eg. no evidence from level I or level II studies and level III studies are available, but they are few and of poor quality, or only level IV studies are available.)

- Evaluation methods have been standardised and clearly specified, involving
  - a standardised discount rate;
  - a standardised comparator; and
  - a standardised approach to the measurement of costs and benefits.
- Setting and context is common to all interventions (i.e. to be part of a national cancer control strategy);
- Australian data has been used for demography, health system costs, disease incidence, risk factors, etc; and
- The costs per DALY ratios are placed within a broader decision-making context provided by the PBMA approach.

These features are developed in the economic protocol set out below. The protocol is written to respond to the checklist of questions for assessing economic evaluations published by Drummond et al. ((Drummond, O'Brien et al. 1997) pp28-29).

12.6.2 The Research Question

Clear definition of the research question is important in economic evaluation and should address three issues: first, the study viewpoint or perspective of the evaluation; second, the study comparators; and third, the study setting and decision-making context.

The perspective for all of the economic studies undertaken in the case study is that of the government as health service funder and provider. While relevant to the decision-making context and consistent with the economic foundation to evaluation recommended in Chapter Four (i.e. the Decision-Making Approach), it is nonetheless a narrow perspective. It does not, for example, include the impact on the private sector or broader impacts outside the health sector – in short, it adopts neither a health sector perspective nor a societal perspective. To the extent that the various interventions evaluated involve the use of private sector resources, these costs are not reflected in the primary analysis, although on occasions they are picked up in the sensitivity analysis (eg. the SunSmart intervention).

Setting and context are important because they inform judgements about the relevance of the study to particular users, together with critical appraisal of the appropriateness of the methods utilised. The setting for the evaluations in the case study is possible adoption of the chosen interventions or options for change on a national basis - i.e. as possible inclusions in a National Cancer Control Strategy. The decision context is strategic planning and priority setting at the macro level (refer Chapter Two), involving the evaluation and ranking of a series of interventions. As the evaluation is taking place within the context of a MEEM/PBMA study, the focus is essentially on allocative efficiency, although technical efficiency issues do arise in the marginal analysis.

12.6.3 Selection and Description of Competing Alternatives

An important question in critically assessing economic evaluations is whether any important alternatives were omitted. This relates both to the correct specification of the "project case" options (i.e. the options for change), as well as to the "base case" comparators (i.e. current practice). In the context of an economic evaluation addressing a single topic or problem, there is usually a reasonably limited set of possibilities. In the context of a study addressing priority setting across a disease group as broad as cancer, there is a very broad range of possibilities. This then raises as an important theoretical and policy issue, the process by which the options for change were selected. While the process of selection is clearly explained in Section 12.3, it needs to be acknowledged that the list of "project cases" was by no means comprehensive. In part this was due to the constraints applying to the trial in terms of available resources and time; in part it is due to the constraints applying to any priority setting exercise in terms of available resources and information bases. The recognition of this practical constraint, particularly in a

multi-intervention decision context, emphasises the importance of clearly specifying the process by which the options for change are generated. It also suggests the need for caution in interpreting the results of the case study. While there are good reasons to support the credentials of interventions evaluated (both in terms of the rationale for their selection for evaluation and their evaluation results) it was important that this should not be over-played.

Turning to the choice of "base case" comparator, this is important because results of economic evaluations are reported as the net cost of the intervention vis-à-vis the comparator in relation to the net benefits achieved. The key question for an economic evaluation to answer is what difference the intervention will make compared to current practice. The comparator to the interventions under review in the case study was "current practice". Occasionally the definition of "current practice" was not clear-cut and two scenarios were used – a "do nothing" current practice and a "status quo" current practice (eg. the colorectal cancer screening evaluation).

Drummond (Drummond, O'Brien et al. 1997) also points out the importance of a clear description of the comparators in an economic evaluation. The briefing paper on each option for change prepared by the research team provided the detailed description of the comparators. An overview is presented in Appendix Six under the heading "The Intervention." Note also that a criterion for selection of the options for change was that "a clear and concrete option" could be specified. Each intervention was assumed to be in "steady-state operation"; i.e. it was fully implemented and operating in accordance with its potential efficacy as established by the available evidence.

12.6.4 Efficacy/Effectiveness of the Interventions

The level of evidence supporting each option for change was clearly set out and summarised under the "level of evidence" filter. The approach adopted recognised the emerging view that there *is* a single framework within which evidence on clinical, public health and behavioural interventions can be assessed. While the nature of the evidence for different kinds of health interventions inevitably varies, and the evidence for public health and social science interventions will often be weaker than that for clinical interventions, the logic used to assess the evidence is the same for all of them. This view of evidence entails a re-categorisation of the facts that make up the evidence under three headings as set out in Section 12.5.2.

12.6.5 Identification of Relevant Costs and Consequences

The study perspective defined above is important because it has direct implications for the inclusion/exclusion criteria for costs and benefits.

Concept of Benefit

The definition of "benefit" has a key role in MEEM/PBMA analysis and was covered in detail in Section 12.5 above. The concept of benefit in the case study was specifically developed to encapsulate the goals and objectives of the National Cancer Control Strategy.

Costs Included/Excluded

On the cost side, the government perspective meant that only costs involved in organising and operating the interventions were included. These are "C1"costs in the typology adopted by Drummond (Drummond, O'Brien et al. 1997). This meant that costs and/or cost offsets impacting on patients (or participants) and their families in attending or complying with the interventions were not included (i.e. "C2" costs). Similarly, costs and/or cost offsets impacting outside the health sector (including production losses and/or gains) were similarly excluded (i.e. "C3" costs). The inclusion of unrelated health care costs in the additional years of life conferred by the intervention is a contentious issue amongst economists (Gold, Siegel et al. 1996; Drummond, O'Brien et al. 1997). Such costs were not included in the case study.

Note that because steady-state operation was chosen in order to simplify the analysis and to achieve comparability between all the interventions considered, the additional costs associated with implementing new programs were not included (eg. start-up costs; learning curve issues; surplus capacity during take-up).

12.6.7 Measurement and Valuation of Costs and Benefits:

General

The costs and resulting benefits for a reference cohort (the Australian population in 1996) were assessed for both the intervention and current practice. All options for change were evaluated using the annualised equivalent approach[206], as more detailed modeling over a 10 or 20 year time horizon was not feasible in the time available (and is generally not feasible within a macro evaluation setting designed for the priority setting decision context). Note, however, that the cost and outcome implications of receiving the intervention or current practice in the one year assessed may extend well into the future and these future implications were included.

The reference year of 1996 was chosen, due to the availability of key data sets (particularly the DALY data set) for this year. Costs and cost offsets for government were measured in real prices for the reference year (1996). The AIHW health sector deflators [AIHW, 1999 #509] were used to adjust prices to the reference year.

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[206] The cost and outcome implications of one full year of operation in steady-state were assessed.

Intervention Costs

Intervention costs were reported in gross and net form i.e. with and without the estimated cost offsets (see below). Pathway analysis was used to identify the component activities of the interventions (refer Appendix Two for further detail). A unit price for each of the activities, together with the data source, was specified. Detailed information on the composition of costs by expenditure type (i.e. capital[207]; staff; consumables; overheads; etc) was generally not provided. This reflects the focus of the case study on allocative efficiency rather than technical efficiency.

Cost Offsets

The calculation of the cost offsets was based on the predicted reduction in disease incidence. The predicted percentage fall in new cases was applied to the estimated health care costs attributed to the cancers involved (refer discussion of MEEM in Chapter Ten). The estimate of health care costs attributed to the specified cancers was taken from the Disease Costs and Impact Study for neoplasms (Mathers, Penm et al. 1998). The health sector costs are based on 'direct costs' only (i.e. expenditure on hospital services, medical services, pharmaceuticals, allied health services and nursing homes) and do not include 'indirect costs' (i.e. production losses due to ill health) or any dollar valuation of pain and suffering. The cost offset was then calculated by applying the percentage reduction in new cases for the specified diseases in the year of effect (i.e. lags are incorporated) to the corresponding 1996 disease cost estimates. This calculation uses the estimate of the current average cost of care to compute future cost offsets. This assumes that the current relationship between cost and incident cases does not change through time. It also assumes that the "average cost" is representative of the costs of care for the prevented cases. The cost offset is then expressed in present value terms utilising a 3% discount rate.

The disease cost estimates utilised maybe conservative because the reference year (1996) arguably involves lower real costs of care than might be expected in the future when the savings will be realised due to changes in demography (population growth and ageing), and more expensive technology. On the other hand, the cost offset estimates based on the DCIS data may be overstated for two reasons. First, DCIS is based on a 'prevalence approach' (i.e. total expenditure in the reference year on all *existing* cases) rather than an 'incidence' approach (i.e. present value of total expenditure - in the reference year and beyond - for complete care of all *new* cases in reference year). The prevalence/incidence distinction is relevant because health promotion programs prevent new cases from occurring, rather than impact on existing disease. To the extent that disease episodes are of a short duration, prevalence-based costings give

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[207] Note that where relevant, capital costs have been annuitised.

similar estimates to the incidence-based costings. In the case of our selected cancers, this will vary from disease to disease. Second, the disease cost estimates cover expenditures by the public sector (i.e. the Commonwealth and State/Local governments) as well as the private sector (i.e. private health insurance, individuals, workers compensation and motor vehicle insurance). Given the perspective of the case study, not all of the estimated cost offset might be deemed relevant for inclusion. The government share[208] of health sector expenditure is typically around 68%, with the Commonwealth government funding two-thirds of this. it is difficult to predict with any certainty the net effect of these offsetting biases. For this reason the cost offset was reported separately so that its impact under alternative assumptions could be examined.

There is also a practical financial issue for government that warrants separate reporting of the cost offsets. The cost offsets are "opportunity cost" estimates – i.e. they are estimates of resources devoted to the treatment of preventable diseases (or de facto screening programs) that could be available for other purposes. Conversion of opportunity cost savings into financial savings involves a number of practical and theoretical considerations and cannot be taken for granted. The practical issues include workforce re-structuring, management policies, political acceptability, professional interests and public reaction. The theoretical issues relate to the cost characteristics of the production function, involving factors such as the mix of 'variable' costs and 'fixed' costs, together with 'lumpiness' in the expansion/contraction of capital equipment and assets.

Health Benefits: Measurement of the DALY Recovered

The health benefit is measured in Disability Adjusted Life Years (DALYs) so that changes in mortality (Years of Life Lost: YLL) and morbidity (Years of Life Lived in Disability: YLD) can be expressed in a single measure. This enables both cost effectiveness ratios (i.e. cost per YLL) and cost utility ratios (i.e. cost per DALY) to be calculated and compared with other available economic assessments. The health benefit is calculated as the difference in DALYs (or YLL) with and without the intervention. The future stream of life years or DALYs recovered for the 1996 reference cohort is discounted at 3%. The assumptions on which the efficacy of the various interventions were based are clearly specified and rated under the "level of evidence" filter (refer Section 12.5.2).

Interventions were selected for the MEEM/PBMA trial where both the mortality component (eg. colorectal cancer screening) and the morbidity component (eg. psychosocial care) of the DALY are the major contributor to the DALY benefit. While the YLD component of the DALY has the significant advantage of being available for a wide range of diseases, it is not as sensitive or

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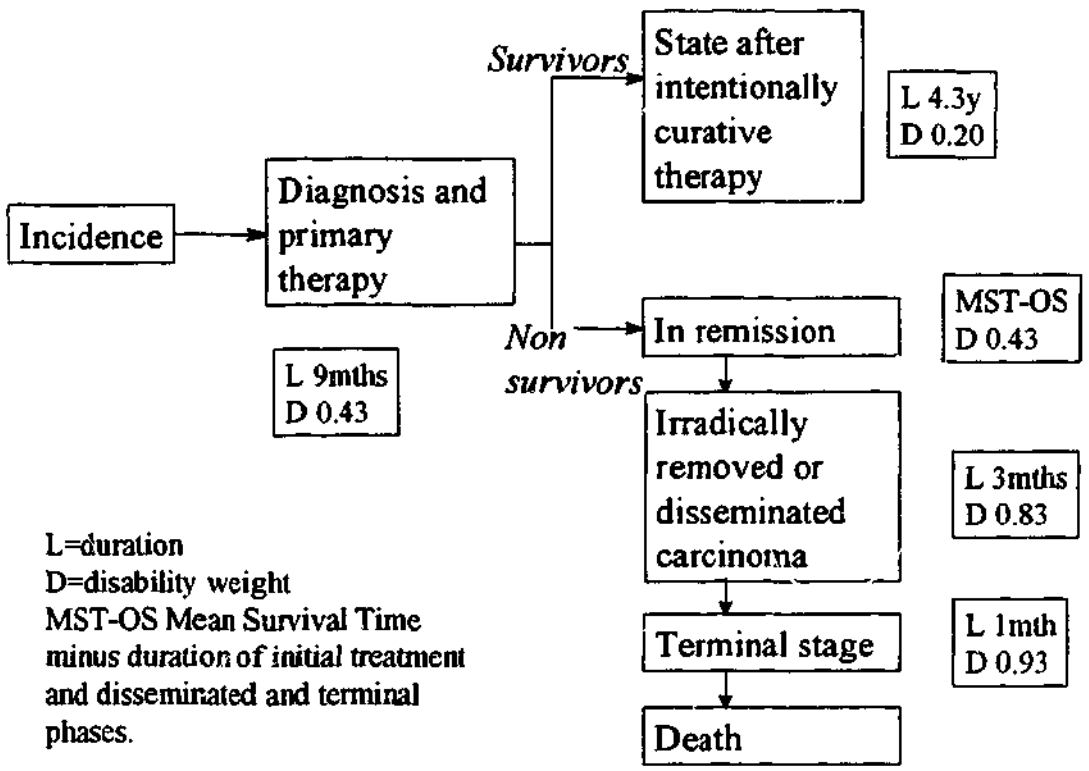
[208] Of the one-third non-government share, private health insurance covers approximately 35%, direct patient contributions 51% and workers compensation/ transport accident insurance 14%.

rigorous as other available quality of life measures (refer discussion in Chapter Eleven). The disease model utilised in the DALY Burden of Disease studies to calculate the YLD is outlined in *Figure 12.1.* This simple model identifies major phases in the disease progression for survivors and non-survivors. Each phase is associated with an altered health state for an average duration and from these the YLDs are calculated. The overall mean survival time and the cure rates are based on National Cancer Statistics Clearing House data. The disability weights are based mostly on the Dutch weights (Stouthard, Essink-Bot et al. 1997), with some adjustments as outlined in the Australian DALY studies (Mathers, Vos et al. 1999; Vos and Begg 1999a; Vos and Begg 1999b). The example shown is for colorectal cancer.

Figure 12.1 The Disease Model Utilised in the DALY Burden of Disease Work (Colorectal Cancer Example)



A sample table (refer Table 12.2) from the associated 'Dismod' worksheet shows the variables used to calculate the YLD for one of the phases of the disease model - *Diagnosis and primary therapy phase*. A YLD is the product of the incidence (I) by the disability weight (D) by the duration (L). Inclusion of discounting at rate *r* brings it back to present day value and the formula becomes a little more complicated:

$$YLD = I \times D \times \frac{(1 - e^{-rL})}{r}$$

This model was used to predict the mortality and hence calculate the YLL. The YLL are estimated from the non-survivors in each age group using the Life Expectancies (LE) for the 1996

Australian Cohort developed for "*The Burden of Disease and Injury in Australia*" (Mathers, Vos et al. 1999). The YLL are first discounted back to the incidence of disease because screening avoids deaths that occur some time in the future and then adjusted for the discounted mean survival time (MST). The final YLL are calculated according to the following formula:

Label1

Where LE = Life expectancy, MST is the mean survival time, r=0.03(the discount rate).

Table 12.2 Sample of the DISMOD Worksheet for Calculating YLDs: Diagnosis and Primary Therapy Phase - Includes Survivors and Non-Survivors

Australia	Population ('00000)	Incidence	Incidence /100,000	Age at onset	Duration (year)	Disability Weight	YLD[a]	YLD /100,000
Males								
<35	48.0	43	1	30.0	0.75	0.43	13.7	0.3
35-39	7.3	58	8	37.0	0.75	0.43	18.5	2.6
40-44	6.8	122	18	42.0	0.75	0.43	38.8	5.7
45-49	6.5	231	35	47.0	0.75	0.43	73.6	11.3
50-54	5.2	384	74	52.0	0.75	0.43	122.4	23.7
55-59	4.2	644	153	57.0	0.75	0.43	205.4	48.9
60-64	3.5	771	218	62.0	0.75	0.43	245.9	69.5
65-69	3.4	992	294	67.0	0.75	0.43	316.4	93.8
70-74	2.8	1141	413	72.0	0.75	0.43	363.8	131.8
75+	3.5	1681	486	80.5	0.75	0.43	536.1	155.1
Total	91.1	6066	67	67.2	0.75	0.43	1934.6	21.2

a: YLD are discounted by 3% but are not age weighted.

12.6.7 Discounting

Discounting was applied to both costs and benefits in the appraisals conducted for the case study. This reflects the fact that individually and as a society we prefer to have dollars or resources now as opposed to later, because we can benefit from them in the interim[209]. As noted above, benefits, costs or cost offsets occurring in the future were discounted at 3%. A 3% discount rate was chosen to match the rate chosen in the Australian DALY studies. This rate also approximates the long-term bond rate, the "rule of thumb" often used in selecting the appropriate discount rate.

12.6.8 Incremental Analysis

All the MEEM/PBMA evaluation results were reported as incremental results; viz as the additional cost (saving) of the option for change compared to the comparator, expressed as a ratio in relation to the net DALYs recovered.

Where appropriate, the interventions were also assessed using marginal analysis. This enabled increasing amounts of investment in the chosen intervention to be compared with the additional benefits conferred. Thus, for the colorectal cancer screening intervention marginal analysis was used to assess the costs and outcomes of widening the age group screened or reducing the interval from biennial to annual screening.

12.6.9 Sensitivity Analysis

In the primary analyses point estimates were utilised to measure benefits, costs and ultimately the cost effectiveness and cost utility ratios for the various interventions. While the best evidence available was utilised, there is always a level of uncertainty associated with cost and outcome estimates. Even data from RCTs, for example, may not be easily transferable to the Australian setting or to the proposed intervention.

The sensitivity analysis for the case study was conducted using the @RISK program. With this software program it is possible to define a probability distribution around each of the variables and put them through multiple iterations (usually 2000). The probability distributions used were based on either the confidence intervals quoted in the literature; the range of parameter values quoted in the literature; or on expert advice on the likely scenarios under Australian conditions. The variables, the values used in the primary economic evaluation and probability distributions used in the simulation model are summarised in the evaluation reports in Appendix Two. Where relevant, threshold analysis was also incorporated into the sensitivity analysis. This enabled an acceptable cost utility result to be specified (say $30,000 per DALY) and the cost and outcome assumptions to be varied in such a way as to assess the level of variation that still achieved this result.

12.6.10 Discussion of Study Results

Drummond (Drummond, O'Brien et al. 1997) raises a number of issues under this heading. A basic theme is whether the cost effectiveness ratios are interpreted in a mechanistic or intelligent fashion. Drummond includes under this notion a concern for the equitable distribution of costs and consequences and issues relating to implementation. In this regard, the whole purpose of placing the MEEM macro C/E ratios within the PBMA framework was to encourage such "intelligent" interpretation. This is given explicit expression through the two-stage approach to ranking the interventions.

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[209] For further discussion of discounting refer Drummond et al (1997) and Gold et al (1996).

Drummond (Drummond, O'Brien et al. 1997) also raises the issue of whether the results were compared with those of others who have investigated the same question (and whether appropriate allowances were made for differences in methods). Where conventional micro economic evaluation results were available for the options assessed in the case study, these were reported and compared with the MEEM macro cost-effectiveness results (refer Appendix Two). The level of consistency between the MEEM macro cost-effectiveness ratios and the results from conventional evaluations was very encouraging.

12.7 Discussion of the PBMA/MEEM Results

12.7.1 Ranking on the Basis of the Cost per DALY Results

Table 12.3 provides a summary of the cost per DALY results. The interventions are ranked on the basis of the macro CEA results – either by their level of "dominance[210]" or the net cost per DALY ratio. Note that three interventions, all addressing important risk factors (i.e. sun exposure; smoking; and inadequate diet), are estimated to be "dominant." Tobacco control is ranked above primary skin cancer prevention as both the anticipated cost offset is higher (i.e. $39.0 M verses $37.4 M) and the anticipated DALYs recovered is higher (i.e. 10,599 DALYs to 9,965). When interventions are not dominant (i.e. the more normal circumstance where net expenditure is involved to secure health gains) they were ranked on the basis of the net cost per DALY ratio. The net cost per DALY estimates provided include the point estimate (i.e. the result from the primary economic analysis) together with the upper and lower bound estimates from the sensitivity analysis using the @RISK software.

Note that for some interventions (eg. colorectal cancer screening) a specific design option has been selected (eg. biennial screening of those aged 55-69). More detailed results showing the marginal analyses of different design options (particularly for colorectal cancer screening) and sensitivity analyses are provided in Appendix Two. The marginal results for colorectal cancer screening suggested that the inclusion of the 70 – 74 age group was cost effective, and whilst costing an additional 12.4 million, improved the efficiency of the program. The Working Party was of the view that the core colorectal cancer screening program should be seen as biennial screening of those aged 55 – 74. For this reason the results for this design variant are also shown in Table 12.3.

Dominant programs have very strong economic credentials for funding. Conversion of opportunity cost savings into financial savings should not be taken for granted, however, as discussed previously. It is for this reason that both gross and net cost estimates were reported in Table

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[210] Dominance is a term that is used in economic evaluation to describe the situation where an intervention is estimated to yield both cost savings vis-à-vis current practice, as well as health status gains.

12.3. If the interventions had been ranked on the gross cost per DALY ratios (i.e. excluding the cost offsets), then the ranking would be slightly different. Primary prevention of skin cancer and tobacco control would swap their positions as first and second; as would the fruit & vegetables media campaign and the breast care nurse intervention as third and fourth.

Before turning to the implications of Table 12.3, it is useful to note that both increments and decrements have been included. If a decrement both saves resources and causes no loss in health status, then it is also "dominant" as for the increments. Unfortunately, this is an unlikely occurrence, unless existing programs are providing no benefit or causing harm. The more likely result is that there will be a small increase in the DALY burden as the opportunity cost of securing the resource savings. If the results of decrements with this outcome are expressed as a ratio to make them comparable with those increments where health gains involve a positive net cost, they need to be carefully interpreted. The easiest way to understand the ratios is to express them in the negative i.e. they are the cost per DALY of maintaining current practice and not accepting the proposed change. Thus the cost per DALY of not increasing the screening interval from two to three years for cervical cancer screening is $516,864, involving an opportunity cost of approximately $50 million per year.

The decrements considered to rationalise Australia's national cervical cancer screening program are likely to be contentious, despite the strength of the results from an economic perspective. In this circumstance, particular care was taken to document the assumptions and data sets used in the analysis. The reliance on Victorian data for a range of parameters[211] was carefully noted, for example, and reference made to the sensitivity analysis so that stakeholder interests in the cancer community could assess the impact of parameter variations.

One of the key implications of the Table 12.3 relates to what conclusions might be drawn in relation to resource allocation. If, for example, a budget of $50 million were available, where would it be spent? Is it possible to fund such a budget from the decrements? Would the benefits from investing the $50 million in the increments outweigh the loss in benefits in the decrements?

The possibility of introducing a national colorectal cancer screening program is being considered at present in Australia and provides a useful case study to address these questions. The introduction of a colorectal cancer screening program providing biennial screens for men and women aged 55-69 was estimated to cost approximately $53.3 million per annum (excluding

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[211] The parameters based on Victorian data include number of women participating in the program; the number of women who had a further assessment & treatment; the unit costs of smears read in public labs; and recruitment, coordination, registry, and training costs. The survival assumptions rely heavily on South Australian and NSW data. Refer Appendix Six for further detail.

offsets). Such a program was estimated to reduce the disease burden from this cancer by 3,187 DALYs each year. This intervention, however, ranks last amongst those evaluated in terms of its net cost per DALY ratio. If that same $50 odd million were used to finance the five interventions that rank above it in the league table, then the DALY burden in the various diseases involved would be reduced by 31,993 DALYs. Such analysis suggests that the interventions ranked above the colorectal cancer screening option have stronger economic claims for funding from the hypothetical budget.

If we consider the decrements as the source of our budget, then the suggested interval change in the cervical cancer screening program would provide the funds at an opportunity cost of increasing the DALY burden from cervical cancer by 98 DALYs per year. Any such conscious increase in the DALY burden deriving from policy decisions carries with it important equity and ethical issues. On the other hand, the equity and ethical implications of not making these changes, if their implementation was contingent on savings being found from existing expenditure, would also need to be considered. Clearly the DALY benefit from either application mentioned above (i.e. a 3,187 DALY reduction from introducing colorectal cancer screening and a 31,993 DALY reduction from the interventions ranked 1st to 5th) considerably outweighs the DALY increase.

12.7.2 Impact of the Second Stage Filters (including Equity)

Table 12.4 provides an overview of the Working Party's discussion of the second stage filters. There are a number of ways in which the second stage filters could have been applied. These range from simple "hand-sorting" of the results by the Working Party along the lines adopted by the Commissioners in the Oregon process (refer Chapter Six) to approaches based on decision theory (such as those adopted in recent PBMA studies (Peacock, Richardson et al. 1997b)). In the event, the filters were treated as dichotomous constraints (i.e. "pass" or "fail") and none of the interventions were ruled-out by them. There are, nonetheless, some important issues raised that the Working Party emphasised should not be ignored. These included attention to the design of the interventions to offset equity concerns (eg. colorectal cancer screening); the need to strengthen the evidence base (eg. psychosocial care by breast care nurses; fruit & vegetables); and the way in which proposals might be implemented (eg. cervical cancer screening). The application of the second stage filters clearly involved a judgement process which the Working Party endeavored to make as explicit as possible by documenting both the process and the content of their judgements.

Table 12.3 Cost per DALY Results

Interventions	Cost (Savings) $ Millions	DALYs Recovered (Lost)	Cost per DALY (Point estimate) $	Cost per DALY (Lower bound) $	Cost per DALY (Upper bound) $
INCREMENTS:					
1st: Tobacco Control: National Tobacco Campaign					
Gross Costs (no offsets)	8.95	10,599	844	544	1,180
Net Costs (or net saving)	(39.07)		Dominant	Dominant	Dominant
2nd: Primary Prevention of Skin Cancer (SunSmart on National Basis)					
Gross Costs (no offsets)	2.53	9,965	254	238	505
Net Costs (or net saving)	(37.4)		Dominant	Dominant	Dominant
3rd: Fruit & Vegetables Media Campaign					
Gross Costs (no offsets)	2.46	3,626	677	513	16,392
Net Costs (or net saving)	(12.15)		Dominant	Dominant	Dominant
4th: Psychosocial Care: Breast Care Nurses					
Gross Costs (no offsets)	4.85	5,186	935	455	1,745
Net Costs (or net saving)	Offsets not estimated				
5th: Psychosocial Care: Psychologists for Cancer Treatment Centres					
Gross Costs (no offsets)	25.7	4,849	5,292	1,612	5,453
Net Costs (or net saving)	Offsets not estimated				
6th: National Colorectal Cancer Screening Program					
(Biennial: Ages 55-69)					
Gross Costs (no offsets)	53.3	3,187	16,718	12,500	44,800
Net Costs (or net saving)	38.1		11,958	10,300	39,700
(Biennial: Ages 55-74)					
Gross Costs (no offsets)	65.6	4,260	15,399		
Net Costs (or net saving)	43.8		10,300		
DECREMENTS:					
1st: Rationalise the National Cervical Cancer (CrCx) Screening Program: Change Screening Interval from 2 to 3 years					
(Net Saving)	(50.6)	(98)	516,864	156,172	955,407
2nd: Rationalise the National CrCx Screening Program: Increase age of commencement from 18 to 25					
(Net Saving)	(23.7)	(30)	790,996	624,242	959,259

Table 12.4 Summary of Cost per DALY Results and Impact of Second Stage Filters

Options (Increments & Decrements)	First Stage Filter: Cost per DALY	Equity Implications	2nd Stage Filter: Levels of Evidence	2nd Stage Filter: Size of the Health Problem	Acceptability & Feasibility
1. Colorectal Cancer Screening (increment)	Biennial 55-69 age group: $11,958 per DALY recovered (net cost est). Biennial 55-74 age group: $10,282 per DALY recovered (net cost est). Annual 55-69 age group: $16, 039 per DALY recovered (net cost est). Addition to biennial program of: 70 to 74 age group: $5,277 per DALY (net cost estimate). 75+ age group: $5,956 per DALY (net cost estimate). 50-54 age group: $23,111 per DALY (net cost estimate). 45-49 age group: $32,616 per DALY (net cost estimate).	There are existing inequities in the incidence & mortality from CRC for low SES, rural/remote and Aboriginal/Torres Strait Islanders. Introduction of a National screening program is likely to increase existing inequities (due to likely utilisation patterns) unless specific action is taken to address equity issues in design & implementation of program. **Consideration of this filter raises important issues for program design.**	"Sufficient well-designed research." Major international trials (4 of 6) reported a reduction in mortality of 12-21% for biennial screening. Only one RCT available for annual screening. **Consideration of this filter increases the weight to be given to a successful intervention.**	High on health burden and health system costs. CRC is second most common cancer affecting both men & women. Medium on potential reduction in the disease burden (i.e. 11% fall in DALYs with biennial screening; 17% with annual). High on potential costs of screening program and potential cost offsets. **Consideration of this filter increases the weight to be given to a successful intervention.**	Financial cost varies hugely depending on design option (i.e. $38 million to over $180 million.) Acceptability issues for participants include availability of counselling and adequate information on cost, benefit & risk. Quality assurance (including positivity rate) will need to be established Physicians still need to be convinced of efficacy of CRC screening. Major feasibility issue is health system inertia -- will be hard to wind-up and harder to wind-down if that becomes necessary. **Consideration of this filter suggests caution and need for careful planning.**
Decision points:	**Important design features to be tested, with significant cost implications (i.e. age; interval; attendance; positivity rate; equity issues). Introducing another national screening program requires very careful consideration due to health system inertia.**				

Table 12.4 Summary of Cost per DALY Results and Impact of Second Stage Filters (Continued)

Options (Increments & Decrements)	First Stage Filter: Cost per DALY	Equity Implications	2nd Stage Filter: Levels of Evidence	2nd Stage Filter: Size of the Health Problem	Acceptability & Feasibility
2. Cervical Cancer Screening (decrements)	**Option One**: 2 yr screening vis-à-vis 3 yr screening: $516,864 per DALY in staying with current policy. Releases $50.6 million per annum. **Option Two**: 25 yr age of commencement: $790,996 per DALY in staying with current policy Releases $23.7 million per annum.	There is higher health burden from cervical cancer in lower SES groups, in remote areas, in some migrant groups and in indigenous women. Proposed changes unlikely to increase inequities associated with screening program. Rather, quite the reverse is true, particularly if some of the savings are used to address inequities in the program.	**Option One**: "Sufficient well-designed research". **Option Two**: Knowledge of the impact of varying age of commencement is inconclusive with a rating of: "Limited evidence of effectiveness". Reliance on Victorian data needs to be kept in mind re external validity.	For Australia as a whole, cervical cancer has a low health burden. The higher incidence and mortality rates in rural/ remote localities and for indigenous women remain a concern however. Potential adverse health effects of proposed changes are minor, particularly when assessed against potential gains elsewhere.	Any proposed change to the National program is likely to face strong opposition from medical practitioners. Use of savings key issue re acceptability. Reaction from the community will depend on how well the changes are explained and communicated, together with use of resources saved.
Decision points	**Strong case on efficiency & efficacy grounds to consider change in interval. External validity of data assumptions needs to be kept in mind.** **Acceptability remains a major obstacle (as it will for most decrements). HPV screening may provide opportunity for change. Proposed use of released funds key issue.**	**Consideration of this filter is at worst neutral and at best supportive of option.**	**Consideration of this filter supports the change in interval, but raises reservations about the change in age of commencement.**	**This filter is potentially very supportive of this option.**	Future action in relation to HPV may provide vehicle for change. **This filter is the major concern for this option.**

Table 12.4 Summary of Cost per DALY Results and Impact of Second Stage Filters (Continued)

Options (Increments & Decrements)	First Stage Filter: Cost per DALY	Equity Implications	2nd Stage Filter: Levels of Evidence	2nd Stage Filter: Size of the Health Problem	Acceptability & Feasibility
3. Primary Prevention of Skin Cancer: SunSmart on National basis (increment) **Decision points:**	$254 per DALY recovered (excluding cost offsets) Dominant if cost offsets included (i.e. saves resources and improved health status). **Few complications with this proposal, but requires Government cooperation and agreement on funding sources.**	Incidence varies directly in relation to intensity of and exposure to UVR. Only target group where equity issue may arise is rural/remote areas. Greatest financial impact will be on private individuals conforming with SunSmart policy guidelines. **Equity filter is largely neutral for this intervention.**	Good evidence exists that educational campaigns can impact on behaviour. A complex chain of events is nonetheless assumed, between behaviour and disease reduction. "Limited evidence of effectiveness" supports this intervention. **Sufficient evidence exists to support intervention.**	Skin cancer (particularly NMSC) is very high on health burden and health system cost. Potential impact of intervention is significant. **Consideration of this filter greatly enhances merit of intervention.**	This intervention is comparatively low cost, requiring little development. It involves little system inertia, being easy to wind-up or contract. High community acceptance anticipated. **This filter also supports intervention.**
4. Improve efficiency of diagnosing skin cancer	Pending the availability of trial data from SA, it was sensible for the evaluation of this intervention to be put on hold.				
5. Psychosocial care: Breast Care Nurses (increment) **Decision points:**	67 full-time Breast Care Nurses: $935 per DALY recovered (indicative but robust result). **Whether evidence base is strong enough to support widespread implementation or whether more cautious approach required.**	The BCN intervention is unlikely to worsen any existing inequalities and provides potential to address special needs groups. Access in rural/remote areas may be a problem **This filter does not pose a problem.**	"Limited evidence of effectiveness" exists from studies of varying quality. **This filter suggests caution as to the next steps to pursue this intervention.**	Breast cancer imposes a major health burden and significant health system costs. Potential impact on breast cancer morbidity is substantial for low cost intervention ($5 m). **This filter supports option.**	Likely to be widely acceptable if efficacy sustained. Feasibility in rural/remote areas needs to be explored. Supply of BCNs in states other than Vic/NSW may need to be addressed through training. **No significant issues posed by this filter.**

Table 12.4 Summary of Cost per DALY Results and Impact of Second Stage Filters (Continued)

Options (Increments & Decrements)	First Stage Filter: Cost per DALY	Equity Implications	2nd Stage Filter: Levels of Evidence	2nd Stage Filter: Size of the Health Problem	Acceptability & Feasibility
6. Psychosocial care: psychologist in cancer centres (increment) **Decision points:**	Introduce psychologists (approximately 290) for cancer patients: $5,292 per DALY recovered. **Funding arrangements for the proposal. Assistance from psychologists is less acceptable to equity target groups.**	This intervention is unlikely to worsen any existing inequalities and provides potential to address special needs groups. Access in rural/remote areas may be a problem **This filter does not pose a problem.**	A number of randomised trials (as well as three recent meta-analyses) support intervention. Efficacy of proposal supported by " sufficient well-designed research." **This filter does not pose a problem, for appropriate interventions.**	As intervention addresses morbidity associated with a range of cancers, it is high on health burden and health system costs. Has potential to significantly reduce cancer morbidity. **This filter supports intervention.**	Acceptability to medical community and consumers is uncertain. Cost of intervention may be an issue to Government. **This filter poses minor concern for the intervention.**
7. Rationalise prostate specific antigen testing (decrement)	PBMA economic appraisal not yet available. Data to support the evaluation will become available from trials being conducted in South Australia.				
8. Tobacco control: National Tobacco Campaign **Decision points:**	$844 per DALY recovered (excluding cost offsets). Dominant if cost offsets included (i.e. saves resources and improves health status). **Second stage filters confirm strong credentials of this intervention.**	The results of surveys of the NTC indicated that the positive effects applied to males and females; to older and younger smokers; and to all levels of educational attainment. **Consideration of this filter does not suggest a problem.**	Causal links between smoking and disease is now firmly established by "well-designed research." Effectiveness of the NTC in modifying smoking behaviour is documented by evidence from behavioural pre and post campaign survey research. **This filter does not pose a problem.**	Smoking is commonly acknowledged as the most important source of preventable disease and health care expenditure. **Consideration of this filter strongly supports intervention.**	Continuation and development of the NTC is likely to be widely acceptable and quite feasible. **This filter reinforces the desirability of this intervention.**

Table 12.4 Summary of Cost per DALY Results and Impact of Second Stage Filters (Continued)

Options (Increments & Decrements)	First Stage Filter: Cost per DALY	Equity Implications	2nd Stage Filter: Levels of Evidence	2nd Stage Filter: Size of the Health Problem	Acceptability & Feasibility
9. Encourage consumption of fruit and vegetables **Decision points:**	$677 per DALY recovered (excluding offsets). Dominant if cost offsets included (i.e. saves resources and improves health status). **Second stage filters confirm credentials of intervention. Clearer costing data would be important, together with strengthening of the evidence base.**	Evaluation of the Victorian campaign suggests existing inequalities in the consumption of fruit & vegetables would be reduced. Impact on four target groups unknown, but not anticipated to be a concern. **Consideration of this filter does not suggest a problem.**	Causal links between inadequate consumption of fruit & vegetables and disease established by "sufficient" evidence. Effectiveness of intervention in modifying behaviour supported by "limited evidence." **Sufficient evidence exists to sustain intervention.**	The diseases causally related to inadequate consumption of fruit & vegetables are major causes of premature mortality and morbidity **This filter reinforces the desirability of this intervention.**	Development of a National "*Fruit 'n' Veg*" campaign is likely to be widely acceptable and quite feasible. **This filter reinforces the desirability of this intervention.**

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Chapter Thirteen: Assessing MEEM against the Checklist

13.1 Introduction

In this chapter the performance of MEEM is assessed against the ten criteria for an ideal approach to priority setting presented in Chapter Seven. The wording of the sub-headings 13.2 to 13.11 summarise the relevant criterion. The criteria reflected four sets of considerations, viz: economic theory; ethics and social justice; the lessons from empirical experiences; and user considerations. These considerations were discussed in Chapter Two and Chapters Four to Six. The assessment is based primarily on the major case study of MEEM/PBMA presented in Chapter Twelve, but account is also taken of the smaller case studies published during the period MEEM was developed, together with the broader potential of MEEM. Included in the assessment is a comparison of the case study with the earlier NCCI consensus-based approach (Section 13.6), as well as a comparison with the CSG survey results (Section 13.3). The views of members of the Working Party are incorporated into the relevant criteria as appropriate and brought together in the conclusion (Section 13.12).

13.2 Criterion One: Is There Clarity in the Research Question?

In MEEM Mark I the intention was to apply the accepted principles underlying applied micro economic evaluation to a multi-project macro setting. The early case studies in smoking cessation (Carter 1992; Carter and Scollo 1999), Coronary Heart Disease (Carter 1994) and skin cancer prevention (Carter, Marks et al. 1999), illustrated that the ten-point Drummond et al. checklist (Drummond, O'Brien et al. 1997) could be applied, including the clear specification of the research question. This demonstrated that the reliance on the development of cost and outcome databases and macro evaluation techniques, did not compromise potential adherence to the standardised evaluation practices set out in the Drummond texts, particularly the Checklist of Annex 3.1 (Drummond, Stoddart et al. 1987; Drummond, O'Brien et al. 1997). From a technical perspective, there was an empirical question of whether the simplifying assumptions necessary in the macro evaluation protocol provided reasonable estimates of answers achieved with more rigorous assumptions. The evidence to date (refer Appendix Two) is very positive in this regard.

As MEEM Mark I was developed and placed within the PBMA framework, the focus given to a clear articulation of the research question was emphasised. This reflected, among other things, a recognition that it would be easier to lose the focus of an evaluation study when a broad instrument like MEEM was being used. The steps in the conduct of the MEEM/PBMA major case study, for example (Chapter Twelve, Section 12.3.2), clearly make this the first step, including the

matching of evaluation technique to the requirements of the research question[212]. This emphasis is not only inherent in the PBMA process itself, but is grounded in the selection of the decision-making approach as the theoretical foundation for MEEM (refer Chapter Four). While a focus on the research question is a characteristic of all good analyses, the focus on the objectives of the decision-maker is an important characteristic of the MEEM/PBMA approach. It means, among other things, that the specification of the research question may well be narrower (i.e. health sector perspective; government perspective) than the more conventional "societal well-being". It is given effect through the care taken in matching technical analysis to the study question, in defining the concept of benefit and in the choice of comparators.

Criterion One also requires recognition of decision context and setting, and whether models clarify their relative strengths and weaknesses in different choice problems. In this regard, the purpose of MEEM was to aid health service planning and priority setting at the macro and meso levels within the health care system. At these levels the marginal analysis by age/sex sub-group possible with MEEM, offers quite reasonable guidance on the allocation of resources to particular forms of treatment and basic parameters of their efficient design. The macro nature of the databases supporting MEEM, together with the macro evaluation protocol, suggest caution, however, in using MEEM to assist fine-grained decisions that are more appropriate to detailed micro economic evaluation. As set out in Chapter Ten, when the decision-making context suggests detailed micro evaluation is appropriate to the research question, then micro evaluation should be the method of choice. In this context MEEM might only have a supplementary role in relation to policy implications and broader health system effects. It is in the situation where the decision context involves multiple projects (i.e. the normal context for priority setting), particularly where triaging of interventions is sought, that MEEM is being put forward as a primary evaluation method.

Conclusion: MEEM seeks a well-defined research question and is clear about those decision contexts to which it is suited. MEEM satisfies Criterion One.

13.3 Criterion Two: Is There a Clear and Appropriate Concept of Benefit? Is There a Mechanism or Process to Aid its Definition?

13.3.1 Discussion of criterion

A key component of criterion two is whether the model has a mechanism or process to define the concept of benefit in a way that captures the perspective and objectives of the decision-makers. It is this question in relation to the NCCI (refer Chapter Eleven) that gave rise to the major case

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[212] As indicated in Section 12.3.2, this involves both the specification of the macro economic evaluation protocol and the PBMA protocol in which the technical analysis is nested.

study. In Section 13.3.2 below, the performance of MEEM/PBMA in achieving greater clarity is discussed. It was also this question, grounded in my reading of the theoretical, ethical and empirical literatures (Chapters Four to Six), that encouraged my trialing of the PBMA approach as a mechanism or process to help articulate and measure "benefit" (Peacock, Richardson et al. 1997b; Carter, Mihalopoulos et al. 2000). Step 5.1 of the MEEM/PBMA process[213] is undertaken specifically to define the concept of benefit. It is given effect through careful discussion in the Working Party (led by the PBMA facilitator) and is also an important issue in the initial discussions with decision-makers in which the PBMA study is authorised. The task of the PBMA facilitator is to assist the Working Party of stakeholders to establish clear connections between the research question, objectives of the organisation/program, and the concept of benefit. Once the various dimensions of benefit are clarified, the facilitator then takes the Working Party through the various ways in which the measurement task can be undertaken. These include the use of a two-stage filter approach (as in the major case study), the use of decision theory to develop a context specific thermometer scale with weighted dimensions (Peacock, Richardson et al. 1997b; Carter, Mihalopoulos et al. 2000), through to simple options appraisal (Cohen 1994; Cohen 1995; Craig, Parkin et al. 1995; Twaddle and Walker 1995). The level of sophistication reflects the time and resources available (an important user consideration) and is a decision for the Working Party. The technical analysis is matched to the research question, rather than the research question massaged to fit the technical analysis.

Note that in contrast to MEEM Mark II, the early case studies based on MEEM Mark I exhibited a narrow concept of benefit that simply assumed health gain as the primary objective (Carter 1992; Carter 1994; Carter, Marks et al. 1999; Carter and Scollo 1999). The judgement that benefits equated with health gain reflected the values of the researcher and did not take into account deliberative discussion with key stakeholders and/or the decision-maker(s). While typical of purely technical approaches to priority setting, particularly economic approaches, MEEM Mark I would only partially satisfy criterion two. The concept of benefit is clear, but the approach did not have an in-built process or mechanism to clearly define the concept of benefit, and was therefore unlikely to capture in a satisfactory way all the dimensions of benefit of concern to the decision-maker(s).

Conclusion: **Like all sound forms of appraisal, the importance of a clear concept of benefit is emphasised in the MEEM approach. Through the PBMA framework, however, MEEM goes further and also provides an in-built mechanism to ensure that the concept of benefit satisfactorily captures the perspective and objectives of the decision-maker.**

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[213] Step 5.1 was "Establish objectives of the organisation and/or program and develop approach to measurement of the benefits."

13.3.2 Comparison of MEEM/PBMA Ranking with the Survey of the Cancer Strategies Group

Early on in the discussions of a possible MEEM/PBMA trial, CSG decided to survey its membership for a ranking of the interventions being considered for inclusion. The decision was taken as both a precautionary measure – in case the MEEM/PBMA trial could not be completed in the short time available – and to measure the contribution of an economic approach to the development of the revised National Cancer Strategy. The CSG ranking provides a broad "reality check" (while clearly not a gold standard) in evaluating the MEEM approach. A copy of the survey instrument is at Appendix Two of the thesis. Members were asked to score 46 possible cancer control actions against the following eight criteria[214]:

- **size of the problem** each action seeks to address;
- **effectiveness** of the action (quality of the evidence basis, size of impact on the problem, capacity of the strategy to satisfy consumers);
- **cost** of the cancer control action;
- **efficiency** of the cancer control action;
- capacity to **reduce inequity;**
- **acceptance** by the community;
- likelihood of successful **implementation** (because of availability of relevant expertise, budget implications, political issues); and
- **overall importance**.

For each intervention, CSG members were asked to score the eight criteria with a number between 1 (lowest score) and 5 (highest score). As with the NCCI survey instrument, members were left to weight the various criteria themselves in arriving at the "overall importance" score. Table 13.1 provides the summary results of the CSG survey for those interventions assessed in the trial, set alongside their corresponding PBMA/MEEM ranking. The CSG columns report the results for all eight dimensions combined, for the "overall importance" dimension only, and for the "efficiency" and "equity" dimensions combined. Table 13.2 provides the more detailed results for the CSG survey. With one exception (colorectal cancer screening) there is reasonable consistency between the CSG survey ranking based on "all eight dimensions combined"[215] and the "overall importance" dimension. The "efficiency and equity combined" score gives a quite different ranking for a number of interventions, particularly tobacco control, colorectal cancer screening, rationalising cervical cancer screening and psychosocial care. Similarly, analysis of individual dimensions (refer Table 13.2) confirms that, as expected, interventions rank differently

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[214] These eight criteria were subsequently discussed and developed by the Working Party into the benefit measurement approach used in the PBMA/MEEM trial (refer Section 12.5).
[215] All dimensions were given equal weight.

depending on the dimension selected. The CSG results confirm the concern that led to the PBMA/MEEM trial – i.e. that clarity as to the concept of benefit is important. Attaching different weights to the various dimensions scored would yield quite different rankings. Further analysis of the results is provided in Appendix Two.

Table 13.1: Comparison of the PBMA Ranking with the CSG Survey Results

Cancer Intervention	PBMA/MEEM Ranking	CSG Survey: Score for all 8 dimensions combined	CSG Survey: Score for "Overall Importance"	CSG Survey: Score for "Efficiency" & "Equity" combined
INCREMENTS:				
Tobacco Control	1st	1st (6 / 46)	1st	4th
Skin Cancer Prevention	2nd	2nd (8 / 46)	2nd (tie)	2nd
Encourage Fruit & Veg. Consumption (Note: cost per DALY result indicative only)	3rd	8th (26 / 46)	6th (tie)	7th
Psychosocial Care	4th & 5th	4th (17 / 46)	6th (tie)	3rd
Colorectal Cancer Screening	6th	7th (25 / 46)	2nd (tie)	6th
DECREMENTS:				
Rationalise Cervical Cancer Screening	Saving of $50.6 m & small DALY increase	5th (19 / 46)	5th	1st
Rationalise Prostate-Specific Antigen Testing	Results not yet available	3rd (14 / 46)	2nd (tie)	5th
Rationalise and Improve Skin Cancer Diagnosis Skills	Results not yet available	6th (23 / 46)	8th	8th

The comparison of the PBMA/MEEM results with the CSG survey (and with the NCCI results presented in Section 13.6.2) confirms the importance of:

- clarity as to the concept of benefit;
- clarity as to the "decision rules" in ranking proposals and when such rules are modified by judgement reflecting broader criteria (Criteria Five and Six); and
- the provision of quality information on the cost, outcomes and efficiency of interventions.

The attention in the PBMA/MEEM process to these issues led to a clearer rationale for the results achieved (that could be subject to later scientific review and revision) and greater consensus between the participants. The range in the scores given and/or size of the standard deviations in the CSG survey suggests a lack of common understanding or consensus on the results. In this context the use of mean scores from such surveys could be quite misleading if they were used to imply a consensus view.

Table 13.2 Detailed Survey Results for Cancer Strategy Group Members

Cancer Control Action (15 responses)	Size of the Problem		'Effectiveness'		'Cost'		'Efficiency'		'Reduces Inequity'		'Acceptance'		'Implementation'		'Overall Importance'		All Eight	Criteria
	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)
(2.2) Tobacco Control (NTC)	4.27	0.93 (5)	3.60	0.88 (3)	3.53	1.09 (3)	3.73	1.00 (3)	2.93	1.24 (2)	3.00	0.52 (3)	3.07	0.68 (3)	4.13	0.88 (5)	28.87	4.24 (28)
(3.4) Fruit & Vegetables Campaign	3.33	1.19 (2)	3.33	0.94 (4)	3.40	1.14 (3)	3.33	1.30 (5)	3.07	1.29 (4)	3.53	0.88 (4)	3.27	1.06 (3)	3.47	1.09 (3)	26.73	6.64 .(30)
(4.1) Skin Cancer Prevention	3.93	1.18 (5)	3.60	1.02 (3)	3.53	1.15 (5)	3.47	0.88 (3)	3.53	1.15 (4)	3.40	1.14 (4)	3.53	0.88 (4)	3.73	1.00 (4)	28.73	6.06 (36)
(5.1) Skin Cancer Diagnosis	3.87	1.02 (4)	3.20	0.91 (3)	3.33	0.94 (3)	3.50	0.82 (3)	2.67	1.19 (2)	3.93	0.93 (5)	3.27	0.77 (3)	3.40	0.71 (4)	26.93	4.52 (31)
(6.2) Rationalise Cervical Cancer Screening	3.13	0.72 (3)	3.60	0.80 (3)	4.07	1.24 (5)	3.93	0.85 (4)	3.13	1.36 (4)	2.67	0.94 (2)	3.40	1.20 (2)	3.53	0.72 (4)	27.47	4.39 (29)
(7.1) Introduction Colorectal Cancer Screening	4.27	0.93 (5)	3.47	1.09 (3)	3.00	1.10 (3)	3.07	0.85 (3)	3.36	1.23 (3)	3.07	1.00 (3)	3.07	0.93 (3)	3.73	1.18 (5)	26.80	5.37 (32)
(10.1) Rationalise PSA testing	4.33	0.70 (5)	3.00	1.03 (3)	3.80	1.11 (5)	3.33	1.14 (3)	3.33	1.01 (4)	3.27	1.06 (4)	3.40	0.80 (3)	3.73	0.77 (4)	28.20	4.34 (30)
(15.1) Psychosocial Care	3.73	1.18 (5)	3.40	1.02 (4)	3.33	1.14 (2)	3.07	0.77 (3)	3.93	1.29 (5)	4.13	1.31 (5)	2.93	0.93 (2)	3.47	1.09 (4)	28.00	6.98 (19)

13.4 Criterion Three: Is There an Acceptable Process for Generating Options for Change?

Criterion three is an important aspect of giving practical effect to the principle that benefits should be compared with their opportunity cost (refer discussion Section 4.3 2). In the context of one-off studies addressing a single illness or problem, there is usually a reasonably limited set of possibilities to consider. In the context of studies addressing priority setting, however, such as the development of national strategies to address whole ICD-9 disease chapters, there is a very broad range of possibilities. Here, the process by which options are generated and selected for inclusion becomes an important design aspect of the protocol. It is for this reason, together with reasons related to the tractability of information collection and assessment, that MEEM's development involved two key aspects, viz: i) adoption and development of the PBMA framework to provide a clear process for the development and selection of options for change; and ii) recognition of the need for the development of an evaluation protocol specifically developed for the priority setting context.

The major case study demonstrated that two key aspects of the MEEM approach satisfy this criterion, viz:

- first, clarity about the steps necessary to generate the options for change, having regard to the specific decision context; and
- second, clarity about the principles that guide the selection process.

Thus a three-step process was adopted in generating options for cancer control (refer Section 12.4). This process recognised the platform provided by the NCCI, the need to involve stakeholders in the trial (via the Workshop), and the needs of the decision-makers (the Working Party and CSG). The selection principles[216] were also clearly specified, having regard to the decision context and the principle of opportunity cost.

<u>Conclusion:</u> MEEM has an explicit mechanism for generating options for change in a theoretically acceptable and tractable way, which pays specific regard to the choice problem and the needs of stakeholders. MEEM satisfies Criterion Three.

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[216] The selection principles were as follows (refer Section 12.4):

- that a clear and concrete intervention could be specified;
- that there was sufficient evidence to make an assessment of efficacy/effectiveness possible;
- that both increments (i.e. options that involve additional expenditure) and decrements (i.e. options that involve reduced expenditure) be included;
- that options from across the complete disease pathway (i.e. from prevention to palliation) be included;
- that options be included that test the assessment of both mortality and/or morbidity impacts on health status; and
- that the perceived importance of options be taken into account, as reflected in the NCCI rankings (NCCI 1998), a survey conducted of CSG members (Department of Health and Aged Care 1999b) and the National Cancer Strategy Development Workshop (Department of Health and Aged Care 1999a).

13.5 Criterion Four: Is Marginal Analysis an Integral Component?

Marginal analysis is a fundamental concept of the economic approach to problem solving, and as such, has been a foundation principle of MEEM since its inception. It was in fact the need for incremental analysis[217] that gave rise to the early descriptive work on health care expenditure patterns and health status data outlined in Chapters Ten and Eleven. All case studies illustrate the application of incremental analysis, while the major case study illustrates that marginal analysis of technical design features is also quite feasible. The evaluations of the colorectal and cervical cancer screening programs, for example, illustrate that marginal analysis of intervention scale/scope (in this case screening frequency) and target/user characteristics (i.e. age group) is not only tractable, but produces accurate results in comparison with existing micro studies (refer Appendix Two).

It is important to note, however, that while MEEM analyses increments or decrements to health service programs (i.e. options for change), it does not use marginal cost/marginal outcome data in the strict orthodox sense of the last unit produced or consumed. The use of the BOD/COI databases in the MEEM approach requires acceptance of the simplifying assumption that average costs/average benefits by age/sex disease sub-groups can be used as reasonable estimates of marginal costs/marginal benefits. Thus, for example, if an intervention prevents 10% of an illness from occurring for men aged 50 plus, then it is assumed in MEEM that 10% of the associated burden of disease in that age cohort can be prevented. As Richardson comments, however, this assumption is not unreasonable and is a common practice in economic evaluation, viz:

> *"The assumption is not unreasonable and commonly made in single intervention studies." (Richardson 2001).*

Further, the assumption of marginal and average being equal at the age/sex sub-group level is not as central to the validity of the MEEM approach as is the identification of marginal increments/decrements to existing programs for evaluation.

Conclusion: MEEM has demonstrated a capacity for both sound incremental analyses (which generates the net CEA ratios to guide allocative efficiency) as well as marginal analysis across several dimensions (which guides the pursuit of technical efficiency). MEEM satisfies Criterion Four.

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[217] The term "marginal analysis" is used in both a generic sense (to capture the idea of change at the margin as opposed to thinking in terms of totals and averages) and in a specific sense (where allocative efficiency is distinguished from technical efficiency). In the pursuit of allocative efficiency, marginal analysis is usually called "incremental analysis" (where the respective options for change are compared to current practice using the net cost/net benefit ratios); while for technical efficiency it retains the name "marginal analysis" (where design characteristics of individual projects are analysed, such as interval or age group in screening options).

13.6 Criterion Five: Are the Decision Rules Clearly Specified?

13.6.1 Discussion of criterion

As a general principle, the MEEM approach features clear specification of the decision rules, together with the role of decision rules in the ranking process. The decision rule adopted in the early MEEM Mark I case studies followed the standard CEA and CUA conventions (refer Chapter Four) of ranking on the basis of cost per life year (or physical outcome measure) or cost per QALY. In MEEM Mark II the CUA rule of ranking on the basis of cost per QALY remained (using DALYs), but was nested in the PBMA framework, and became only one step (albeit an important step) in the overall ranking process. The full ranking process in MEEM Mark II is designed to give effect to broader notions of benefit that may be part of the decision-maker's objectives. This often includes, for example, notions of distributive equity, which might be incorporated either through i) the application of weights to the DALYs (such as equity weights or Nord's CVA (Nord 1999)); ii) a two step process to ranking (as per the major case study); or iii) a combination of the two approaches. The choice of approach is one for the Working Party, having regard to the decision context. In this decision the economist leading the MEEM/PBMA exercise should assist the Working Party members.

The MEEM approach also recognises that rigour in the application of PBMA has been a source of concern for some economists (eg (Posnett and Street 1996; Peacock, Richardson et al. 1997b; Peacock and Edwards 1997c)) and that decision theory can be used to improve the rigour and clarity of the options appraisal process by which multiple dimensions of benefit are identified, weighted and aggregated. Thus, for example, rather than the second stage filters in the major case study being treated as dichotomous variables, an options appraisal approach could have been used to integrate all elements of decision-maker objectives into a single benefit score. While decision theory was not used in the context of the major case study – largely due to time constraints – this option is certainly consistent with the MEEM approach and would increase the decision rule component of the ranking procedure.

Finally, it is important to note that while the MEEM approach places importance on clarifying the decision rule, it does not place pure reliance on decision rules. This reflects a number of considerations. First, not all arguments in the social welfare function will necessarily lend themselves to inclusion via a technical decision rule. It would be difficult, for example, to see how the value placed on procedural justice by the community, could be effectively dealt with in this way. Similarly, other factors, such as "acceptability" are inherently "judgement-based" rather than "fact-based". Second, for some stakeholders and some decision contexts, a heavy reliance on technical analysis would be unacceptable, particularly for dimensions of value having a heavy ethical orientation. Third, due regard has been paid to the evidence from empirical experience (Chapter Six) that the mechanical adoption of technical rules simply doesn't work. At best, such an approach is likely to lack support across the range of stakeholders necessary to impact on

decision-making; at worst, it could lead to the rejection of the economic approach to priority setting as introspective and unhelpful to real world problem solving.

Conclusion: Both the decision rules, as well as the way in which they are utilised in the overall ranking process are clearly specified in the MEEM approach. MEEM satisfies Criterion Five.

13.6.2 Comparison of the MEEM/PBMA Ranking with the 1997 NCCI Results

The NCCI developed a set of consensus-based priorities for cancer control as outlined in Section 12.2[218]. Table 13.3 presents the ranking of the interventions assessed in the MEEM/PBMA trial set alongside the ranking of these interventions in the NCCI consensus-based approach. The NCCI columns report the place of each intervention in terms of the questionnaire results for the 147 proposed actions, the top 21 short-listed proposals, together with an indication of whether or not they made the list of 13 interventions recommended for priority implementation. The key findings arising from this comparison, set out below, clearly illustrate the impact of no clear decision rule in the NCCI study.

Table 13.3: Comparison of PBMA Ranking with the 1997 NCCI Results

Cancer Intervention	PBMA Ranking	NCCI: Included in the 13 priority actions	NCCI: Ranking in the short-listed 21	NCCI: Ranking in the 147 (and score out of 5)
INCREMENTS:				
Tobacco Control	1st	Yes	1 / 21	2 / 147 (3.25)
Skin Cancer Prevention	2nd	No	2 / 21	5 / 147 (3.13)
Encourage Fruit & Veg. Consumption (Note: cost per DALY result indicative only)	3rd	No	Not in top 21	79 / 147 (2.51)
Psychosocial Care	4th & 5th	Yes	14 / 21	75 / 147 (2.53)
Colorectal Cancer Screening	6th	Yes	7 / 21	12 / 147 (3.02)
DECREMENTS:				
Rationalise Cervical Cancer Screening	Saving of $50.6 m & small DALY increase	No. (Not raised in the NCCI exercise)	No. (Not raised in the NCCI exercise)	No. (Not raised in the NCCI exercise)
Rationalise Prostate-Specific Antigen Testing	Results not yet available	Yes	8 / 21	15 / 147 (2.99)
Rationalise and Improve Skin Cancer Diagnosis Skills	Results not yet available	Yes	9 / 21	8 / 147 (3.08)

[218] The process adopted by the NCCI involved:

- the generation of a list of 36 topic areas in cancer control;
- the development of proposals for up to 10 actions by expert working parties assigned to each of the 36 areas;
- a winnowing process by which 19 key stakeholders, including the NCCI Management Committee and Priority Steering Committee, reduced the number of proposed actions from 276 to 147;
- sending a questionnaire on the 147 proposed actions to every organisation with interests bearing on cancer control in Australia (667 questionnaires to stakeholders);
- conducting workshops in each State and Territory, attended by 242 expert participants, to discuss 30 proposed actions given priority in the questionnaire responses; and
- selection by the NCCI Management Committee of 13 proposed actions for priority implementation from a final set of 21 short-listed proposals.

The exact match between the top two interventions in the PBMA trial (i.e. tobacco control and primary skin cancer prevention) and the NCCI top two interventions suggest that the merit of some interventions clearly standout under a range of priority setting approaches. The PBMA approach, however, provides a clearer rationale for the ranking (i.e. reflects their cost per DALY result). The omission of skin cancer primary prevention from the final 13 for priority implementation seems questionable with the benefit of hindsight. The decision may have reflected the time frame (i.e. interventions must have an impact within 5 years); the view that activities were already taking place at the State/Territory level - albeit poorly funded – and/or the absence of information at that time clearly articulating the strength of its economic credentials.

The omission from the whole NCCI process of options to rationalise the national cervical cancer screening program, is similarly questionable, particularly since the economic arguments and overseas precedents for these changes had been known for some time (i.e. since the national evaluation in 1990). The strong focus within the PBMA/MEEM approach of considering both increments and decrements is no doubt an important difference here. The potential merit of encouraging the consumption of fruit and vegetables is very different between the two priority setting exercises. The ranking of third in the MEEM/PBMA study is much stronger than its 79th out of 147 in the NCCI survey. Undoubtedly the NCCI result reflects the lack of rigorous data on this intervention, which remains a problem today. While the economic results from the MEEM/PBMA trial must be regarded as indicative only – given the data assumptions that had to be made – the results are nonetheless impressive. Any intervention that holds promise of a net resource saving while delivering substantial health gains must be taken very seriously.

The psychosocial care strategy performed creditably in both rankings, but the rationale is clearer in the MEEM/PBMA trial (where it reflects the cost per DALY result). For the NCCI ranking, the strategy moved from 75th out of the 147 to 14th in the top 21 and then into the final 13 without any clear rationale being apparent. In some ways this is not surprising, because the provision of psychosocial care remains a somewhat controversial area, particularly for those not familiar with the available research. This was also demonstrated, for example, in the survey of CSG members (see Table 13.2) with a wide range in the scores given for this option. The colorectal cancer screening proposal performs more strongly in the earlier NCCI survey than the MEEM/PBMA trial, which is interesting given its epidemiological and economic credentials have strengthened in the last few years. While this proposal comes in last of the increments considered in the case study, its cost utility result (i.e. $12,000 approx. per DALY) is stronger than both the current cervical and breast cancer screening programs.

13.7 Criterion Six: Role of Judgement Clearly Specified

Recognition of the role and importance of judgement reflects the empirical experience, together with the need to clarify ethical values. The international literature on priority setting highlights the view that explicit rationing at all levels involves both the use of techniques and the application of

judgement if intuitively sensible results are to be achieved (Ham and Coulter 2000). A clear set of principles, logical decision rules and a thorough process, can greatly aid the application and legitimacy of rationing decisions in the eyes of stakeholders, but they cannot take away the need for judgement.

There is clear recognition of the need for judgement in the MEEM approach, together with acceptance that such judgement needs to be made explicit if priority setting is not to default back to implicit practices. As with a number of the criteria addressed above, the acceptance of the PBMA framework as the appropriate vehicle in which to bed the technical analysis is a reflection of this recognition. The major case study in Chapter Twelve provides an important example of how the need for judgement can be integrated with technical analysis in an explicit and practical way. In this example, factors requiring judgement were grouped together in the second stage filter and applied as dichotomous variables. Other approaches, such as the hand adjustments adopted by the Oregon commissioners are possible, but it is important that the rationale and process for such adjustments are made explicit. There is much to be said for the old maxim, "Light is the best antiseptic". It is worth noting that the comparison of the MEEM results with the survey of CSG stakeholders represents a systematic first step towards comparison of MEEM with a purely subjective approach to priority setting.

A weakness in the case study was the lack of in-depth discussion and teasing-out of the ethical issues presented in Chapter Five. To a large extent this reflected the tight time constraint, the established aims and objectives of the cancer control strategy and a common mindset amongst participants (mostly epidemiologists, clinicians and economists) on how to deal with equity. While a fuller exploration of ethical issues is certainly possible within the MEEM approach, one suspects that practical constraints will always rear their head and that Richardson's "empirical ethics" will remain an important task to accomplish.

Conclusion: The need for judgement, as well as an explicit process for integrating technical information and issues of judgement, is clearly recognised in the MEEM approach. MEEM satisfies Criterion Six

13.8 Criterion Seven: Data Needs Made Tractable

Criterion Seven asks whether the model has a mechanism for making the data needs of the evaluation tractable. As highlighted in several chapters of the thesis, this has been a major thrust of the MEEM project since its inception. The empirical evidence in Chapter Six also highlighted that data limitations have played a major role in limiting the role and credibility of economic evaluation.

The major innovation in data management under the MEEM approach has been the development and/or use of ongoing descriptive databases on health expenditure and health status that

facilitate incremental analysis with current practice (refer Chapters Ten and Eleven). The DALY database, for example, both assists with estimating the health gain (when combined with the efficacy data) and can aid judgements about "size of the problem" (when size is an agreed dimension of benefit). Similarly, the health expenditure database both assists with estimating any cost offsets, together with judgements of problem size based on impact on health sector resource utilisation. This makes macro evaluation a viable proposition and limits the data needs of applying MEEM to levels achievable with a small research team. More specifically, the context specific data needs are:

i) efficacy/effectiveness data on the options for change (the existence of which is a pre-requisite for option selection);
ii) resource utilisation data associated with the options for change (usually based on the activity pathways[219]), together with routine unit cost assumptions; and
iii) data needs specific to broader notions of benefit (such as distributive equity; feasibility; acceptability; quality of the evidence base) with which the Working Party is expected to assist.

The issue of equity weights warrants separate comment. Tractable ways of managing these data needs are still in the developmental stage at present. As discussed in Chapter Eleven, progress has been made in developing the equity weights (based on vertical equity), but more work is required to integrate them with the DALY database. It is anticipated that equity weights will, in due course, become part of the ongoing databases, which decision-makers can choose to apply or opt for an alternative approach.

Apart from the ongoing databases, the data needs of MEEM are made tractable by a number of other features of the approach. These include:

i) first, the focus on the development of an evaluation protocol that pays careful regard to the priority setting context (termed the "macro evaluation protocol" to distinguish it from the more detailed expectations of micro evaluation);
ii) second, the focus on option selection so that a comprehensive but manageable number of interventions is assessed at any one time;
iii) third, the suitability of most data sets to computer storage and manipulation; and
iv) fourth, the potential for the whole process to become easier as further studies are undertaken and a MEEM "case law" is developed (as per Daniel's ideas on procedural justice).

Because the data needs of MEEM are tractable, application of the MEEM approach is possible with a small research team to gather/develop the context specific databases. The major case

study, for example, was implemented with a small research team equivalent to 2-3 full-time research staff. The tractability of the MEEM approach also suggests a potential for MEEM to be institutionalised as a routine part of the priority setting/planning process, with connections possible to other pre-existing data sets (such as data holdings on intervention efficacy[220]; manuals of resource unit costs[221]; and disease incidence/prevalence/risk factor data sets).

Conclusion: The case study has demonstrated that MEEM provides an approach to priority setting in which the data needs are tractable. MEEM thus satisfies Criterion Seven.

13.9 Criterion Eight: Due Process

Criterion eight asks whether the model of priority setting places the technical analysis within a process for decision-making that contributes to the legitimacy of the decisions taken and their acceptability to stakeholders. As with a number of the criteria, the main vehicle for meeting this criterion has been the adoption of the PBMA framework to complement the technical analysis. The involvement of stakeholders within the Working Party constituted to carry out the PBMA task potentially meets important aspects of this criterion. Key issues that arise, however, include:

i) the extent to which all stakeholder interests are adequately represented;
ii) the extent to which the decision-making processes adopted within the Working Party are regarded as "fair and reasonable" (i.e. explicit, consistent, principled, democratic, fair, impartial and based on relevant and credible information); and
iii) the extent to which individual participants see themselves as having had an effective voice.

While there is certainly a conscious attempt to achieve these attributes, as demonstrated by the major case study, clearly there is potential for the performance of the MEEM/PBMA model to vary from application to application. There is thus an important role for the economist facilitator to take any new group through these principles and to explain their relevance and importance[222]. Further, while participants in the case study were supportive of the MEEM/PBMA approach and saw it as an important improvement in the way in which decisions were taken, no member (including the present author) believed we have the process just right. Further work will be required to fine-tune the process to achieve "accountability for reasonableness", aided by empirical feedback by participants and those affected by the decisions.

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[219] Note that a principle of option selection requires that options can be specified in concrete terms.
[220] Such as the Commonwealth's PHEBAM project (Public Health Evidence-Based Assessment Model).
[221] Such as that which exists to aid economic evaluation in the pharmaceutical area.
[222] One aspect of this complex issue is the way in which group decisions/scores are taken, particularly whether by seeking simple means or by group consensus after informed discussion. While an issue of judgement, my clear preference after trialing both approaches in several PBMA studies is for the group consensus approach. Participants of the studies support this view.

Conclusion: The MEEM approach has the potential to meet the due process criterion, but there is still room for improvement (particularly in relation to clarity about ethical values) and careful ongoing monitoring of performance on this criterion is essential.

13.10 Criterion Nine: Rigour in Measurement of Costs and Benefits

Both the theoretical design and current applications of MEEM demonstrate a rigorous approach to the measurement of costs and benefits, within the context of priority setting. Emphasis is placed on the specification of both a clear protocol for the conduct of the PBMA framework as well as an economic evaluation protocol for the conduct of the technical analysis. The macro evaluation protocol ensures standardised evaluation methods are applied across all options assessed; that sensitivity analysis of key parameters is undertaken using the @Risk software; that a standardised approach is taken to data collection and analysis; and that careful regard is paid to the quality of evidence. The evidence from the case study (refer Appendix Two) confirms that the MEEM CEA results compare very favorably with the results of conventional micro economic studies.

It is important to note, however, that while current methods[223] for integrating the equity dimension are applied with due regard for rigour, the measurement of equity is still at a developmental stage.

Conclusion: MEEM, both in design and application, demonstrates rigour in the measurement of costs and benefits. MEEM meets Criterion Nine.

13.11 Criterion Ten: Reporting/Implementation

Criterion Ten asks whether priority setting models report results in a way that meet the concerns of decision-makers. The steps that underlie the MEEM/PBMA approach (particularly the focus on aims and objectives and a clear concept of benefit), together with the focus on the decision-making approach ensure that this criterion is met. Further, the important role of the Working Party in MEEM/PBMA helps to ensure that, if appropriately constituted and chaired, all relevant matters of interest to decision-makers are included and analysed. The major case study confirmed the potential in MEEM for reporting a range of issues of concern to decision-makers. This included guidance on what weight can be can be placed on the results in terms of the strength of evidence and rigour of the evaluation methods, as well as broader issues such as distributive equity, feasibility of implementation, acceptability to stakeholders, importance of the problem addressed and financial implications.

Conclusion: The analysis and reporting of results under the MEEM approach ensures that issues of concern to decision-makers are addressed. MEEM satisfies Criterion Ten.

13.12 Conclusion

This final chapter of the thesis has sought to evaluate the performance of the MEEM/PBMA approach to priority setting, drawing particularly on the major case study presented in Chapter Twelve. The case study was not a theoretical exercise, it was a real evaluation undertaken to assist decision-makers allocate real resources. It therefore provided a sound basis for assessing whether the MEEM/PBMA constitutes a rigorous and sensible approach to priority setting. The options assessed in the trial covered health promotion, illness prevention, diagnosis and cure/care components of the disease pathway. Outcomes included both mortality and morbidity dimensions of health gain. The major case study tested the capacity of MEEM to:

- deal with quite divergent options in the disease pathway from prevention through to palliation;
- measure and weight benefits involving multiple dimensions and different levels of evidence;
- integrate both "technical" and "consensus" approaches to priority setting;
- break down priority setting into manageable tasks; and
- be acceptable to a wide range of stakeholders.

The performance of MEEM may be assessed either in terms of explicit evaluative criteria or by the less formal assessment of the reception and reaction of those who sought the cancer control pilot study, as well as the broader research community.

With respect to the first approach, this chapter has employed ten criteria by which to judge the features of an ideal approach to priority setting. The criteria are based on four considerations – economic theory; ethics; empirical evidence; and user considerations – each carefully developed and justified in Parts A and B of the thesis. The checklist presented in Chapter Seven brings together a broader range of criteria than in any other evaluative study published to date in the health economics literature. It represents a comprehensive framework for priority setting that is both realistic and theoretically sound. It is clear from the assessment presented above, that while improvements are certainly possible, MEEM performs well with regard to these ten criteria.

Importantly, MEEM satisfies those criteria that have been a stumbling block for other economic models (particularly tractable data needs, stakeholder acceptability and due process). It has done this without compromising the elements that sustain its theoretical credentials (i.e. marginal analysis; use of opportunity cost and a clear logical connection between objectives/perspective and concept of benefit). While other economic models have been restricted or compromised by their large data needs and/or over-reliance on the literature, MEEM has an in-built mechanism for

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[223] Whether by the second-stage filter approach or using thermometer scales and decision theory.

making its data needs tractable through the standing databases. While other purely technical models have struggled at times in achieving acceptability or legitimacy for the actions recommended, MEEM has placed the technical analysis within the PBMA framework to actively involve stakeholders in the decision-making process. While other economic approaches have been criticised for a mechanical application of decision rules, MEEM has recognised that if intuitively sensible results are to be achieved, priority setting must involve both the use of economic techniques and the explicit application of judgement, particularly where economics fails to provide satisfactory methods or answers. A clear set of principles, logical decision rules and a thorough process, can greatly aid the rigour and legitimacy of priority setting activities, but they cannot take away the need for judgement in their application.

Based on the formal assessment MEEM represents a significant addition to the economic toolkit. The strong performance of MEEM across the broad range of criteria reflects not only its focus on improving the technical analysis in the specific decision context of priority setting (through the macro evaluation protocol and the standing databases); but also its evolution from a purely technical approach to one that places the technical analysis in a broader framework provided by PBMA. This evolution recognises the lessons from empirical experience, as well as the importance of ethics and social justice in normative economics. MEEM goes beyond the limitations of conventional economics to take into account administrative, political, procedural, as well as equity considerations. That is, it is in many ways a return to the old concept of "political economy", or achieving the achievable within an economic framework. The essential contribution of MEEM is thus about empirical tractability; about achieving efficiency in an applied microeconomics research task; and thereby increasing the relevance of economic evaluation for decision-makers.

With respect to the informal assessment, the overall merit of the MEEM/PBMA approach was discussed on several occasions in the various meetings of the Working Party. The clear view that emerged from these discussions was that the approach trialed represented:

> "[A] *quantum leap forward in the quality of information available for decision-making*" *(Professor Mark Elwood, Working Party Member).*

Both the information base (i.e. the briefing papers) together with the process by which the deliberative judgements were achieved, were viewed in a very positive light. More specifically, the use of an evidence-based approach facilitated by a suitably qualified research team assembling information on efficacy/effectiveness and efficiency was strongly supported. The type and quality of information, the method of its collection and presentation, and the clarity of its intended use were viewed as important improvements over the NCCI priority setting process of 1997. The emphasis of the MEEM/PBMA approach on achieving a clear concept of benefit linked to program objectives was also strongly supported by the Working Party. While members saw this discussion and its translation into clear measurement techniques as a challenging process, it

was nonetheless accepted as an important and worthwhile task. While there were reservations by some members on aspects of the benefit measurement process[224] adopted, the two-stage process was deemed appropriate and a sensible way to proceed. It was also recognised that these reservations were technical issues that could be varied without taking away from the over-arching MEEM/PBMA approach in which they were employed. Members of the Working Party concluded that the MEEM/PBMA process showed great promise of being an important addition to the strategic planning process for cancer control in Australia.

This positive assessment by the Working Party has recently been endorsed in the feedback on the Draft National Cancer Strategy Report released for public consultation. For example, the summary of comments from the broader health services research community included the following feedback:

> *"Should serve as a model of priority setting in other health areas..."*
> *Professor Stephen Leeder, Dean, Faculty of Medicine, University of Sydney*
>
> *"Decision-making and priority setting techniques are impressive..."*
> *Dr Gabriel Shuster, Director, North West Tasmanian Division of General Practice*
>
> *"Inclusion of the economic analysis very valuable..."*
> *Professor Bryant Stokes, Chief Medical Officer, Health Department of Western Australia*
>
> *"Note and applaud inclusion of substantial economic analysis in consideration of proposals..."*
> *Professor Michael Daube, Chief Executive Officer, Cancer Foundation of Western Australia Inc*

This very positive assessment from both the formal and informal evaluations is not to suggest, however, that future development and refinement of MEEM is not possible or warranted. The discussion presented above and in Part D of the thesis suggests, for example, the following priorities for further research in subsequent MEEM case studies:

- development of a standing database on equity weights (matched to the level of disaggregation of the DALY database by target population sub-groups) to facilitate the inclusion of distributive equity in priority setting;
- investigation of the feasibility of combining the first and second stages of the benefit measurement process into a single index score, using options appraisal or similar techniques based on decision theory;
- investigation of the best way of facilitating the involvement of the consumer representative on the Working Party; and
- investigation of the potential to improve discussions (including clarification of ethical issues) and stakeholder involvement within the Working Party by drawing on

[224] Some members of the Working Party commented, for example, on what they perceived to be an over-emphasis on quantitative methods as opposed to qualitative methods, and questioned the accuracy of the disability weights in the Years Lived with Disability (YLD) component of the DALY.

techniques offered by the behavioural science discipline (such as the nominal group techniques discussed in Chapter Eight).

In economics the gold standard for assessing benefits is "revealed preference". Consequently, it is perhaps appropriate to conclude the assessment of this study by noting, that based upon the major case study, the Victorian and Commonwealth departments of health have jointly commissioned a major MEEM/PBMA-based study of interventions in the mental health field. Further, a proposal to conduct a major priority setting exercise in cardiovascular disease based on the MEEM/PBMA approach was successful in winning a competitive grant in health economics from the Strategic Research Development Committee (SRDC). I am optimistic that these further case studies will confirm the credentials of MEEM as a viable and valid addition to the economic toolkit.

13.12 References

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PART E: APPENDICES

Appendix One: List of Publications based on MEEM

In this Appendix the various papers and publications that were produced over the course of my research on the MEEM concept are brought together. The publications are categorised under four headings, viz:

1. Publications on the concept and purpose of the MEEM approach;
2. Publications that utilise the COI estimates produced as a standing database for MEEM;
3. Publications that reflect the use of MEEM to assist policy development (such as the potential impact of national health goals and targets) or the evaluation of single interventions; and
4. Publications that focus on, or include examples of, the macro evaluation of multiple interventions.

The list is comprehensive but not complete, in that various organisations have utilised aspects of the MEEM work in their own publications (such as the AIHW reporting COI estimates in their biennial flagship publication "Australia's Health" since 1994).

1. Publications & Conference Papers on the concept and purpose of the MEEM Approach

- Carter, R. (1992) "Macro economic evaluation model for health policy", Proceedings of the Annual Conference of the Australian Evaluation Society. Melbourne.
- Carter, R et al. (1992) "Macro economic evaluation model for health policy", Proceedings of the 24th Annual Conference of the Public Health Association of Australia, Canberra.
- Carter, R. (1993). "Macro Economic Evaluation Model", Proceedings of the Second European Conference of Health Economists, Paris.
- Carter, R (1993) "Economic Approach to Health Promotion: A Macro Approach to Assist Health Policy", Economic Planning Advisory Council Seminar "Investing In Health – A Challenging Future", Canberra.
- Carter, R. (1994). "A Macro Approach to Economic Appraisal in the Health Sector." The Australian Economic Review **106** (2nd Quarter, 1994): 105-112.
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- Carter, R (2000) "Priority Setting in Cancer Control: Using DALYs in an Evidence-based Approach to PBMA". Proceedings of the Third International Conference on Priorities in Health Care, Amsterdam.

2. Description of the costs of illness in Australia

In the early phase of MEEMs development, descriptive economic papers were prepared on the COI methodology itself, together with applications to a number of risk factors, diseases and/or ICD-9 chapters. These papers are listed below, showing those papers I first-authored, followed by those papers I co-authored. Members of the MEEM/DCIS research team were encouraged to publish and first-author papers in their own right.

- Carter, R. and R. Penm. (1993). The Cost of Injury in Australia. Canberra, AIHW/NCHPE Research Report.

- Carter, R. and R. Penm. (1993). The Economics of Cancer in Australia. Canberra, AIHW/NCHPE Research Paper.

- Carter, R., M. Pinyopusarerk, et al. (1993). The Economics of Cardiovascular Disease in Australia. Canberra, AIHW/NCHPE.

- Carter, R., M. Pinyopusarerk, et al. (1993). The Economics of Disease in Australia: Interim Report for the NHMRC Working Party on Prevention Programs. Canberra, AIHW/NCHPE.

- Antioch, K., Waters, A-M., Brown, S. and Carter, R. (1992). Disease Costs of HIV/AIDS. 24th Annual Conference of the Public Health Association of Australia, Canberra, Public Health Association of Australia.

- Crowley, S., Antioch, K., Carter, R., Waters, A-M., Conway, L. and Mathers, C. (1992). The Cost of Diet-Related Disease. Canberra, AIHW & National Centre for Health Program Evaluation.

- Conway, L., Pinyopusarerk, M., Carter, R., Penm, R. and Stevenson, C. (1993). The Public Health Significance of Drug and Alcohol Abuse in Australia. International Symposium on the Economics of Drug and Alcohol Abuse, Canberra, Commonwealth Department of Health.

- Segal, L., R. Carter, et al. (1994). "The Cost of Obesity." PharmacoEconomics **5** (Suppl. 1): 45-52.

- Segal, L. and R. Carter (1995). The economics of diabetes care in Australia. International textbook on Diabetes Mellitus. K. Alberti, R. De Fronzo and P. Zimmet. Melbourne.

- Antioch, K., Waters, A-M., Brown, S. and Carter, R. (1995). Disease Costs of Tuberculosis and Syphilis in Australia. Canberra, AIHW.

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- Waters, A.-M., Jelfs, P., Bennett, S. and Carter, R. (1996). Tobacco Use and its Health Impact in Australia. Canberra, AIHW.

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- Mathers, C., Stevenson, C., Carter, R. and Penm, R. (1998). Disease costing methodology used in the Disease Costs and Impact Study 1993-94. Canberra, AIHW.

- Waters, A-M., Mathers, C., Carter, R. and Penm, R. (1998). Health System Costs of Cardiovascular Disease and Diabetes in Australia, 1993-94. Canberra, AIHW.

3. Policy development and evaluation of single interventions

Once the COI database was in place, the first trials of the MEEM approach involved its application to single interventions and policy development issues (such as the potential impact of health goals and targets). The publications resulting from this stage of the research are set out below. It should be noted that some of the research work under this category was presented in the MEEM papers listed under headings 1 or 2 and the publications are not repeated here.

- Carter, R., R. Marks, et al. (1999). "Could a national skin cancer primary prevention campaign in

Australia be worthwhile: an economic perspective." Health Promotion International **14**(1): 73-82.

- Carter, R. and M. Scollo (1999). Economic Evaluation of the National Tobacco Campaign. Melbourne, Anti Cancer Council of Victoria.

4. Macro economic evaluation of multiple interventions using the MEEM approach

The primary purpose for developing the MEEM approach was to facilitate priority setting. Papers that reflect this application are set out below. The papers listed include both some very early applications carried out in order to appraise MEEMs potential, as well as more recent papers related to the major case study reported in Chapter Twelve.

- Carter, R. (1992). Macro Economic Evaluation Model: Case Study on Smoking. Canberra, Australian Institute of Health: 1-33.

- Carter, R (1993) "Economic Approach to Health Promotion: A Macro Approach to Assist Health Policy", Economic Planning Advisory Council Seminar "Investing in Health – A Challenging Future", Canberra. [Early case study on coronary heart disease]

- Carter, R. (1994). "A Macro Approach to Economic Appraisal in the Health Sector." The Australian Economic Review **106** (2nd Quarter, 1994): 105-112. [Early case study on coronary heart disease]

- Carter, R (2000) "Priority Setting in Cancer Control: Using DALYs in an Evidence-based Approach to PBMA". Proceedings of the Third International Conference on Priorities in Health Care, Amsterdam.

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Appendix Two: Support Documents for the Major Case Study Application of MEEM in PART D: Chapter Twelve

a) Members of the Working Group and Research Team

Members of the National Cancer Strategy Working Group

Professor Bruce Armstrong
Director, Cancer Control Information Centre
Cancer Council of NSW

Mr. Andrew Benson
A/Director, Asthma & Cancer Control Section
Commonwealth Department of Health and Aged Care

Professor Robert Burton
Director, Anti-Cancer Council of Victoria

Associate Professor Robert Carter
Centre for Health Program Evaluation (CHPE)
Austin and Repatriation Medical Centre,

Professor Alan Coates
Chief Executive Officer
Australian Cancer Society

Professor Mark Elwood
Director, National Cancer Control Initiative

Associate Professor William Hart
Assistant Director, Public Health Division
Victorian Department of Human Services

Dr Paul Ireland
Deputy Director, National Cancer Control Initiative

Dr Janet Spink
Consumer Participant, Health Issues Centre Inc.

Although not official members of the Working Group, the following regularly attended meetings also:

Ms Christine Stone
Senior Project Officer & Epidemiologist
Victorian Department of Human Services

Ms Elizabeth Hall
Principal Writer, National Cancer Strategy: 2001-2003 (released for public consultation)

Mr. Steve Nerlich
Project Officer, Asthma & Cancer Control Section, Commonwealth Department of Health and Aged Care

Members of Research Team for the MEEM/PBMA Trial

Project Director: Project Director: A/Professor Robert Carter, Centre for Health Program Evaluation (CHPE). Wrote the project submission and negotiated its implementation and funding. Wrote the detailed evaluation protocol for the technical analysis, directed the application of the evaluation methods, and assisted in preparation of all intervention briefing papers. Guided the Working Group (refer membership Appendix Two) through all aspects of the MEEM/PBMA priority setting process, involving a series of meetings over a nine month period. Wrote-up the trial results, including the published reports, drawing on the technical analysis contained in the intervention briefing papers and Working Group decisions.

Senior Project Officer: Ms Christine Stone, Epidemiologist, seconded from Public Health and Development Division, Victorian Department of Human Services, full-time (6 months). Assisted with the project organisation, documentation and reporting formats. Led work on the colorectal cancer screening briefing paper; the skin cancer prevention briefing paper and commenced work on the skin cancer diagnosis paper.

Project Officer: Ms Jane Hocking, Epidemiologist and Public Health Trainee on Placement, Public Health and Development, Victorian DHS, full-time (3 months). Led work on the cervical cancer screening briefing paper and commenced work on the PSA testing paper.

Project Officer: Ms Cathy Mihalopoulos, Research Fellow (Health Economics), CHPE, part-time (2 months). Led work on the two Psychosocial Care briefing papers

Project Officer: Mr. Steven Crowley, Senior Lecturer (Health Economics), CHPE, part-time (1 month). Led work on the fruit and vegetables briefing paper.

Project Adviser on equity weights: Dr Stuart Peacock, Senior Lecturer (Health Economics), CHPE. Prepared briefing paper on development of the equity weights.

Project Adviser on DALYs: Dr Theo Vos, Public Health and Development, Victorian DHS. Assisted project staff in use of DALYs and @Risk simulation software for sensitivity testing. Assisted with preparation of the tobacco control and fruit & vegetables briefing papers

b) Full List of Options Considered in the Major Case Study

The options for change in the major case study were classified into one of the following five groups:

1 ***Options for change*** – defined as interventions where sufficient evidence exists to indicate that incremental strategies would be associated with significant health gain and decremental strategies would be associated with little or no reduction in health gain.

2 ***Possible options for change*** – defined as interventions where some evidence exists to indicate that incremental strategies would be associated with health gain and decremental strategies would be associated with little or no reduction in health gain. These options may need more work to specify to a level of precision where they can be evaluated.

3 ***Monitor developments/liaison*** – defined as interventions that are currently being worked on and/or implemented in another context and where it is too early or inappropriate to perform an economic evaluation at present.

4 ***Research strategies*** - are possible interventions that need more research before they can be evaluated i.e. evidence does not yet exist to sustain their efficacy/effectiveness credentials and a clear intervention cannot be specified.

5 ***Motherhood strategies*** – defined as those ideas for action that were considered to have merit but were too broad and abstract to evaluate (and for which specific research work was not developed).

The numbers assigned the options are identical to those used in the report of the Cancer Strategy Development Workshop [Department of Health and Aged Care, 1999a #497]. The full list of options is set out below, classified into one of the five groups.

Group 1 - Interventions to be evaluated in the PBMA/MEEM trial

2 Reducing Smoking Prevalence

2.2 Take further regulatory steps to decrease pollution of indoor air with tobacco smoke; interventions to decrease uptake of smoking by children and teenagers; interventions to increase smoking cessation among adults; and legislation to eliminate residual advertising of tobacco products.

2.3 Continue to increase the real cost of tobacco smoking by fiscal means.

4 Reduce the risk of skin cancer

4.1 Develop a national SunSmart program through expansion of existing State and Territory programs.

5 Improve skills in diagnosing skin cancer

Develop programs to increase the specificity of general practitioner diagnosis of skin cancer

6 Improve efficiency of cervical screening

6.2 Review the national cervical screening program and consider: increasing the screening interval from two to three years; review starting to screen women at a later age than the current 20 years; determining a number of normal smears after which screening should stop. (Note linkage to 6.1 HPV testing).

7 Improve detection of colorectal cancer

7.1 Develop a population-based screening program for colorectal cancer, based on faecal occult

blood testing.

7.2 Research the acceptability and feasibility of such a screening program.

10 Rationalise prostate specific antigen testing

10 Develop public education programs on the implications of a positive prostate specific antigen (PSA) test to reduce the demand for PSA testing in Australia. There are two interventions (NCCI options 1 & 3) to cost for this strategy.

1) Education program for General Practitioners in the field of prostate cancer and urinary symptoms.
2) A national community education program regarding prostate cancer, following a proposed education program on prostate cancer and urinary symptoms for GPs. This should ensure proper counseling for men who request PSA testing.

12 Develop guidelines in areas of need

12.2 Develop guidelines on follow-up of patients who have received potentially curative treatment and financial incentives for adherence to such guidelines. (Start with breast and CRC). The intervention to cost here is the implications (including patient satisfaction) of not paying for excessive follow up.

14 Improve palliative care

14.5 Implement guidelines for pain management. The intervention to cost here is patient controlled analgesia.

15 Define, implement and monitor psychosocial care

Interventions to cost are provision of psychologist in each cancer unit/centre (one full-time psychologist in each cancer centre or unit); and provision of breast cancer support nurse for women with newly diagnosed disease.

Group 2 – Possible Interventions for PBMA/MEEM trial

These interventions could be evaluated but may need more work to develop up as an intervention. They will only be done if resources are available.

3 Increase consumption of fruit and vegetables

3.3 Develop economic and regulatory measures that will encourage increased intake of fruit and vegetables.

18 Organise education and resources for those with familial cancers

18.1 Develop State/Territory-based resources for cancer-related genetic advice.
18.2 Ensure equitable provision of resources to reduce the impact of high penetrance familial cancers.

20 Meet urgent national needs in data collection

20.2 Improve data collection, particularly stage of presentation, treatment as related to guidelines, outcomes (survival, disease-free survival), on a population basis.

Group 3 – Monitor Developments/Liaison

These options are currently being worked on and therefore it may be too early to perform an economic evaluation on them. Some still need some clarification and are labelled with

1 System-wide changes

1.1 Identify and reduce activities in cancer control that are harmful, useless or of unknown, but probably low, efficacy.

6 Improve efficiency of cervical screening

6.1 Investigate the application of human Papilloma virus (HPV) testing in cervical screening. Future possibility of screening and HPV testing at 25, 35 and 45yrs only.

8 Increase efficiency of breast cancer screening

8.1 Link the Medicare benefit for mammography outside BreastScreen Australia to referral from an accredited breast assessment or breast cancer treatment service.

8.2 Accredit breast assessment services and introduce appropriate financial benefits for care given by accredited services.

10 Rationalise prostate specific antigen testing

10.2 From original NCCI options - Guidelines should be developed to ensure that men with a possible diagnosis of prostate cancer are appropriately investigated and counselled, and receive optimum treatment with QOL issues addressed.

14 Improve palliative care

14.4 Coordinate activities with the national Palliative Care Strategy 1999-2003. A strategy is currently being developed.

21 Improve quality of breast cancer care

21.1 Accredit breast assessment and breast cancer treatment services and introduce a higher Medicare benefit for care given by accredited services. Intervention is development of centres of excellence and financial incentives to support these centres.

Group 4 – Research

These options need more research in the area before they can be evaluated.

1 System-wide changes

1.3. Develop incentives to reward evidence-based practice.

1.4. Improve the capacity of the system to provide equitable access to highly specialized services for people living in regional areas.

2 Reducing Smoking Prevalence

2.1 Investigate ways to reduce inequalities in health status resulting from the socioeconomic gradient in smoking prevalence.

3 Increase consumption of fruit and vegetables

3.1 Identify barriers to change in dietary behaviour.

3.2 Develop evidence-based programs for changing dietary behaviour in ways that will reduce cancer risk.

5 Improve skills in diagnosing skin cancer

5.1 Develop programs to increase the specificity of general practitioner diagnosis of skin cancer. (Decrease missed lesions)

5.2 Support research into the efficacy of population screening for melanoma.

9 Improve outcomes from ovarian cancer

Address variation in practice and emerging information on genetic risk, through the development of guidelines and a practice survey.

11 Investigate treatment uncertainties in prostate cancer

11.1 Improve the management of screen-detected prostate cancer through a prospective audit where participation is linked to payment; monitoring of existing randomised trials comparing treatment with watchful waiting. Consider need for a similar trial in Australia.

11.2 Conduct research to define discriminators of cancer aggressiveness.

13 Evaluate and facilitate multidisciplinary care

13.1 Further develop models of evidence-based multidisciplinary care.

13.2 Conduct trials of shared care models to identify that will decrease patient travel and the cost of specialist services.

14 Improve palliative care

14.1 Investigate ways to improve the quality of care for people dying from cancer.

15 Define, implement and monitor psychosocial care

15.1 Define elements of appropriate psychosocial care for cancer patients and develop strategies to implement these.

16 Promote participation in cancer control within general practice

16.1 Include generic aspects of caring for patients with cancer in undergraduate medical training.

16.2 Promote general practitioner participation in early diagnosis of cancer through changes to reimbursement and accreditation.

17 Continue the national commitment to research

17.1 Conduct research into high impact areas of ignorance identified through guideline development.

17.2 Ensure adequate ongoing infrastructure funding for an autonomous national clinical trials research program.

17.3 Monitor and evaluate the impact of advances in molecular genetics on cancer in Australia.

19 Facilitate the involvement of consumers

19.1 Increase availability of cancer information and evidence-based guidelines for consumers.

19.2 Increase the proportion of the population who can make informed choices about cancer control.

20 Meet urgent national needs in data collection

20.3 Conduct research into measurement of outcomes, including quality of life, and outcomes-based funding. Collect data on new technologies through trials or prospective audit.

Group 5 – Motherhood

These options are too vague to evaluate as specific proposals.

1 System-wide change

1.2. Evaluate new technologies quickly before they become established in clinical practice.

3 Increase consumption of fruit and vegetables

3.4 Where possible, integrate health promotion campaigns across cancer and other lifestyle-related diseases such as cardiovascular disease and diabetes.

12 Develop guidelines in areas of need

12.1 Identify and resource the development of clinical guidelines for different cancers in potentially

high impact areas.

14 Improve palliative care

14.2 Incorporate training in pain and other symptom control in the education of all health professionals involved in cancer control.

14.3 Develop a palliative care information and advisory network.

20 Meet urgent national needs in data collection

20.1 Improve the availability of data for monitoring cancer control at all levels of the system, with feedback.

2c) Summary of the Macro Economic Evaluations undertaken on the Selected Options for Change

Option: Introduce a national colorectal cancer (CRC) screening program (Increment)

The Intervention

Background

The possible introduction of a national colorectal cancer screening program has received active review in the last year or two, in both research and policy arenas. Previously it was included in the NCCI of 1997 (*NCCI, 1998*) and more recently it was included in the National Cancer Strategy Development Workshop (*DHAC, 1999a*). This intervention is among the most topical of those evaluated in this PBMA trial and for this reason it is reported in greater depth in this report.

Description

The PBMA evaluation is of colorectal cancer screening options directed at an average-risk population (asymptomatic and no family history or first degree relative diagnosed later than 55 years) between specified ages using Haemoccult II to detect faecal occult blood. The evaluation protocol assumes that a national program has reached "steady-state" operation and presents the net costs and net benefits of one year of screening[1]. The minimum screening program (i.e. biennial screening for the 55-69 age group) is compared to the current state in which an official screening program does not exist. Possible cost offsets from a reduction in de facto screening are considered in the cost estimates.

Marginal analysis is undertaken of the cost and health gains achieved by committing additional resources to the screening program. Moving from biennial to annual screening, as well as screening additional age groups, are analysed. Results are undertaken for the reference year 1996 and discounting at 3% for both costs and benefits is incorporated.

The Health Benefit

The health benefit is measured in DALYs so that changes in mortality (YLL) and morbidity (YLD) can be expressed in a single measure. The health benefit of a screening program can be calculated by the difference between the DALYs with and without a screening program. The major source of health benefit from the introduction of population screening using Faecal Occult Blood Testing (FOBT) is the earlier detection of colorectal cancer (CRC)[2]. The proportion of patients diagnosed with early stage cancers (i.e. Dukes stage A or B cancer) will increase and later stage cancers (i.e. Dukes stage C or D cancer) will decrease. The original work on *The Burden of Disease and Injury in Australia* (*Mathers et al, 1999*) has treated CRC as a single disease with a single predicted survival rate. In order to model the change in proportion in each disease stage, it was necessary to separate the disease into the four

[1] All options for change in this pilot PBMA are evaluated using the annualised equivalent approach, as more detailed modeling over a 10 or 20 year time horizon was not feasible in the time available.

[2] In this evaluation it is assumed that the incidence of CRC will settle down to the pre-screening rate after the screening program has reached steady-state. Early after the introduction of the program there will be an overall increase in detection of cancers most of which would have become symptomatic at a later stage (the prevalence of lifetime-latent cancers at age 50 years being only 0.2%). The early increase corresponds to the diagnosis of cancers from screening in addition to the symptomatic cancers picked up previously. Current research reports that after approximately 10 years of a screening program a significant change in incidence was not detected (*Mandel, 1993; Hardcastle, 1996; Kronborg, 1996; and Kewenter, 1994*). However after 18 years of annual screening the incidence has been reported to decrease (*Mandel, 1999*). Health gains arising from the prevention of CRC are not included in this analysis.

stage-specific models with different survival rates. The proportion of each cancer stage after the introduction of screening was determined from the published literature.

There are four randomised control trials evaluating the effectiveness of FOBT for population screening for CRC (*Mandel, 1993 and 1999; Hardcastle, 1996; Kronborg, 1996; and Kewenter, 1994*). The details of the DALY modeling are spelt out in the briefing paper (available separately) and illustrated in Appendix Four. The key assumptions are summarised in Table 4 below. Tables 2 and 3 summarise the key estimates of DALYs recovered with different screening strategies.

Table A1 Estimated Change in Burden of Disease (BOD) by Age and Sex with a Biennial Screening Program for CRC Screening

Australia	Incidence	Mortality	YLDs	YLL	DALYs	% Change in mortality	% Change in DALY
MALES							
<35	0	3	0	71	71	14	12
35-39	0	4	0	81	81	14	12
40-44	0	8	0	158	158	14	12
45-49	0	15	0	273	274	14	12
50-54	0	25	1	406	407	14	12
55-59	0	41	0	594	594	14	12
60-64	0	49	0	602	602	14	11
65-69	0	63	-6	636	631	14	11
70-74	0	73	-6	579	573	14	10
75+	0	95	-17	575	558	11	8
Total	0	375	-27	3975	3948	13	11
FEMALES							
<35	0	3	0	86	86	14	12
35-39	0	3	0	74	74	14	12
40-44	0	6	0	135	135	14	12
45-49	0	12	0	238	239	14	12
50-54	0	18	1	335	335	14	12
55-59	0	26	1	427	428	14	12
60-64	0	30	1	432	433	14	12
65-69	0	42	-4	503	499	14	11
70-74	0	52	-5	505	501	14	11
75+	0	107	-31	801	770	11	8
Total	0	301	-35	3535	3500	12	11

Table A2 Estimated Change in BOD by Age and Sex with an Annual Screening Program for CRC

Australia	Incidence	Mortality	YLDs	YLL	DALYs	% Change in mortality	% Change in DALY
MALES							
<35	0	4	0	113	113	22	20
35-39	0	6	0	129	129	22	20
40-44	0	12	0	251	252	22	19
45-49	0	24	1	435	436	22	19
50-54	0	39	1	646	647	22	19
55-59	0	66	0	945	945	22	19
60-64	0	78	0	959	959	22	18
65-69	0	101	-9	1013	1004	22	17
70-74	0	116	-10	922	912	22	17
75+	0	151	-27	915	889	17	12
Total	0	597	-43	6328	6285	20	17
FEMALES							
<35	0	5	0	137	137	22	20
35-39	0	5	0	118	118	22	20
40-44	0	10	0	215	216	22	19
45-49	0	19	1	380	380	22	19
50-54	0	29	1	533	534	22	19
55-59	0	42	1	680	681	22	19
60-64	0	48	2	687	689	22	19
65-69	0	67	-6	801	795	22	18
70-74	0	83	-7	804	797	22	17
75+	0	171	-49	1274	1225	17	13
Total	0	479	-56	5627	5571	20	17

Introduction of a biennial screening program directed to the 55-69 year-old age-group is estimated to result in 251 less deaths per annum (3,194 YLL), a small increase in YLD and a decrease in overall burden of disease by 3,187 DALYs per cohort screened. Annual screening is estimated to yield a 50% improvement in health benefit (ie an additional 1,886 DALYs recovered). Addition of the older age group (69+) recovers significantly more DALYs than addition of the younger age group (45-54) for both annual and biennial screening options.

These results correspond to an 11-14% reduction in mortality and an 8-12% reduction in DALYs for biennial screening depending on which age group or groups are included in the screening program. The results are a little conservative compared to the empirical results of the actual trials (Nottingham: 15%; Funen: 18%; Minnesota: 21%). The sensitivity analysis (refer 5.2.4) addresses the impact of higher mortality reductions with a mean of 13% and a Standard Deviation (SD) of 3.6. For annual screening a 17-22% reduction in mortality and a 12-19% reduction in DALYs is forecast. There is a small increase in YLDs because of the increased survivors and the five years before they are disability free (refer to the disease model explained in Appendix Four).

Table A3 Summary of Epidemiological Sources and Assumptions in Evaluation of CRC

1	Incidence, mortality and age of onset for colorectal cancer (ICD-9 codes 153, 154) in the Australian population is based on data from the National Cancer Statistics Clearing House
2	Mean survival time was calculated from the above data by the authors of "*The Burden of Disease and Injury in Australia*" (*1999*).
3	The disease model with disability weights (D) and duration (L) associated with each phase for survivors and non-survivors were obtained from *The Burden of Disease and Injury in Australia* 1999. The disability weights were from the Dutch disability weight study (*Stouthard, 1997*).
4	The National Burden of Disease (BOD) estimates were re-modeled from 10 to 5 year age groups using five-year incidence and mortality data.
5	The National BOD estimates were re-modeled into stage-specific spreadsheets. The incidence cases were apportioned to the ratio of the four Dukes stages - A, B, C and D - in Australia currently and then as predicted after the introduction of screening. Australia-wide data on the CRC stages are not available. The current ratio of stages A: B: C: D (0.14: 0.33: 0.31: 0.21) were calculated from the South Australia data as were the five year survival rates for each stage (87.4%: 70.2%: 42.0%: 5.3%).
6	South Australian data on stages are very similar to the combined data from the controls in the international RCT studies (ratio of A: B: C: D was 0.14: 0.36: 0.28: 0.22).
7	There is no Australian data on the change in stages after screening. International reports were used from four randomised control trials to predict the reduction in mortality after biennial screening. Stage distribution was modeled to achieve that same reduction in mortality (the ratios of A: B: C: D used were 0.26: 0.28: 0.32: 0.15 – taken from the Kewenter study).
8	The stage change for annual screening was more difficult as only one study reported annual screening. The ratio of mortality reduction with annual screening to the reduction with biennial screening (33: 21) was used to predict the change in stage distribution giving a final ratio of A: B: C: D of 0.30: 0.31: 0.26: 0.13.
9	The National BOD study used the observed mortality rate to calculate the YLL. The predicted mortality from the incidence, stages and survival rates is used to estimate the YLL.
10	The health benefits achieved in the trials are pro-rated to a wider age group.
11	All health benefits are discounted at 3% per annum

The Health Service Costs

The costs considered in this paper are the health services costs from the government funder/provider perspective. The screening pathway has been defined to include the costs of recruitment, screening, diagnosis, treatment, palliation, follow-up/ surveillance and associated infrastructure (eg. registry). Costs of the screened 1996 population are estimated and compared with the estimated costs of the unscreened 1996 population using current rates of de facto screening, diagnosis, treatment and follow-up.

The first step in assessing costs is to identify the type and number of health services that are currently being utilised. A prediction is then required of how the utilisation pattern will change in the presence of a national screening program. Then unit costs are assigned to each of the services involved.

Health Service Utilisation

Screening, recruitment and diagnostic work-up:

There are costs associated with the screening program and tests, the diagnostic colonoscopy with General Practitioner (GP) and medical specialist visits, and the treatment of complications of the colonoscopy. The major complication is perforation of the bowel. The number of screens is dependent on the compliance rate. The uptake of screening reported in the RCTs is in the order of 66% and ranges between 46% and 90% (*Towler, 1998*). In the current situation 'de facto screening' is about 2% (*Victorian Human Services estimate, Mandel 1993*). The resulting diagnostic work-up rate is 2-3% after biennial screening with non-rehydrated smears (*Hardcastle, 1996; Kronborg, 1996*) and 9.8% after annual screening using hydrated smears (*Mandel, 1993*). The Mandel study has a high positivity rate and a high endoscopy rate. The health benefit of this study may be a result of a program in which almost 40% of the participants were endoscopied, a quasi screen by endoscopy. Using the biennial rate of 2-3% provides an estimate of the endoscopy rate after annual screening using non-rehydrated smears as would occur in a screening program in Australia. Each colonoscopy is associated with a complication rate. The complication rate is assumed to be 4 perforations per 12,245 colonoscopies (*Mandel, 1993*).

Current incidence of colonoscopies:

Estimating by how much the current number of colonoscopies could decrease after the introduction of a screening program is complex (i.e. estimating *"excess"* colonoscopies). The Victorian Hospital Inpatient Data for 1996 was used to identify the total number of colonoscopies performed in each age group that were not for follow-up after surgery. Inspection of the International Classification of Diseases – Version 9 (ICD-9) codes for the principle diagnosis of these reveals that at least 70% of these colonoscopies will not be replaced by the FOBT because they are for conditions such as diverticulitis, irritable colon, anal haemorrhage, fistula or fissure. The 15% that are for vague gastrointestinal symptoms are the maximum colonoscopies that may decrease with the introduction of a screening program. The total number of colonoscopies in Australia are assumed to be four times the Victorian number based on population differentials (4.1 times) and health insurance commission data on colonoscopies (3.8 times).

Treatment:

The number of treatments was determined from the stage specific BOD worksheets generated for the health benefit calculations. Likewise, the number of cases requiring palliative care was determined from the estimated mortality.

Follow-up surveillance:

The NHMRC guidelines recommendation is that each adenoma greater than 10mm should be followed-up in 3-5 years by colonoscopy. Adenomas greater than 10mm were found in 25% of individuals with a positive FOBT (*Hardcastle, 1996; Kronborg, 1996*). Less than 7% of the Victorian colonoscopies are for benign adenomas but the size is unknown. The estimates in this study assume that 25% of positive FOBTs will be followed-up and that each follow-up will consist of a colonoscopy, medical consults and associated complications.

Infrastructure:

The infrastructure for recruitment, co-ordination and registry is based on the cervical cancer program costs for Victoria and scaled up for the national level. These costs are not dependent on the number of screens (i.e. they are treated as fixed costs) and so are counted once in the base program costs.

The assumptions made in estimating the utilisation of health services in both the current Australian situation and after the introduction of a national screening program are summarised in Table 5.

Table A4 Health Service Utilization Assumptions for CRC Screening

Health Service	No screening program (current Australian situation)	Biennial screening program	Annual screening program
Screens/population	2%	66% (effectively 33%)[1]	66%
Positivity rate (colonoscopy rate) /screened population	2%	2%	2%
"Excess" colonoscopies (de facto screening	Up to 15% of current colonoscopies	0-15%	0-15%
Treatment	Age and stage specific	Age and stage specific	Age and stage specific
Palliation	Age and stage specific mortality	Age and stage specific mortality	Age and stage specific mortality
Follow-up surveillance		25% of positive FOBT	25% of positive FOBT
Complications perforation/CSCPY	0.000327	0.000327	0.000327

1. Note that with a biennial screening program half the population will be screened each year.

Health Service Unit Costs (i.e. Cost per Service)

The health service unit costs are those associated with infrastructure, screening, diagnostic work-up, treatment, palliation, follow-up surveillance and complications. Table 6 summarises the unit cost data used in the study.

Infrastructure costs:

Infrastructure costs for recruitment, coordination and registry functions for a national program are difficult to determine. The costs for regional programs or pilot studies underestimate the costs for a national program. We assume that a national CRC screening program would be organised in a similar way to the national cervical cancer screening program and have modeled off their infrastructure costs.

Screening costs:

Screening costs include the cost of the kit, kit transport and processing, together with a visit to the GP who could provide advice on the test particularly the implications of a positive test. Gow (*1999*) costed the kits at $4, transport to return kits at $4 and processing as $9. We include another $3 for distribution to GPs and $22 for the GP visit, to give a total cost of $42 per screen.

Diagnostic work-up:

A recent Australian study by Bolin (*1999*) determined costs of colonoscopies by a survey of colonoscopy centres. The medical charges for the initial specialist consult and follow-up consult were based on the 1996 Australian Medical Association (AMA) List of Medical Services and Fees.

Treatment costs and follow-up surveillance:

Treatment costs were from Oncology Units from public and private hospitals as reported in Bolin (*1999*). They are based on surgical management of stage A and stage B cancer, surgical plus adjuvant chemotherapy for stage C cancer and surgical plus palliative chemotherapy for stage D cancer. Palliation was not costed in their study, so the estimates of Salkeld (*1996*) were utilised for this component. The follow-up surveillance costs included colonoscopy, medical consultations and perforations. These costs will be incurred in four years time and discounting was applied.

Table A5 The Health Service Unit Costs of CRC

Screening Pathway	Service	Unit	Cost $A 1996	Source
Infrastructure	Recruitment, coordination and registry	Program	$7.9 M	Commonwealth & Vic screening program
Screens	Kit, transport, processing	Screen	$20	Gow 1999
	GP visit	Screen	$22	NCCI pilot study
Diagnostic work-up	Colonoscopy	pos FOBT	$803	Bolin 1999
	Initial visit + follow-up	pos FOBT	$176	Bolin 1999
Complications	Perforation	4 per 12,246 colonoscopies	$15,200	Bolin 1999
Treatment	Dukes A	stage specific	$13,715	Bolin 1999
	Dukes B	stage specific	$13,715	Bolin 1999
	Dukes C	stage specific	$21,831	Bolin 1999
	Dukes D	stage specific	$18,726	Bolin 1999
Palliation	Advanced	Mortality	$23,835	Salkeld 1996
Follow-up surveillance	Diagnostic work-up see above	25% positive FOBT	$874[1]	Bolin 1999

1. Costs incurred are on average in four years time, therefore discounting has been applied.

The Cost Effectiveness Results

Economic analysis combines a consideration of both the costs and consequences of investing in different alternatives. Tables 7 and 8 below summarise the health benefit and cost estimates that result from application of the various assumptions spelt out above, together with the average cost effectiveness (C/E) ratio (i.e. cost per YLL) and cost utility (C/U) ratios (ie cost per DALY) of different screening design options. The "average" C/E or C/U ratio simply presents total costs of a chosen intervention (net of those costs that would be incurred without the intervention) over the total benefits that can be attributed to the intervention (i.e. net of those benefits that would be experienced without the intervention). While these results are useful to inform a decision on whether or not the chosen intervention design represents value-for-money compared with the status quo (i.e. allocative efficiency), they do not address the question of which particular intervention design is the most efficient (i.e. technical efficiency).

For the intervention design decision, marginal C/E and/or C/U results are required. These ratios report the additional costs relative to the additional benefits of increasing the resources devoted to the chosen intervention. Thus the marginal ratios show the additional costs of moving from biennial screening to annual screening, relative to the additional health gain from this design issue. Various combinations of age group and interval can be examined using marginal analysis techniques. Of course average and marginal ratios are related, in that it is preferable to work out the appropriate design features using marginal analysis and then utilise this particular design in the average results that usually find their way into the summaries and recommendations. Tables 9 and 10 summarise the marginal results using the cost per DALY ratios.

The tables summarise the health gain, cost and average C/E and C/U ratios for various screening design options. In relation to the costs reported, the "gross" annual costs are the costs of the screening program alone. "Net" costs are presented in three formulations. "Cost 1" is the cost of the screening pathway including the projected treatment savings, but not any consequences from reducing de facto screening or from increased follow-up. "Cost 2" includes "Cost 1" plus the additional resource savings available from reducing de facto screening with colonoscopy. "Cost 3" is "Cost 2"

plus the additional expense anticipated from increased follow-up activity. While these varying cost assumptions make a difference to the C/E and C/U ratios, they are not as significant as the assumptions made about the age groups screened. These values represent the annual incremental costs of a national CRC screening program in steady-state operation. Costs in the early implementation years are likely to be higher (as for example with the national breast cancer screening program - see *AHTAC 1997, Carter and Cheok, 1994*) while future costs might be lower (if the CRC incidence starts to decrease and there are associated savings).

Table A6 Benefits, Costs, and C/E & C/U Results for Biennial CRC Screening

	45-49 year olds	50-54 year olds	55-69 year olds	70-74 year olds	75 and over
Health Benefit					
Incidence	0	0	0	0	0
Mortality	27	43	252	125	202
YLL	512	741	3,194	1,084	1,376
YLD	1	1	(7)	(11)	(47)
DALY	512	742	3,187	1,073	1,328
Costs in millions					
Infrastructure			7.9		
Screen	17.9	14.1	25.9	8.4	12.6
Screening -CSCPY	6.9	5.4	11.8	3.2	4.8
Screening Clinical Exam	1.5	1.2	2.6	0.7	1.1
Perforation	0.04	0.03	0.07	0.02	0.03
Total screen costs (Gross costs)	**26.3**	**20.7**	**53.3**	**12.3**	**18.5**
15% reduction in colonoscopy rate	(3.8)	(3.9)	(11.2)	(3.8)	(5.2)
Treatment costs	(0.8)	(1.3)	(7.6)	(3.7)	(6.2)
Follow up costs	2.1	1.6	3.6	1.0	1.5
Net Costs in millions					
'Costs 1': Screening costs plus treatment savings	25.5	19.4	45.7	8.5	12.3
'Costs 2': Screening costs plus treatment savings plus 15% reduction in colonoscopies savings	21.7	15.5	34.5	4.7	7.1
'Costs 3': Screening costs plus treatment savings plus 15% reduction in colonoscopies savings plus follow up surveillance costs	23.8	17.1	38.1	5.7	8.6
Cost utility/effectiveness ratios					
Gross costs/ DALY	51,381	27,845	16,718	11,438	13,911
'Costs 1'/ DALY	49,823	26,115	14,347	7,944	9,259
'Costs 2'/ DALY	42,344	20,890	10,822	4,365	5,361
'Costs 3'/ DALY	46,442	23,111	11,958	5,277	6,470
Gross costs/ YLL	51,476	27,888	16,681	11,323	13,432
'Costs 1'/ YLL	49,914	26,156	14,315	7,865	8,941
'Costs 2'/ YLL	42,422	20,923	10,798	4,321	5,176
'Costs 3'/ YLL	46,528	23,147	11,932	5,224	6,248

Note: All cost and benefits are incremental, present value (1996) and annual.

Table A7 Benefits, Costs and C/E & C/U Results for Annual CRC Screening

	45-49 year olds	50-54 year olds	55-69yr Base program	70-74 year olds	75 and over
Health Benefit					
Incidence	0	0	0	0	0
Mortality	42	68	402	199	321
YLL	814	1,179	5,084	1,726	2,190
YLD	1	2	(11)	(17)	(75)
DALY	816	1,181	5,073	1,708	2,114
Costs in millions					
Infrastructure			7.9		
Screen	35.9	28.1	69.7	16.7	25.2
Screening CSCPY	13.7	10.8	23.6	6.4	9.6
Screening Clinical Exam	3.0	2.4	5.2	1.4	2.1
Perforation	0.08	0.07	0.15	0.04	0.06
Total screen costs (Gross Costs)	**52.7**	**41.3**	**98.7**	**24.6**	**37.0**
15% reduction in colonoscopy rate	(3.8)	(3.9)	(11.2)	(3.8)	(5.2)
Treatment costs	(1.4)	(2.3)	(13.3)	(6.6)	(11.0)
Follow-up costs	4.2	3.3	7.2	2.0	2.9
Net Costs in millions					
'Costs 1': Screening costs plus treatment savings	51.3	39.1	85.3	17.9	25.9
'Costs 2': Screening costs plus treatment savings plus 15% reduction in colonoscopies savings	47.4	35.2	74.1	14.1	20.8
'Costs 3': Screening costs plus treatment savings plus 15% reduction in colonoscopies savings plus follow up surveillance costs	51.6	38.5	81.4	16.1	23.7
Cost utility/effectiveness ratios					
Gross costs/DALY	64,557	34,985	19,450	14,371	17,478
'Costs 1'/DALY	62,832	33,071	16,825	10,504	12,274
'Costs 2'/DALY	58,134	29,788	14,611	8,255	9,825
'Costs 3'/DALY	63,283	32,579	16,039	9,402	11,219
Gross costs/YLL	64,676	35,039	19,407	14,227	16,877
'Costs 1'/YLL	62,947	33,122	16,788	10,399	11,852
'Costs 2'/YLL	58,241	29,835	14,578	8,173	9,487
'Costs 3'/YLL	63,399	32,629	16,003	9,307	10,833

Note: all cost and benefits are incremental, present value (1996) and annual.
The base program includes infrastructure costs of $7.9M.

Table A8 Marginal Cost Utility Results for CRC Screening

Colorectal Cancer Screening Program	DALYs recovered	Financial Cost $M	Cost per DALY recovered $
Core Investment in CRC Screening (biennial screening of 55-69)			
Gross annual costs	3,187	53.3	16,718
Net annual costs	3,187	38.1	11,958
Marginal Cost Utility of Additional Expenditures	**Additional DALYs**	**Additional Cost $M**	**Marginal Cost per DALY**
A: Addition of the 70-74 age group (i.e. biennial screening of 55-74 yr-olds)			
Gross annual costs	1,073	12.3	11,438
Net annual costs	1,073	5.7	5,277
B: Addition of the 75 and over age group (i.e. biennial screening of 55 and over)			
Gross annual costs	2,401	30.8	12,806
Net annual costs	2,401	14.3	5,937
C: Addition of the 50-54 age group (i.e. biennial screening of 50-69)			
Gross annual costs	742	20.7	27,845
Net annual costs	742	17.1	23,111
D: Addition of 45-49 age group (i.e. biennial screening of 45-69)			
Gross annual costs	1,254	47.0	37,480
Net annual costs	1,254	40.9	32,644
E: Addition of Annual Screening (i.e. annual screening of 55-69)			
Gross annual costs	1,886	45.4	24,067
Net annual costs	1,886	43.3	22,933
F: Addition of Annual Screening plus 70-74 age group (i.e. annual screening of 55-74 yr-olds)			
Gross annual costs	3,594	69.9	19,458
Net annual costs	3,594	59.3	16,502
G: Addition of Annual Screening plus 75+ age group (i.e. annual screening of 55+ yr-olds)			
Gross annual costs	5,709	106.9	18,725
Net annual costs	5,709	83.0	14,545
H: Addition of Annual Screening plus 50-54 age group (i.e. annual screening of 50-69 yr-olds)			
Gross annual costs	3,067	86.7	28,271
Net annual costs	3,067	81.7	26,647
I: Addition of Annual Screening plus 45-49 age group (i.e. annual screening of 45+ yr-olds)			
Gross annual costs	3,883	139.4	35,895
Net annual costs	3,883	133.3	34,345

Table A9 Ranking of Additional Expenditures Over Core CRC Screening Program by Financial Cost, DALYs Recovered and Cost Utility Ratios

Ranking by Financial Cost $Millions	Ranking by DALYs Recovered	Ranking by Cost Utility Ratio
1 Investment A; B; C $12.3M to $30.8M (Net: $5.7M to $17.1)	1 Investment G (5,709)	1 Investment A; B ($5,300 to $13,000 per DALY recovered)
2 Investments D; E $45.4M to $47.0M (Net: $40.9 to $43.3M	2 Investment F; H; I (3,067 – 3,882)	2 Investment F; G ($14,500 to $19,500 per DALY recovered)
3 Investment F; G; H $69.9M to $107.0M (Net: $59.3M to 83.1M)	3 Investment E; B (1,886 – 2,401)	3 Investment C; E; H ($23,000 to $28,300 per DALY recovered)
4 Investment I $139.4 M (Net: $133.4 M)	4 Investment A; D (1,073 – 1,254)	4 Investment I; D ($32,600 to $37,500 per DALY recovered)
	5 Investment C (742)	
Note: Base Investment is: Gross costs: $53.3M Net costs: $ 38.1M	Note: Base Program DALYs recovered are: 3,187	Note: Base Program Cost Utility is: $12,000 to $16,700 per DALY recovered

Best Buys:
Adding biennial screening of older age groups; adding annual screening of older age groups; going to annual screening for 55-69 and annual or biennial for 50+

Worst Buys:
Adding the 45-49 age group to biennial; adding the 45-49 age group to annual

Sensitivity analysis:

In the primary analysis point estimates were utilised to measure benefits, costs and ultimately cost effectiveness ratios. While the best evidence available has been utilised, there is always a level of uncertainty associated with estimates. Even data from RCTs, for example, may not be easily transferable to the Australian setting or the proposed intervention.

Using @RISK software it is possible to define a probability distribution around each of the variables and put them through multiple iterations. The probability distributions we used are from the confidence intervals quoted in the literature, from the range of parameter values quoted in the literature and from expert advice on the likely scenarios under Australian conditions. The variables, the values used in the primary economic evaluation and probability distributions used in the simulation model are summarised in the Table 11.

Table A10 Variables and Distribution used in Sensitivity Analysis of CRC Screening

Variable	Primary Analysis	Sensitivity analysis	Rationale for distribution
Current rate of screening	2%	Triangular distribution from 0.015 peaking at 0.03 and ending at 0.07.	2% (*Mandel 1993*), 5% NCCI project proposal
Compliance with screening program	66%	Triangular distribution from 40%, peaking at 66% and ending at 82%	66% meta analysis (*Towler 1998*), 50% NCCI proposal, 40% to 82% Working Party
Positivity rate/colonoscopy rate	2%	Triangular distribution from 0.015 peaking at 0.03 and ending at 0.07.	2% (*Hardcastle 1996, Kronberg 1996*), 5% in NCCI proposal
Excess colonoscopies	15%	Uniform distribution between 0% and 15%	Calculated from inpatient data.
Follow-up surveillance of polyps	25%	Triangular distribution from 7%, peaking at 20% and ending at 30%	RCTs 25%; UK Steering Committee, Expert Opinion
Program / $AUS1996	$7.9 million	Uniform distribution of reported costs +/-10%	Consistent with other cost variations
Costs of colonoscopy	$803	Uniform distribution of reported costs +/-20%	Costs were fairly consistent from Australian reports, but vary widely between public and private sector.
Other costs	as stated in assumptions	Uniform distribution of reported costs +/-10%	Costs were fairly consistent from Australian reports, but vary between public and private sector.
Mortality (biennial) reduction	14%	Normal distribution (mean 13,SD 3.6)	Modification of modeled change in mortality with CI from literature
Mortality (annual) reduction	22%	Normal distribution (mean 21, SD 7.0)	Modification of modeled change in mortality with CI from literature

Sensitivity analysis applied to the biennial and annual screening programs shows the range of possible benefits, costs and C/U and C/E ratios given the information we currently have on CRC screening in Australia. The upper limit (UL) and lower limit (LL) of this range are from the 2.5th and 97.5th percentiles of the distribution (produced by 2000 simulations performed by the software). Table 12 provides the sensitivity results for biennial screening. Similar results for annual screening and the marginal analysis are contained in the briefing paper available separately.

For the base CRC screening program (ie biennial screening; 55-69 age group) the point estimate for the gross cost was $53.3 million and the uncertainty interval is $44 - $87 million. For the net cost the point estimate was $ 38.1 million and the uncertainty interval is $34 - $83 million. The point estimate for the DALYs recovered is 3,187 (uncertainty interval of 1,356 – 4,906), giving a cost utility ratio of $12,000 per DALY using net costs (uncertainty interval of $10,300 - $39,700) and $16,700 per DALY for gross costs (with an uncertainty interval of $12,500 to 44,800).

The major influences of uncertainty on the costs are the FOBT positivity rate, the compliance with screening and to a lesser extent the reduction in colonoscopies. The major influences on the cost utility results are the mortality and the FOBT positivity rate. Other influences are the compliance with screening, the cost of the colonoscopies and the number of colonoscopies that are decreased by the presence of a screening program.

The @RISK software produces a series of sensitivity analyses that identify the input distributions that are significant in determining the output variable value. The mortality rate and the positivity rate of the FOBT were strongly associated with all cost utility ratios (with most R^2 around 0.5 to 0.6). Compliance with screening, the costs of the colonoscopy and the number of excess colonoscopies were moderately associated with the cost utility ratios with an R^2 of approximately 0.2.

Table A11 Sensitivity Analysis: Range of Incremental Benefits, Costs and C/E or C/U for Biennial CRC Screening

	45-49		50-54		55-69		70-74		75+	
	LL-	UL	LL-	UL	LL-	UL	LL-	UL	LL-	UL
Health Benefit										
Mortality	11	41	18	66	108	388	53	193	86	310
YLL	218	787	316	1,140	1,363	4,916	463	1,669	587	2,117
DALY	219	788	317	1,141	1,356	4,906	452	1,658	540	2,070
Costs ($M)										
Gross	21.3	46.1	16.7	36.1	44.3	87.4	9.9	21.5	15.0	32.3
Costs 1	20.5	45.3	15.5	35.0	37.1	79.7	6.2	17.8	8.8	26.2
Costs 2	18.4	43.2	13.4	32.6	30.9	73.6	4.0	16.0	5.9	23.6
Costs 3	19.9	48.1	14.4	36.7	33.6	83.0	4.8	18.4	7.1	27.1
C/U; C/E										
Gross/DALY	39,532	141,274	21,419	76,575	12,498	44,833	8,771	31,666	10,551	39,838
1/ DALY	38,525	138,374	20,170	72,482	11,030	39,408	6,142	24,615	7,138	29,801
2/ DALY	35,101	128,762	18,164	67,010	9,523	34,659	4,201	21,017	4,998	25,462
3/ DALY	37,964	144,479	19,501	74,116	10,323	39,738	4,981	23,908	6,000	29,260
Gross/DALY	39,558	141,715	21,432	77,068	12,482	44,623	8,702	31,173	10,322	36,979
1/ YLL	38,577	138,637	20,193	72,643	11,003	39,285	6,083	24,185	6,939	27,773
2/ YLL	35,178	129,239	18,173	67,114	9,512	34,584	4,180	20,562	4,872	23,847
3/ YLL	38,011	144,894	19,531	75,431	10,307	39,473	4,933	23,405	5,818	27,258

Comparison with other economic studies

There have been a number of economic evaluations of screening using FOBT and they are listed below in Table 13. The cost effectiveness ratios range from a low of $7,965/YLL to $56,205/YLL in $AUS 1996. This is not surprising since the various studies have used a variety of modeling techniques, different input variables, have modeled over different age groups and have used a mixture of annual or biennial screening designs. In particular, our analysis has demonstrated that including younger age groups will increase the average cost/YLL. Different studies have also included different costs and cost offsets in addition to the costs of the basic screening program.

Our result [3] of $17,000/YLL (gross) or $12,000/YLL (net) is at the lower end of the spectrum. This may be because we have modeled the program in steady-state operation, rather than including the start-up and implementation period. Costs are higher early in the implementation of any national screening program. Our range from the sensitivity analysis of $12,500 to $45,000 (gross costs) and $10,500 and $39,500 (net costs) includes most of the reported C/E values, except for the earlier results estimated by England ($7,965 in 1989) and Wagner ($56,205 in 1991), together with the Danish study by Gyrd-Hansen (*1998*) and the UK study by Whynes (*1998*). Wagner has since calculated lower figures of approximately $14,000 and $19,000 (in 1996). This reflects the general judgement by researchers in the field that the mortality benefit attributable to CRC screening is improving.

Discussion of Results

The cost utility results reported above confirm the strengthening economic credentials of a national CRC screening program. Assessment of the intervention in terms of the second stage filters, including equity, is set out below.

[3] Note we are using the YLL component of the DALY only in this comparison, as the studies being assessed did not include a morbidity measure in their evaluations.

Equity

There are differences in the incidence and mortality from CRC across our four equity target groups (ie Aboriginal and Torres Strait Islander peoples (ATSI), low socioeconomic status (SES), rural/ remote areas and NESB). On an international level, the incidence of CRC is high in Australia and is higher in those who are Australian-born than those not born in Australia. Similarly, the mortality rate is higher (refer equity weights at Appendix Five). The trend in mortality is higher in males of lower socioeconomic status. Lower survival rates in lower SES groups are thought to be due to delays in seeking care (CRC Guidelines 1999). There is a small increase in mortality in rural areas. For ATSI peoples the available evidence is limited, but suggests that the incidence of CRC is lower but the mortality is higher. Some of these differences may be due to barriers in accessing health care services and these barriers may impact on the effectiveness of any screening program.

Table A12 Previous Economic Evaluations on CRC Screening

Paper	Cost per LYS ($AUD 1996)	Comments
England 1989	$7,965	
Eddy 1990	$14,860	Model,
Tsuji 1991	$29,068	Compared to 'no screen', some direct costs to patients
Byers 1992	$14,312	
Shimbo 1994	$30,399 (B), $13,936 (I)	Compared immunological (I) with biochemical (B)
Wagner (OTA 1990) 1991	$56,205	Model, comparator 'no screen'
Brown 1993	$44,014	Eddy model, Mandel, comparator controls from trial.
Salkeld 1996	$25,700	Mandel, comparator 'no screen'
Wagner 1996	$18,826 $13,732	Eddy model, comparator 'no screen'
Gyrd-Hansen 1998	$2,653 - $6,633	Model, Kronborg data, comparator 'no screen', costs and incremental costs
Bolin 1999	$36,132 $33,494	OTA model
	Cost per QALY	
Whynes 1998	Males: $4,504 $11,476 Females: $2,768 - $9,994	Model, Hardcastle data, NHS comparator breast cancer, incremental simulations 1) rial 2) K population 3) + lifetime costs, 4) change compliance at screen 4 5) high initial compliance

An important equity issue is that the introduction of a national CRC screening program is likely to increase existing inequalities in CRC mortality. It is known from the current screening programs in breast and cervical cancer that the lower SES groups tend to utilise the screening services less and that there are additional access/utilisation issues for women in rural/remote areas. It is important that steps are taken to identify, decrease and if possible, remove these barriers if a screening program is introduced.

Screening programs as a form of intervention will not score well on the equity filter. The degree to which they increase any existing inequities in the disease burden will depend on what measures are taken in program design and implementation to specifically address the needs of the disadvantaged groups. For interventions with these characteristics, therefore, equity weighting of the outcomes needs to be addressed in consideration of technical efficiency, as well as in the broader concept of allocative efficiency.

Size of the health problem

In 1996 CRC was the second most common cancer affecting both men and women in Australia (over 11,000 new cases) and the second most common cause of death from cancer (almost 5,000). In terms of YLL (over 55,000), YLD (over 11,000) and DALYs (almost 67,000) it was the second highest disease recorded in *The Burden of Disease and Injury in Australia* (*Mathers, Vos and Stevenson, 1999*).

CRC is more common in men than in women. The incidence increases after the age of 40 and rises sharply and progressively from the age of 50 years. Incidence trends are increasing for males and females (1.1%, 0.9% per annum) but mortality rates are decreasing (0.4%, 1.3%). (*NHPA/AIHW, 1997*).

The total health system costs of $204.9 million in 1993/94 make CRC the second highest neoplasm on this criterion. (*AIHW, 1998*).

Consideration of the size of the problem increases the weight that would be given to a successful screening program.

Level of evidence

The efficacy of CRC screening is established by "sufficient well-designed research". There is level 1 evidence of the efficacy of screening using FOBT, Haemoccult II, to reduce the mortality from CRC. Major international trials (four of six were RCTs) reported a reduction in mortality in the order of 12-21% for biennial screening. The one RCT including annual screening reported a 33% reduction in mortality. These papers are summarised in the briefing paper available separately.

Acceptability

Acceptability of the program to participants, the health industry and the government as funder, is dependent on a number of issues being addressed. Most have been dealt with by other screening programs, so they should not be insurmountable. Issues include adequate information and counselling for participants, adequate information and education of the health industry and sufficient information for the government(s) to make decisions on moving from research to practice.

Background:

The American Cancer Society, the American Gastroenterological Association and the American Society for Gastrointestinal Endoscopy have endorsed FOBT as a screening test for CRC. The British Government in 1998 has announced plans for two pilot studies of biennial FOBT.

The UK report suggests critical issues are the resource limitations eg. radiologists and quality limitations in moving from research to practice.

Consumers/participants:

Potential adverse effects for individuals include:

- a positive test also means that a currently well individual will undergo an invasive procedure;
- physical complications of diagnostic tests;
- anxiety and discomfort for those with false positives;
- labeling with suspected or confirmed disease;
- concern about access to and cost of diagnostic procedures;
- insufficient or inadequate counselling;
- misleading sense of security from false negative test; and
- concern for those excluded by screening range.

Health industry:

- Physicians still need to be convinced of the benefits of FOBT screening for CRC;
- Achieving cost offsets regarding de facto screening with colonoscopy;

- Effective follow-up of positive tests;
- Quality assurance; and
- Provision of trained and skilled colonoscopists.

Government as funder:

- Large cost variation by design option;
- Cost sharing between levels of government;
- Funding for pilot testing program;
- Ongoing commitment eg. follow-up / surveillance
- Cost effectiveness dependent on participation rates, positivity rates, follow-up of positive tests and the complication rates in the Australian context.

Feasibility

A major feasibility issue is "system inertia", that is, a national CRC screening program will be slow to build-up and if implemented, would be very hard to wind down. There is not a strong political drive to introduce the program from the viewpoint of "men's or women's health". Other system issues that may or may not contribute to the inertia problem include:

- building the infrastructure to administer the program, be it a central registry, electoral role or GP managed program; testing facilities;
- finding skilled and trained colonoscopists and associated facilities[4];
- quality assurance for colonoscopies and laboratory testing;
- adequate follow-up of positive FOBT; and
- ensuring adequate participation in the screening program.

[4] It is important that there are sufficient colonoscopists with adequate expertise and training. There are probably enough to provide support for a biennial or annual screening program for those over 55 years of age. At a recent bowel cancer conference it was estimated (*by Cowen, A*) that there were 900 colonoscopists accredited by the Conjoint Committee in Australia. If we assume a 66% participation rate and a 2% positivity rate the number of colonoscopies per annum for the different age groups are in the table. This means that for a base program of biennial screening of the 55-69 year old age group there would be 14,717 extra colonoscopies per annum or 16 extra per colonoscopist per annum. With a 5% positivity rate this would increase to 40 extra per colonoscopist per annum. Shifting to an annual program approximately doubles this figure - still less than 100 extra per colonoscopist per annum. Including those over 69 years of age, a 5% positivity, annual screening gives 137 extra per colonoscopist per annum or less than 3 more per week.

Current number of colonoscopies and additional expected assuming a 2% positivity rate.

Age group	Total CSCPY done in 1996	Biennial screening	Annual screening
45-49	24,956	8,538	17,077
50-54	25,468	6,698	13,395
55-59	24,336	5,460	10,921
60-64	23,620	4,689	9,378
65-69	26,296	4,568	9,136
70-74	25,484	3,981	7,961
75+	34,192	5,991	11,982

Option: Improve the efficiency of the national cervical cancer screening program (Decrement)

The Intervention

Background

Following a review of the earlier opportunistic approach that had been operating since the 1950's, Australia introduced a National Cervical Screening Program in 1991. This PBMA will investigate the potential cost savings and changes in health benefits associated with altering policy aspects of the National Cervical Screening Program. At the National Cancer Strategy Development Workshop (*DHAC, 1999a*) two strategies were raised for consideration as possible decrements:

1 an increase in the screening interval from two to three years; and
2 screening of women to commence at a later age than 18 years.

This intervention is the most contentious of the decrements considered in this PBMA trial and for this reason is reported at greater depth than the other options for change. While every attempt has been made to use representative and up-to-date information, the generalisability of data sources should be considered. In particular, reliance on Victorian data for a range of parameters[5] should be noted and the sensitivity analysis examined to assess the impact of parameter variations.

The options for change

More specifically, the interventions assessed in the PBMA trial were defined as:

- Option One: Routine screening carried out every three years for women who have no symptoms or history suggestive of cervical pathology. All women who have ever been sexually active should commence having pap smears between ages of 18 and 20 years, or after first sexual intercourse, whichever is later. No change is proposed to other aspects of current policy.[6]

- Option Two: Routine screening carried out every two years for women who have no symptoms or history suggestive of cervical pathology. All women who have ever been sexually active should commence having pap smears at age 25 years. No change is proposed to other aspects of current policy.

Cost effectiveness was evaluated by comparing the above screening options with the current National Cervical Screening Program. It was assumed that the options had been implemented and the program had achieved "steady-state" operation. Costs and benefits were estimated for women screened in one

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[5] As the report details in section 5.3.3, the parameters based on Victorian data include number of women participating in the program; the number of women who had a further assessment & treatment; the unit costs of smears read in public labs; and recruitment, coordination, registry, and training costs. The survival assumptions rely on NSW and South Australian data.

[6] The policy of the National Cervical Screening Program states (*AHMAC, 1995*):

"Routine screening with pap smears should be carried out every two years for women who have no symptoms or history suggestive of cervical pathology. All women who have ever been sexually active should commence having pap smears between the ages of 18 and 20 years, or after first sexual intercourse, whichever is later. In some cases, it may be appropriate to start screening before 18 years of age. Pap smears may cease at the age of 70 years for women who have had two normal pap smears within the last five years. Women over 70 years who have never had a Pap smear, or who request a Pap smear, should be screened."

This policy applies only to women without symptoms that could be due to cervical pathology. Women with a past history of high-grade cervical lesions, or who are being followed up for a previous abnormal smear should be managed in accordance with the NHMRC guidelines.

full year of operation with 1996 as the reference year. For further details of the economic evaluation protocol refer Appendix Six.

The Health Benefit

The YLDs, YLLs and DALYs associated with cervical cancer in Australia are calculated based on 1996 Australian incidence rates and compared with those estimated should the proposed options for change in the screening program be introduced. The DALY methodology used is adapted from "*The Burden of Disease and Injury in Australia*"(*Mathers, 1999*) and "*The Victorian Burden of Disease Study: Mortality*" (*Vos, 1999*) and is explained in Appendix Four.

DALY BOD associated with the current cervical cancer screening program (i.e. 2 year screening interval commencing at age 18 to 20 years)

The DALYs associated with cervical cancer in Australia based on 1996 incidence rates and the current National Cervical Screening Program are shown in Table 14. All calculations assume the 1996 National Cervical Screening Program participation rates. Note that the DALY methodology uses 1996 incidence rates to model mortality rates. Thus, the mortality rates shown represent the number of deaths we would expect given 1996 incidence[7] and New South Wales 5 year survival rates[8].

Table A13 BOD Associated with Cervical Cancer with Current Screening Program (ie 2 year screening interval commencing at age 18 to 20 years)

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLL	DALYs
0-4	6.3	0	0.0	0	0.0	0	0	0
5-14	12.7	0	0.0	0	0.0	0	0	0
15-24	13.1	15	1.1	3	0.2	14	66	80
25-34	14.3	113	7.9	19	1.3	109	461	570
35-44	14.1	255	18.1	44	3.1	246	932	1177
45-54	11.4	180	15.8	56	4.9	170	1008	1178
55-64	7.6	125	16.4	42	5.5	116	598	714
65-74	6.8	121	17.7	52	7.6	105	504	609
75+	5.6	114	20.3	66	11.7	87	507	594
Total	92.0	923	10.0	281	3.1	847	4076	4923

The DALYs were calculated assuming 5 year survival rates of 82.9% for women aged less than 44 years, 69.1% for those aged 45 to 54 years, 66.2% for those aged 55 to 64 years, 57.3% for those aged 65 to 74 years and 42.2% for women aged 75 years or older[9].

DALY BOD associated with modified cervical cancer screening program (i.e. with 3 year screening interval commencing at 18 to 20 years of age)

The DALYs associated with cervical cancer based on 1996 incidence and a 3-year screening interval is shown in Table 15. The assumptions used in the calculations are:

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[7] AIHW, 1999

[8] Supramanium, 1999

[9] Mean survival rates are taken from NSW data for survival from cervical cancer, 1980-1995 (*Supramanium, 1999*).

- 2% increase in cervical cancer incidence[10]. This 2% increase will be applied to the underlying cervical cancer incidence – that which would exist if there were no cervical screening;
- this 2% increase will apply to all age groups[11];
- the age specific increase in incidence will be calculated as follows[12]:

$$I_o = \frac{I_1}{(1-x)}$$

where $x = 0.933 \times$ participation rate

I_o = underlying incidence

I_1 = 1996 incidence

where Ir = age specific incidence based on 1996 data (*AIHW, 1999*)

- there will be a negligible change in the rate of cervical intraepithelial neoplasia per woman screened[13];
- there will be a negligible change in the staging of cervical cancer at diagnosis[14];and
- 1996 participation rates will still apply.

Table A14 BOD Associated with Cervical Cancer with 3-Year Screening Interval Commencing at Age 18 to 20 years

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLL	DALYs
0-4	6.3	0	0.0	0	0.0	0	0	0
5-14	12.7	0	0.0	0	0.0	0	0	0
15-24	13.1	15	1.2	3	0.2	15	67	82
25-34	14.3	115	8.1	20	1.4	111	470	581
35-44	14.1	260	18.5	44	3.2	251	950	1201
45-54	11.4	184	16.1	57	5.0	173	1029	1202
55-64	7.6	128	16.7	43	5.6	118	610	728
65-74	6.8	123	18.1	53	7.7	107	514	622
75+	5.6	116	20.7	67	12.0	89	517	606
Total	92.0	941	10.2	287	3.1	864	4157	5022

A change in the screening interval from 2 to 3 years will be associated with (Table 16):

- **an additional 18 cases of cervical cancer diagnosed each year;**
- **an additional 6 deaths from cervical cancer each year;**
- **an additional 17 YLDs from cervical cancer each year;**
- **an additional 82 YLL from cervical cancer each year;**
- **an additional 98 DALYs from cervical cancer each year.**

[10] Day NE. The epidemiological basis for evaluating different screening policies. In Hakama M, Miller AB, Day NE ed. Screening for Cancer of the Cervix. IRAC, Lyon 1986.
[11] Personal communication with Professor Bruce Armstrong.
[12] Personal communication with Working Party members and Dr H. Mitchell.
[13] Personal communication with Working Party members and Dr H. Mitchell. Any increase in severity of CIN would incur additional YLDs.
[14] Personal communication with Working Party members and Dr H. Mitchell.

Note that while it has been assumed that participation rates will remain constant at 1996/1997 values, the national participation rates increased by 1.5% between the two periods of 1996/1997 and 1997/1998 (*AIHW, in press*).

Table A15 Change in BOD Associated With Shifting Cervical Cancer Screening Interval from 2 to 3 years (Table 15 - Table 14)

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLL	DALYs
0-4	6.3	0	0	0	0	0	0	0
5-14	12.7	0	0	0	0	0	0	0
15-24	13.1	0	0	0	0	0	1	2
25-34	14.3	2	0	0	0	2	9	11
35-44	14.1	5	0	1	0	5	19	24
45-54	11.4	4	0	1	0	3	20	24
55-64	7.6	2	0	1	0	2	12	14
65-74	6.8	2	0	1	0	2	10	12
75+	5.6	2	0	1	0	2	10	12
Total	92.0	18	0	6	0	17	82	98

DALY BOD associated with cervical cancer screening program with 2 year screening interval and commencing screening at 25 years of age:

There is doubt as to the impact increasing the age at first screen will have on cervical cancer incidence, mortality and stage at diagnosis. Of the 15 cancers diagnosed amongst women aged 24 years or younger during 1996, 6 (40%) were micro-invasive (*AIHW, 1999*). South Australian data showed that 75% of cancers diagnosed between 1977 and 1997 amongst women aged less than 40 years were localised (*South Australian Cancer Registry, 1999*). It is likely that any symptomatic invasive cancer will still be diagnosed amongst women less than 25 years of age (ie women will present to a medical practitioner with symptoms). However, expert opinion has suggested that a delay in the detection of asymptomatic invasive disease in women under 25, may lead to more advanced disease at diagnosis[15]. Given that a significant proportion of cervical cancer in women under 25 years is micro-invasive, it is likely that there will be more stage 1B[16] cancer if screening is postponed to age 25 years.

It is also possible that there will be an additional increase in cancer incidence among women aged 25 to 29 years as a result of cervical intraepithelial neoplasia being unlikely to have been diagnosed or treated during earlier years. This is supported by the results of a recent study (*Holowaty, 1999*) that showed that untreated moderate or severe dysplasia relative to mild dysplasia was associated with an increased risk of progression to carcinoma in situ or worse. New South Wales data has also shown that about 25% of CIN1, if biopsied, will be found to be a high-grade lesion[17].

In summary, commencing screening at the later age of 25 years may be associated with:

- **an increased incidence of cervical cancer amongst women aged 25 to 29 years as a result of: 1) asymptomatic cancer in young women not being diagnosed until screening commences at age 25 and; 2) cervical intraepithelial neoplasia amongst women aged younger than 25 years progressing to invasive cancer by time of first screening.**

- **a shift towards more advanced disease at time of diagnosis.**

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[15] Personal communication with Working Party and Dr H. Mitchell.
[16] Stage 1A and stage 1B can be classified as localised invasive cancer.
[17] Personal communication with Professor Bruce Armstrong.

The calculation of DALYs for cervical cancer utilises 5-year survival rates. Additional survival data is available from New South Wales (*Supramaniam, 1999*) and South Australia (*South Australian Cancer Registry, 1999*) that compares survival rates for localised, regional and distant spread of disease and micro-invasive and invasive disease. It does not, however, compare survival rates for the different FIGO stages of disease. As stage 1B is considered to be localised disease, we are unable to calculate DALYs comparing stage 1A (micro-invasive) and stage 1B disease. In view of the difficulties associated with the estimation of any change in cervical cancer incidence, mortality and stage at diagnosis with the delay of screening to age 25 years, four different scenarios were analysed in the briefing paper. The most conservative (i.e. pessimistic) of those scenarios (scenario 4) is presented below.

Scenario 4

The assumptions in scenario 4 are as follows:

- cases of invasive cervical cancer (NOT micro-invasive cancer) will be diagnosed amongst women less than 25 years of age[18];
- micro-invasive disease previously diagnosed amongst women aged under 25 years will now be diagnosed in women aged 25 years, when screening commences[19];
- in addition to the above assumption, there will be a 2% increase in the incidence of both micro-invasive and invasive cancer in women aged 25 to 29 years[20];
- 1996 participation rates will still apply;
- there will be no change in the incidence of cervical intraepithelial neoplasia[21];
- 50% of micro-invasive carcinoma previously diagnosed in women under 24 will be diagnosed as invasive cancer at ages 25-29 years.

The calculation of DALYs by **stage** (micro-invasive vs invasive) of disease requires re-calibration of the DALY model and recalculation of the baseline DALY values. In order to account for the different stages of disease, a separate model is run for each stage and the results (including incident cases, mortality, YLDs and DALYs) are added together to produce the total burden of disease for cervical cancer. The survival data for these stages are based on South Australian data (*South Australian Cancer Registry, 1999*). The 5-year survivals are 99% and 68% for micro-invasive and invasive cancer respectively. In order to account for the different 5-year survivals by age (refer Table 17), the survival for each age group is calculated as follows:

$$\text{survival} = \left[\frac{\text{survival for age group}}{\text{survival for reference age group (< 40yrs)}} \right] \times \text{stage specific survival}$$

Table A16 Five-Year Survival Rates for Micro-Invasive and Invasive Cervical Cancer by Age

Age Group	Micro-invasive	Invasive
0-39 yrs	99%	68%
40-49 yrs	92.3%	63%
50-59 yrs	80%	55%
60-69 yrs	70%	48%
70+ yrs	48%	33%

[18] It is likely that invasive cancer will be symptomatic and diagnosed among women aged under 25 years.
[19] This assumes that micro-invasive cancer will remain asymptomatic.
[20] Undiagnosed and untreated CIN in women younger than 25 years may progress to invasive cancer in women 25 years or older –personal communication with members of Working Party and Dr H. Mitchell.
[21] Any increase in CIN will incur additional DALYs.

As these survival rates are different from those used above where screening intervals were compared, we can expect to find different baseline DALY measures. However, we are interested in relative DALY measures only (i.e. the difference between the base case and a proposed option under a consistent set of assumptions) and so any difference in baseline totals between the different models is not significant for our purposes.

Table 18 shows the revised baseline DALY values for cervical cancer based on a 2 year program with screening commencing at 18 to 20 years of age.

Table A17 BOD Associated with Cervical Cancer with a 2-Year Screening Interval Commencing at Age 18 to 20 Years (Baseline Data)

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLL	DALYs
0-4	6.3	0	0.0	0	0.0	0	0	0
5-14	12.7	0	0.0	0	0.0	0	0	0
15-19	6.2	1	0.2	0	0.1	1	8	9
20-24	6.9	14	2.0	3	0.4	13	67	81
25-29	7.1	43	6.1	8	1.2	41	211	252
30-34	7.2	70	9.7	17	2.3	67	401	468
35-44	14.1	255	18.1	70	5.0	242	1531	1773
45-54	13.4	180	13.4	68	5.1	171	1276	1447
55-64	7.6	125	16.4	57	7.5	116	870	986
65-74	6.8	121	17.8	69	10.1	102	743	846
75+	5.6	114	20.4	76	13.6	85	472	558
Total	92.0	923	10.0	367	4.0	838	5580	6418

Table 19 shows the impact on DALYs of a program with a 2 year screening interval and screening beginning at age 25 under the assumptions of scenario 4.

Table A18 BOD Associated with Cervical Cancer with a 2 Year Screening Interval Commencing at Age 25 Years (Scenario 4)

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLLs	DALYs
0-4	6.3	0	0.0	0	0.0	0	0	0
5-14	12.7	0	0.0	0	0.0	0	0	0
15-19	6.2	1	0.2	0	0.1	1	8	9
20-24	6.9	8	1.2	3	0.4	8	66	73
25-29	7.1	50	7.1	10	1.4	48	240	288
30-34	7.2	70	9.7	17	2.3	67	401	468
35-44	14.1	255	18.1	70	5.0	242	1531	1773
45-54	13.4	180	13.4	68	5.1	171	1276	1447
55-64	7.6	125	16.4	57	7.5	116	870	986
65-74	6.8	121	17.8	69	10.1	102	743	846
75+	5.6	114	20.4	76	13.6	85	472	558
Total	92.0	924	10.0	368	4.0	839	5609	6447

Commencing screening at age 25 years rather then at age 18 years under scenario 4 (worst case scenario) is associated with (Table 20):

- **an additional 1.4 cases of cervical cancer amongst women aged 25 to 29 years;**
- **1 additional death from cervical cancer amongst women aged 25 to 29 years;**
- **an additional 1 YLD;**
- **an additional 29 YLLs; and**
- **an additional 30 DALYs.**

It is difficult to avoid the conclusion that under a reasonable and quite conservative set of assumptions, the deleterious effects of the proposed change to the national screening program are relatively minor. This is particularly so, when the possible DALYs recoverable in alternative applications of the funds involved are taken into account. The DALYs achievable through a number of the interventions assessed in this PBMA pilot for example (that could be funded with the resources involved in maintaining the current screening policy) are 4,000 DALYs and higher.

Table A19 Changes in Burden of Disease Associated with Increasing the Age at First Cervical Cancer Screen from 18 to 25 Years (Table 19 – Table 18)

Age	Population '00000	Incident Cases	Incidence Per 100,000	Deaths	Mortality Per 100,000	YLDs	YLL	DALYs
0-4	6.3	0	0.0	0	0.0	0	0	0
5-14	12.7	0	0.0	0	0.0	0	0	0
15-19	6.2	0	0.0	0	0.0	0	0	0
20-24	6.9	-6	-0.9	-0	-0.0	-6	-2	-7
25-29	7.1	7	1.0	1	0.2	7	29	36
30-34	7.2	-0	-0.0	-0	-0.0	-0	-0	-0
35-44	14.1	0	0.0	0	0.0	0	0	0
45-54	13.4	0	0.0	0	0.0	0	0	0
55-64	7.6	0	0.0	0	0.0	0	0	0
65-74	6.8	0	0.0	0	0.0	0	0	0
75+	5.6	0	0.0	0	0.0	0	0	0
Total	92.0	1.4	0.0	1.2	0.0	1	29	30

The Health Service Costs

Health service costs are defined to include the recruitment of women, the costs of smear taking and reading, diagnosis, treatment of cervical abnormalities, the cost of registries and the training of medical and scientific staff. These costs are estimated for the program options and compared with an estimate of the costs involved in running the National Cervical Screening Program. All costs are based on a program running in "steady-state" operation for the reference year 1996. Costs are measured by combining estimates for health service utilisation with estimates for the unit cost of the health services involved. Cost estimates are made for Victoria and then pro-rated up for Australia. The key assumptions are set out below.

Health Service Utilisation

The number of women participating in the program

Base program: as per the Victorian Cervical Cytology Registry (VCCR) data for the 3-year period from 1995-1997.

Option 1: assumed to be the same as the base program.

Option 2: assumed to be the same as the base program but excluding women under 25 years of age.

The number of women who had a smear in one year

Base program: as per the VCCR data for 1996[22].
Option 1: calculated as the number of women currently participating in the program[23] divided by the estimated screening interval based on a 3 yearly screening policy (see below).
Option 2: assumed to be the same as the base program, but excluding those aged younger than 25 years.

The number of smears read in a year

Base program: based on VCCR data for 1996
Option 1: estimated as the number of women screened in one year multiplied by the average number of smears per woman in the base program.
Option 2: estimated as the number of women screened in one year multiplied by the average number of smears per woman in the base program.

Population at risk

Base program: based on the Victorian 1996 ABS resident population[24] of women aged 15 years and older with an intact uterus[25]. Although the target population of the program is 18 to 69 year olds, some women have screens at ages outside this target group and as such, this analysis is not restricted to the program target population.
Option 1: as for base program.
Option 2: as for base program.

Participation rates

Base program: based on Victorian participation rates during 1995/1997. These are calculated by dividing the number of women participating in the program during 1995/1997 by the population of women with an intact uterus.
Option 1: as for base program.
Option 2: as for base program.

Interval between smears

Base program: age specific screening intervals are calculated as follows:

$$\text{screening interval} = \left[\frac{\text{total no. participating in 3 yr program, 1995/1997}}{\text{no. women screened in one year}} \times 12 \text{ (converts interval to months)} \right]$$

Option 1: although the base program is based on a 2 year screening program, women screen at different intervals. The estimated age specific screening intervals that may operate in a program with a 3 year screening policy are calculated as follows:

$$\text{screening interval} = \left[\frac{\text{base program interval (months)}}{\text{24 (months)}} \times \text{36 months} \right]$$

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[22] Source: Victorian Cervical Cytology Register (VCCR)
[23] Source: AIHW (1998)
[24] Source: ABS (1997).
[25] Based on hysterectomy fractions, Australia, 1995. Source: AIHW (1998).

Option 2: assumes base program screening intervals

The annual number of screening smears (as distinct from diagnostic smears)

Base program: estimated as 80% of the number of smears in a year based on Straton et al (*1994*).
Option 1: as for base program
Option 2: as for base program

The age specific percentages of women who have further assessment and treatment.

Base program: is based on 1996 data provided by Dr Heather Mitchell of the VCCR on squamous pathology. Table 21 below shows the abnormality detection rate by age and by degree of abnormality. The proportion of women with endocervical abnormalities is taken from the report (*Mitchell, 1997*).

Option 1: With the exception of invasive squamous cell carcinoma, base program age specific percentages for pre-invasive abnormalities are assumed. The age specific percentage of women with invasive cancer will increase as a result of the increase in cervical cancer incidence. This assumption is based on a 2% increase in the incidence of cervical cancer[26].

Option 2: With the exception of invasive squamous cell carcinoma, base program age specific percentages for pre-invasive abnormalities are assumed. The age specific percentage of women with invasive cancer will change as a result of any change in cervical cancer incidence (see different scenarios). The assumptions in the four different scenarios for this option are outlined in the briefing paper on cervical cancer screening available separately.

Table A20 Abnormality Detection Rate For First Smear Report Of Squamous Cells During 1996

Age	Atypia/HPV	Inconclusive	CIN1	CIN2	CIN3	Poss Inv/SCC
15-19	7.6%	0.2%	1.6%	0.5%	0.1%	0.0%
20-24	7.2%	0.0%	2.3%	0.9%	0.2%	0.0%
25-29	4.3%	0.8%	1.5%	0.6%	0.4%	0.0%
30-34	2.7%	0.6%	1.0%	0.5%	0.4%	0.0%
35-39	2.2%	0.5%	0.7%	0.3%	0.2%	0.0%
40-44	2.0%	0.5%	0.6%	0.2%	0.2%	0.0%
45-49	2.0%	0.5%	0.5%	0.1%	0.1%	0.0%
50-54	1.4%	0.6%	0.4%	0.1%	0.1%	0.0%
55-59	1.2%	0.6%	0.3%	0.1%	0.1%	0.0%
60-64	1.2%	0.6%	0.2%	0.0%	0.1%	0.0%
65-69	0.9%	0.6%	0.2%	0.1%	0.0%	0.1%
70 +	1.1%	0.7%	0.2%	0.1%	0.1%	0.3%
Total	2.8%	0.5%	0.9%	0.3%	0.2%	0.0%

Source: Dr H Mitchell, VCCR

[26] Personal communication with Working Party members.

Health Service Unit Costs (i.e. Cost Per Service)

Smear taking

Base program: estimated as the Medicare rebate paid for a GP consultation of $21 multiplied by the annual number of screens. This is based on fee for item number 23 in the Medicare Benefits Schedule effective 1 November 1999, deflated to 1996 prices. Although the majority of pap smears are collected by GPs (*AHMAC 1991*), a number are taken within specialist health clinics such as family planning clinics, women's health centres, sexual health clinics, and hospital outpatient settings. This evaluation assumes that non-GP smear takers have the same costs as GPs. This is the assumption made in the Cervical Screening Evaluation Committee report "*Cervical Cancer Screening in Australia: Options for Change* " (*AHMAC, 1991*).

Option 1: as for base program.
Option 2: as for base program.

The cost to the Government of a smear read in a private laboratory

Base program: is estimated as the sum of the Medicare rebate paid for item number 73053 or 73055 in the Medicare Benefits Schedule effective 1 November 1999 ($15 deflated to 1996 prices), plus the Medicare rebate for the patient episode initiation item number 73901 ($6.50 deflated to 1996 prices). The total cost to Government is the above benefit paid multiplied by the number of screens read in a private laboratory.

Option 1: as for base program.
Option 2: as for base program.

The cost to the Government of a smear read in a public pathology laboratory

Base program: is based on the actual cost per smear read of $15.15[27] (1996 prices). The total cost to Government is the cost per smear read multiplied by the number of screens read in a public pathology service. It is assumed that the unit cost to government for smears read in a public laboratory other than the Victorian Cervical Cytology Service is $15.50 per smear.

Option 1: as for base program.
Option 2: as for base program.

Proportion of smears read in public and private laboratories

Base program: assumed to be 15 : 85 ratio of public vs private[28].

Option 1: assumed to be same as base program.
Option 2: assumed to be same as base program.

The cost to the Government per episode of treatment for abnormalities detected by screening

Base program: taken from Bragget and Carter (*1993*) and inflated to 1996 prices. Costs per episode were based on an 8-year treatment path and are shown in Table 22.

Option 1: as for base program.
Option 2: as for base program.

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[27] Cost of a smear read at the Victorian Cytology Service – (*Source: Department of Human Services*)
[28] For Australia wide - personal communication with Dr H Mitchell.

Table A21 Estimated Average Cost to the Government Per Abnormality Treatment Episode ($1996)

Disease Stage	$A Treatment Cost
Minor reactive/inflammatory changes	100.37
Mild atypia	338.44
Inconclusive	911.18
CIN1	954.97
CIN2	972.15
CIN3	972.15
Possible invasive cancer	1734.32
Invasive squamous cell carcinoma	5797.29

Source: Bragget and Carter inflated to 1996 prices.

Recruitment coordination, registry and training costs

Base program: during 1996, the cost to Government for running the program in Victoria was as follows:

- $875,694 for recruitment;
- $884,498 for the registry and training of 1 pathologist, 5 scientists and 1 liaison physician.

Option 1: as for base program.
Option 2: as for base program.

Cost estimates

The cost estimates that result from applying the assumptions set out above are presented in Table 23, along with a summary of the outcome estimates. The cost and outcome estimates for the current National Cervical Screening Program (i.e. "Base Program") are specified in the left-hand column. The results for the options for change are specified in the right-hand column. Both the options for change offer the possibility of substantial resource savings - that is $50.7 million per annum in the case of triennial screening; and $23.7 million per annum in the case of a delayed age of commencement. The health status loss for each of these options is small in DALY terms, yielding very strong cost effectiveness results.

Table A22 Change in Health Benefit and Marginal Costs Associated with the Cervical Cancer Screening Options, Victoria, 1996

	Base Program Costs and Health Benefit	Marginal Changes to Base Program				
		Option 1 3 yrly start 18	Option 2 2 yrly start 25 Scenario 1	Option 2 2 yrly start 25 Scenario 2	Option 2 2 yrly start 25 Scenario 3	Option 2 2 yrly start 25 Scenario 4
Health Benefit (Australian Data)						
Incidence cases	923	(18)[29]	0	0	(2)	(1)
Deaths	281	(6)	0	(1)	(1)	(1)
YLL	4076	(82)	7	(21)	(27)	(29)
YLD	847	(17)	0	0	(1)	(1)
DALY	4923	(98)	7	(21)	(29)	(30)
Number women screened (Vic Data)	557,514	371,676	496,058	496,058	496,058	496,058
Total Costs (Victorian Data)[30]						
Smear taken and screened	$20,448,013	$13,632,008	$18,193,983	$18,193,983	$18,193,983	$18,193,983
Treatment	$18,671,964	$12,824,794	$14,993,183	$14,993,183	$14,993,560	$14,993,522
Registry	$884,498	$884,498	$884,498	$884,498	$884,498	$884,498
Recruitment	$875,694	$875,694	$875,694	$875,694	$875,694	$875,694
Total Cost	$40,880,168	$28,216,995	$34,947,358	$34,947,358	$34,947,735	$34,947,697
Cost per woman screened	$73.33	$75.92	$70.45	$70.45	$70.45	$70.45
Potential savings (Victorian Data)						
Smear taken and screened		$6,816,005	$2,254,030	$2,254,030	$2,254,030	$2,254,030
Treatment		$5,847,170	$3,678,781	$3,678,781	$3,678,404	$3,678,442
Registry		0	0	0	0	0
Recruitment		0	0	0	0	0
Total potential savings (cost offsets)		$12,663,175	$5,932,811	$5,932,811	$5,932,433	$5,932,472
Total Costs for Australia[31]	$163,520,672	$112,867,980	$139,789,432	$139,789,432	$139,790,940	$139,790,788
Potential cost savings for Australia		$50,652,692	$23,731,240	$23,731,240	$23,729,732	$23,729,884

[29] Note () indicates a negative number i.e.: an increase in DALYs or cost increase.
[30] Assuming a 15:85 split for public vs private.
[31] Assuming that Victorian women represent 25% of the number of women in the National Cervical Screening Program.

Cost Effectiveness Results

The cost effectiveness results obtained from combining the cost and outcome estimates in Table 23 are set out in Table 24. If the results are expressed as a ratio to make them comparable with the increment options, they need to be carefully interpreted. The easiest way to understand the ratios is to express them in the negative, that is, they are the cost per DALY of not adopting the proposed change. Expressed in this way, then the marginal cost effectiveness ratio of not moving to triennial screening is $516,864 per DALY. The marginal cost effectiveness ratio of not implementing a delayed commencement age (of age 25) is $790,996 per DALY. On economic efficiency grounds these results provide a very strong rationale for accepting the proposed changes. If the changes are to be rejected, then there needs to be an equally strong reason (or reasons) based on the equity dimension of benefit or the second stage filters.

One possible objection is the ethical objection of consciously implementing a change that may involve an increase in the DALY burden attributable to cervical cancer. While the DALYs lost are important in their own right - particularly the premature deaths involved - the overarching issue is whether substantially more DALYs (and more deaths) could be recovered (prevented) by using the resources in another application. This alternative application could be in terms of the National Cervical Cancer Screening Program (such as the recruitment of hard to reach women) or in other health programs altogether. Certainly it should be possible to recover substantially more DALYs in cancer control with $51 million per year than 98 DALYs achieved in maintaining biennial screening. Similarly, the $24 million tied up in maintaining the current commencement age could undoubtedly be utilised in ways that recover more DALYs than 30 (worst case scenario).

Table A23 Cost Utility Results for National Cervical Screening Program based on the Proposed Options

	Option 1 3 yrly start 18	Option 2 2 yrly start 25 Scenario 1	Option 2 2 yrly start 25 Scenario 2	Option 2 2 yrly start 25 Scenario 3	Option 2 2 yrly start 25 Scenario 4
Cost saving	$50,652,692	$23731,240	$23,731,240	$23,729,732	$23,729,884
DALY increase	98	0[32]	21	29	30
YLL increase	82	7	21	27	29
Cost effectiveness ratios of not accepting the options	$516,864 per DALY $617,716 per YLL	DALY/YLL saving & cost saving ("Dominance")	$1,130,059 per DALY $1,130,059 per YLL	$818,267 per DALY $878,879 per YLL	$790,996 per DALY $818,272 per YLL

Sensitivity analysis

Sensitivity analysis is undertaken to consider the impact of uncertainty on the outcomes of interest - the benefits, the costs and ultimately the cost effectiveness of our proposed interventions. While the best evidence available has been used in the primary analysis, there is still uncertainty around many of the estimates. In particular, many parameters are based on Victorian sources, while the survival rates used in the DALY calculations are from South Australian sources. The generalisability to these assumptions to the Australian setting needs to be considered. Other variables are from small studies to determine costs of programs and treatment, or from expert opinion on what may occur with a national program.

The multi-way probabilistic sensitivity analysis is performed using @RISK software. Using this software a probability distribution is defined around each of the variables and they are put through 2000 iterations. The distribution used is either from the confidence intervals quoted in the literature,

[32] Corresponds to a small DALY decrease.

from the range of values quoted in the literature and/or from expert advice on the likely scenarios under Australian conditions.

Option One: Changing screening interval from 2 to 3 years

Probability distributions:

The variables, the values used in the primary economic evaluation and probability distributions used in the simulation model are summarised in the Table 25 below. Multiple variables were linked to a single value that had a defined distribution when it was thought that those variables were in some way related. This has the effect that when a high value was selected from that distribution during the simulation all variables were multiplied by that high value. For example, participation rates, number of smears screened and the abnormality detection rate are all linked to a single distribution. In reality we would expect that when the participation rate is higher, the number of smears screened and the number of abnormalities detected would be higher and vice versa. This is what the model simulates.

Costs and benefits:

Compared with the base run estimate of a $50.6 million in savings, altering the above parameters in the costing model resulted in savings of between $40.1 million and $61.2 million. These are still very significant potential savings to the Government.

The base run estimate of the increase in DALYs associated with a 3 year screening interval was 98 (i.e. a minor increase in the disease burden). Altering the cervical cancer incidence as detailed above, resulted in a DALY increase of between 50 and 147 DALYs. The range in the cost effectiveness ratios, therefore, is $156,172 per DALY to $955,407 per DALY. Moving to a triennial screening interval remains a very efficient option strong in the sensitivity analysis.

Table A24 Variables and Distribution used in Sensitivity Analysis of Changing from 2 to 3 Yearly Interval

Variable	Primary Analysis	Sensitivity Analysis	Rationale for distribution
Increase in incidence	2%	Normal distribution (mean of 2% and SD 0.5% i.e. incidence varies between 1%-3%)	Expert advice on the likely scenario under Australian conditions.
I Number participating in the program II Number of smears screened III Abnormality detection rate	age and program specific values	Values in primary analysis multiplied by a normal distribution (mean of 1 and SD 0.05% i.e. parameters vary by + or – 10%).	Expert advice on the likely scenario under Australian conditions.
I Average cost per treatment episode II Smear costs	abnormality specific	Values in primary analysis multiplied by a normal distribution (mean of 1 and SD 0.05% i.e. parameters vary by + or – 10%).	Expert advice on the likely scenario under Australian conditions.

Option Two: Commencing screening at 25 years

Probability distributions:

As set out above, multiple variables were linked to the cancer incidence rate that had a defined distribution. The variables, the values used in the primary economic evaluation and probability distributions used in the simulation model are summarised in Table 26.

Table A25 Variables and Distribution used in Sensitivity Analysis of Changing Age for Commencement of Screening to 25

Variable	Primary analysis	Sensitivity analysis	Rationale for distribution
Increase in incidence in 25 to 29 yr age group	2%	Normal distribution (mean of 2% and SD 0.5%)	Expert advice on the likely scenario under Australian conditions.
I) Number participating in the program II) Number of smears screened III) Abnormality detection rate IV) Expected number of abnormalities with increase to 25 years	age and program specific values	Values in primary analysis multiplied by a normal distribution (mean of 1 and SD 0.05%).	Expert advice on the likely scenario under Australian conditions.
i) Average cost per treatment episode ii) Smear costs	abnormality specific	Values in primary analysis multiplied by a normal distribution (mean of 1 and SD 0.05%).	Expert advice on the likely scenario under Australian conditions.

Costs and benefits:

The estimated costs saving in the primary analysis from changing the starting age for cervical cancer screening to 25 years is $23.7 million per annum. The sensitivity analysis suggests that the annual savings might be as low as $20.6 million or as high as $25.9 million. Similarly, the anticipated change in health benefit in the primary analysis was an increase in deaths by 1 and an increase in DALYs by 30. The sensitivity analysis suggests that the increase in DALYs may vary between 27 and 33, with the anticipated increase in deaths staying at one.

The range in the cost effectiveness ratios, therefore, is $624,242 per DALY to $959,259 per DALY. The efficiency implications of not accepting a delayed commencement age remain strong in the sensitivity analysis.

Comparison of results with micro economic evaluation results

There are an increasing number of economic evaluations of cervical cancer screening in the international literature. The most authoritative evaluation applied to the Australian setting remains the national AHMAC evaluation chaired by Dr Heather Mitchell and conducted in the 1988 to 1990 period (*AHMAC, 1991*). While the methods employed in the economic evaluation of the AHMAC study are not the same as those employed in the PBMA trial, the results are nonetheless quite consistent in their broad direction.

On the issue of interval, the AHMAC study found the marginal cost effectiveness of moving from three yearly screening to two yearly screening to be $100,571 per life year (in 1996 dollars). The current study found a marginal cost utility ratio of $516,864 per DALY, with a range of $156,172 to $955,407

per DALY in the sensitivity analysis. While the different methods[33] employed make it difficult to closely compare the two results, the conclusion to be drawn from the two studies is the same – a three yearly screening interval is strongly preferred to a two yearly screening interval from an economic perspective. This conclusion is reinforced by the international literature.

In relation to age of commencement, the AHMAC study found a marginal cost effectiveness of $886,776 per life year (in 1996 dollars) for including the 18-24 age group in the program. The current study estimated a similar result, with a cost per DALY ratio of $790,996 for their inclusion and a sensitivity range of $624,242 to $959,259 per DALY. As with interval, the conclusion on the economic rationale is clear and is consistent with the international literature.

Discussion of Results

Equity

Both health status measures (eg. cancer incidence and mortality rates) and access / utilisation measures (eg. screening participation rates) can be used to examine equity implications. Table 27 provides available information on incidence/mortality rates for rural/remote and ATSI women. The equity weights at Appendix Five show higher cervical cancer burden in the lower SES groups, in remote areas, in some NESB groups and in indigenous women. While accurate data is not available, participation rates similarly do not appear to be as high among our equity target groups, particularly ATSI women.

As with most screening programs, there are important equity issues to be addressed in the current National Cervical Cancer Screening Program. The proposed changes are unlikely to further any existing inequity in the program. Rather, quite the reverse is true, particularly if the potential savings are used to address existing inequities within the program.

Depending on the proposed use for the savings generated, the equity filter could raise the priority given to these decrement options.

Table A26 Cervical Cancer Incidence and Mortality by Population Group, Australia

Population Group	Incidence per 100,000 (95%CI) (1995-1996 data)	Mortality per 100,000 (95%CI) (1995-1997 data)
Metropolitan	6.5 (6.1, 6.8)	2.9 (2.7, 3.2)
Rural	6.2 (5.6, 6.7)	3.3 (2.9, 3.7)
Remote	8.9 (6.6, 11.3)	4.7 (2.9, 6.6)
Indigenous	n/a	27.6 (13.1, 37.5)
Non-Indigenous		3.0 (1.9, 2.8)

Source: AIHW, in press

Size of the problem

For Australia as a whole, cervical cancer has a medium to low disease burden impact. Cervical cancer, for example, was the ninth most frequently diagnosed new cancer with a lifetime risk of incidence of 1 in 130 for Australian women (*AIHW, 1999; AIHW, in press*). The higher incidence and mortality rates in rural/remote women and in ATSI women, however, are a cause for concern.

The adverse health status impacts of the proposed changes are minor, particularly when assessed in an opportunity cost context (i.e. health gains that could be secured by using the funds involved in more cost-effective applications).

[33] The differences include study perspective; discount rate; period of analysis; definition of benefit (ie life year gained verses DALY) and mortality modeling assumptions.

Level of evidence

The efficacy of cervical cancer screening is established by "*sufficient well-designed research*".[34] Similarly, knowledge of the impact of changing screening interval is based on solid scientific evidence (ie "*sufficient evidence of effectiveness*"). Knowledge of the impact of varying age of commencement is inconclusive (ie "*limited evidence of effectiveness*"). The basis for these judgements is considered below.

A working group of the International Agency for Research on Cancer (IARC) conducted a comprehensive analysis of data from several large screening programs (*Day, 1986*). The group analysed data from screening programs conducted in the 1960s and 1970s in eight countries in North America and Europe to determine the reduction in probability of invasive cancer caused by screening at different frequencies. Table 28 and Table 29 detail the effects of different screening frequencies on the cumulative rate of invasive cervical cancer.

Table A27 Percentage Reduction in the Cumulative Rate of Invasive Cervical Cancer over the Age Range 35-64, with Different Frequencies of Screening

Screening Frequency	%Reduction in Cumulative Rate[1]	No. of Tests
1	93.3	30
2	93.3	15
3	91.4	10
5	83.9	6
10	64.2	3

[1] Assuming a screen occurs at age 35 and that a previous screen has been performed
Source: Day, 1986

Table A28 Effect of Different Screening Policies Starting at Age 20 (Assuming Incidence Rates of the Type Seen in Western Europe)

Incidence assumed at ages 20-64 years			
20-24 5 per 100,000 B. Effect of different screening policies	25-29 15 per 100,000	30-34 25 per 100,000	35-64 45 per 100,000
Screening schedule	Cumulative rate per 100,000	% reduction in rate	No. of tests
No screening	1575		
Screening every 5 yrs, 20-64	257.6	83.6	9
Screening every 5 yrs, 25-64	286.7	81.8	8
Screening every 5 yrs, 35-64	478.8	69.6	6
Screening every yr 20-34, then every 5 yrs, 35-64	232.3	85.5	21
Screening age 25, 26, 30 then every 5 yrs	274.5	82.6	9

[34] Cervical cancer screening was first trialed in British Columbia in 1949. A program evaluation by Anderson et al (1988) found the significant reduction in the morbidity and mortality from invasive squamous cell carcinoma was attributable to the screening program. Evidence about the effectiveness of cervical cancer screening is provided by: population based studies (*Johannesson, 1978; Day, 1984; Hakama, 1985, Dunn, 1981; Miller, 1976; Quinn, 1999*); case control studies (*Clarke, 1979; LaVecchia, 1984; Aristizabal, 1984; MacGregor, 1985; van der Graaf, 1988; Oleses, 1988; Sato, 1997*); analysis of data from large screening programs (Day, 1986); and analysis of the natural history of cervical cancer with mathematical models (*Shun Zhang, 1982; Eddy, 1987*). None of the studies has been a randomised controlled trial. With such widespread use of the Pap smear today, it is not considered ethical to undertake randomised controlled trials (*Marcus, 1998*).

Screening every 3 yrs, 20-64	137.8	91.2	15
Screening every 3 yrs, 26-64	161.0	89.8	13
Screening every 3 yrs, 35-64	352.8	77.6	10
Screening every yr, 20-34 then every 3 yrs, 35-64	131.2	91.7	25
Screening age 25, 26, 29 then every 3 yrs	156.6	90.1	14
Screening every yr, 20-64	105.0	93.3	45

Source: Day, 1986

While some may argue that the data in Tables 28 and 29 are out of date, it is still the most comprehensive analysis of screening data available. The information in Tables 28 and 29 has been combined with current expert opinion in the preceding analysis to estimate the change in health that would result from the proposed changes to cervical screening policy.

Acceptability/feasibility

The current two-yearly screening policy in Australia is more conservative than policies operating in several overseas countries (refer Table 30).

Table A29 Screening Policies and Cervical Cancer Incidence and Mortality Operating Overseas

Country	Interval	Incidence	Mortality	Comments
Australia	2 yearly	9.4 per 100,000 (1996) fallen by 29% since 1983	2.9 per 100,000 (1996) fallen by 34% since 1983	National policy
USA	at least every 3 years	7.4 per 100,000 (1995) fallen by 48% since 1973	3.0 per 100,000 (1995) fallen by 35% since 1975	Recommended, but at the discretion of physician
Canada	3 yearly	9.4 per 100,000 (1994) fallen by 57% since 1969	2.7 per 100,000 (1994) fallen by 54% since 1969	National policy
UK	3-5 yearly	~10 per 100,000 (1995) 35% lower than in 1980s	3.7 per 100,000 (1997) fallen by 39% since 1987	National policy

There was considerable debate regarding the screening interval and the age of screening commencement in the development of the current "*Organised Approach to Cervical Screening*" (*AHMAC, 1991*). While $50.6 million represents significant savings to the Government if the screening interval was to be changed to three years, it is anticipated that there would be strong opposition from some in the medical arena to any loosening of the screening policy. Greater opposition could be anticipated to any proposed change to age of commencement, particularly since the evidence base is weaker.

It is also anticipated that there would be consumer opposition to any additional incident cases or deaths from cervical cancer. However, there is also an important issue for the community of whether significantly more DALYs could be recovered or deaths prevented by using the potential savings in another application. This alternative application could be within the National Cervical Screening Program (such as the recruitment of hard to reach women) or in another health program all together (such as the introduction of a national colorectal cancer screening program).

There has also been considerable debate regarding the existence of Human Papilloma Virus (HPV) negative cervical cancer. A recent study found that the worldwide prevalence of HPV in cervical

cancer is 99.7% (*Walboomers, 1999*). The presence of HPV in virtually all cervical cancers implies the highest worldwide attributable fraction so far reported for a specific cause of any major human cancer. The extreme rarity of HPV-negative cancers reinforces the rationale for HPV testing in addition to, or even instead of cervical cytology in routine cervical screening. It is likely that in the future, HPV testing will become part of the National Cervical Screening Program in Australia and its introduction will have an impact on the amount of and frequency of pap smear screening. The Victorian Cytology Service in collaboration with the NCCI is currently designing a large trial to investigate the efficacy and feasibility of HPV testing on cervical specimens[35]. However, until HPV testing becomes the accepted screening method there should be continued debate with regards cervical screening policy.

Clearly there are important acceptability issues that would need to be carefully assessed before modifying cervical cancer screening policy. This is likely to be the case for most decrements, however, and as such need to be kept in perspective.

Option: Introduce a national skin cancer prevention program (Increment)

The Intervention

Background

An intervention targeted at the prevention of skin cancer was part of the NCCI (*1998*) and discussed at the Cancer Strategy Development Workshop (*DHAC, 1999a*). The strategy for evaluation in this economic analysis is the extension of existing State and Territory skin cancer prevention activities into a national coordinated program based on the Victorian SunSmart program.

While the primary evaluation is from a government viewpoint (as potential funder of the intervention) the cost impact on individuals is considered in the sensitivity analysis. The estimated benefits of a comprehensive national skin cancer program are compared with a "current practice" comparator.

A conventional cost effectiveness study was recently published on this strategy (*Carter et al., 1999*) and some of the data for this evaluation, particularly the cost implications, are based on that study. While the results of Carter study and the current study are broadly similar (ie both show the strategy to be highly cost effective), there are differences in the methods adopted, particularly in the estimation of benefits.

Description

The option evaluated corresponds to the NCCI strategy:

> (4.1) Develop a national SunSmart program through expansion of existing State and Territory programs.

It comprises three elements (*Hill 1993*):

- a comprehensive education strategy including mass media, teaching resources and a sunlight protection policy and practice code;
- structural changes including guidelines for workers' sun protection and downward pressure on the price of sunscreens; and
- a variety of sponsorships.

[35] Personal communication with Professor R Burton.

SunSmart provides a useful model to appraise a national campaign, not only because of its comprehensive nature, but because it was introduced over a base level program (ie the "slip, slop, slap" campaign) that had been running for several years with a more modest budget characteristic of current activities in many parts of Australia.

The Health Benefit

The DALYs associated with melanoma and non-melanotic skin cancer (NMSC) and the change expected with a prevention program in place were derived by adapting the methodology from "*The Burden of Disease and Injury in Australia*" (*Mathers, Vos and Stevenson, 1999*) and "*The Victorian Burden of Disease Study: Mortality*" (*Vos and Begg, 1999*). YLL that are calculated as part of the DALY are reported in addition to the DALY to enable comparisons with other cost effectiveness studies.

The DALY benefit is estimated by analysis linking predicted changes in sunburn (due to the intervention) to corresponding reductions in total lifetime Ultraviolet Radiation Exposure (UVR), and hence to anticipated outcomes in terms of reduced incidence of melanoma and NMSC. The lag period before reduced incidence is experienced was set at 10 years for melanoma, NMSC and solar keratoses (ie the benefits will be experienced in 2006 by our reference population).

The calculation of the health benefit involves a number of steps:

- estimate the 1996 BOD for melanoma and NMSC;
- estimate the BOD for 2006 for melanoma with and without a SunSmart program operating in 1996;
- estimate the health benefit for non-melanocytic skin cancer using the 1996 ratio of deaths, YLL and DALY due to melanoma compared to NMSC.

It is assumed in these calculations that the incidence of melanoma increases at its current rate, but the mortality rate remains the same as in 1996. Further, no disability weight is attached to solar keratosis.

Cost offsets to the Government flowing from the reduction in management costs for skin cancer were estimated and deducted from the cost of the intervention (refer Section 5.4.3).

Comparison of the 1996 BOD for melanoma and NMSC

The BOD for melanoma and NMSC in 1996 (refer Table 31) is taken directly from the *Burden of Disease and Injury in Australia* (*Mathers, Vos and Stevenson, 1999*). While NMSC is the most common cancer diagnosed, affecting a large number of individuals, the burden of disease is less than a quarter that due to melanoma.

Table A30 Summary of BOD for Melanoma and Non-Melanotic Skin (NMSC) Lesions

	Incidence cases	Incidence Rate	YLD	Mortality	YLL	DALY
Melanoma	7,797	57	6,896	978	13,114	20,010
NMSC	282,825	2,064	1,002	398	3,558	4,560
Ratio NMSC/Melanoma	36.27	36.27	0.15	0.41	0.27	0.23

Estimation of the BOD for melanoma and NMSC in 2006 in the absence of a National SunSmart program

The BOD for melanoma in 2006 is estimated by using projected population values instead of the 1996 population values on the worksheets provided by the authors of "*The Burden of Disease and*

Injury in Australia" (*Mathers, Vos and Stevenson, 1999*). The worksheets are modified to include an increase in the incidence of melanoma equal to the current rate of 2.2% p.a. in males and 1.7% p.a. in females (*AACR & AIHW 1999*). The mortality rates are assumed to be unchanged. Because of the short time lines for this study, the NMSC burden is calculated from the melanoma burden by assuming that the deaths, YLL and DALY relationships for melanoma and NMSC are similar to those reported in "*The Burden of Disease and Injury in Australia*" (*Mathers, Vos and Stevenson, 1999*). The results are reported in Table 32.

Table A31 Summary of Estimated BOD for Melanoma and Non-Melanotic Skin (NMSC) Lesions in 2006

	Total population '00,000 in 2006	Incidence cases	Incidence Rate	YLD*	Mortality	YLL*	DALY*
Melanoma	203.7	11,591	57	7,874	2,315	19,062	26,936
NMSC	203.7	420,437	2,064	1,048	926	5,147	6,195

* Benefit discounted back to 1996.

Estimation of the BOD for melanoma and NMSC in 2006 after a National SunSmart program in 1996

Extensive and thorough evaluation of the Victorian SunSmart program demonstrated substantial attitudinal and behavioural shifts, including increased hat wearing and sunscreen use. A reduction in the crude proportion of sunburn in the Victorian population from 11% to 7% was demonstrated, with the adjusted odds ratio being as follows: year 2 / year 1: 0.75 (CI 0.57- 0.99) and year 3 / year 1: 0.59 (CI 0.43 – 0.81) (*Hill et al., 1993*). Given the demonstrated one-third reduction in the incidence of sunburn, it was assumed by Carter and colleagues (*1999*) that a 20% reduction in UVR exposure was plausible and that this equated with a 30% fall in cancer incidence. The assumed fall in cancer incidence is a critical assumption and implies substantial and sustained reductions in sunburn. It is impossible to say what the real relationship will be, but more conservative assumptions of between 15% and 30% falls are tested in the sensitivity analysis (refer 5.4.4).

Part of the health benefit from the extension of the SunSmart campaign to a national level is due to a reduction of incidence of and therefore the mortality from melanoma. Following Carter et al. (*1999*), a 30.2% reduction in the incidence of melanoma is modeled in the spreadsheets to determine the burden of disease after the campaign. This results in a health benefit of 699 fewer deaths corresponding to 5,757 fewer years of life lost and 8,135 fewer DALYs.

The rest of the health benefit from the extension of the SunSmart campaign to a national level is a reduction of incidence of, and therefore the mortality from, NMSC. Maintaining the same ratio of deaths, YLL and DALY due to NMSC to melanoma, of 0.4, 0.27 and 0.23 respectively, the health benefit of reducing NMSC can be estimated from the benefit of reducing melanoma. The deaths will decrease by 280 corresponding to 1,538 years of life lost (YLL) and 1,830 DALY.

Table A32 Summary of Health Benefit due to a Reduction of Melanoma and NMSC Lesions

	YLD	Mortality	YLL	DALY
Melanoma	2,378	699	5,757	8,135
NMSC	292	280	1,538	1,830
TOTAL	2,670	979	7,295	9,965

The Health Service Costs

The costs considered in this analysis are the estimated cost to the Federal Government of funding a comprehensive national health promotion campaign, co-ordinating initiatives in education, structural changes and sponsorships, less any savings in health care costs that could be anticipated from a reduction in management costs for skin cancer.

The costs of the national campaign of $5.04 million are based on the SunSmart average cost of 28 cents per person in the 1998/99 to 1990/91 period, applied to the Australian population of 18 million people (*ACCV 1997*). Current average expenditure across Australia in 1995/96 was 14 cents per person or $2.51 million (*Carter et al., 1999*). The net additional cost is therefore $2.53 million.

Health care offsets

The total recurrent health services expenditure in 1993/94 on melanoma and NMSC has been estimated previously (*Carter et al., 1999*) and was inflated to 1996 values (Table 34). These costs include hospital admissions, hospital bed days, outpatients, medical consultations, prescriptions written, referrals to allied health professionals and nursing home admissions. Solar keratoses were costed separately and are based on HIC data (*Carter, 1999*). The costs for skin cancers developing from exposure in 1996 are not incurred until after the lag phase. For melanomas, NMSC and solar keratosis a lag phase of 10 years was assumed. The future costs were discounted by 3% per annum to present value (PV).

Table A33 Health Care Costs for Skin Cancers

	1993/94 costs (million)	1996 costs (million)	Discounted costs # (million)	Best case savings (million)
Melanoma	$18.7	$20.4	$15.2	$4.6
NMSC	$95.7	$104.4	$77.6	$23.4
Solar keratosis	$55.6	$52.8	$39.3	$11.9
Total cost (1996 PV)			$132.1	$39.9

* Inflated by 1.09 to 1996 values.
\# Discounted by 3% per annum to present value.

The difficulty is to determine by how much these change after the introduction of a primary prevention program. The best-case scenario is that the costs change in the same proportion as the incidence eg. a reduction of approximately 30%. This represents a cost savings of $39.9 million present value (1996).

The Cost Effectiveness Results

Table 35 summarises the health gain, cost and average C/E and C/U ratios for a national primary prevention campaign compared with the 'status quo'. Also reported in Table 35 are the results when the costs impacting on individuals of complying with SunSmart recommendations are included.

From the Government's perspective the program is highly cost effective. With cost offsets included, the intervention is "dominant" i.e. it both saves money and reduces the health burden. With the cost offsets excluded, the option still yields cost effectiveness ratios of $347 per YLL and $254 per DALY.

When the costs impacting on individuals are included in the analysis (i.e. a broader perspective) then the cost effectiveness ratios are not quite as strong. Cost per DALY results under $20,000 would still be generally regarded as suggesting strong economic credentials.

Table A34 Incremental Benefits, Costs & Cost-Effectiveness of SunSmart Program

	Program costs ($Million)	Costs offsets ($Million)	Net savings ($Million)	YLL	DALY	$/YLL No offsets	$/DALY No offsets
Program compared with status quo (30% reduction)	2.53	39.9	37.4	7,295	9,965	347	254
	National SunSmart Program compared with status quo (30% reduction			National SunSmart Program compared with status quo (30% reduction) including costs to individuals			
Health benefit							
YLL		7,295			7,295		
DALY		9,965			9,965		
Costs							
Program costs ($million)		2.53			152.9		
Costs offsets (savings) ($million)		(39.9)			(39.9)		
Net costs ($million)		(37.4)			113.0		
Cost Utility or C/E							
$/YLL no offsets		347			20,960		
$/DALY no offsets		254			15,343		
$/YLL including offsets					15,489		
$/DALY including offsets					11,339		

Note: Savings are figures in brackets

Sensitivity analysis

A probabilistic sensitivity analysis was performed using the @RISK software. In the primary analysis reported above, the value with the strongest evidence from the literature for each of the variables was used. In the sensitivity analysis a probability distribution is put around the variables (refer Table 36). The results of the sensitivity analysis are shown in Table 37. The results of the sensitivity analysis suggest that some confidence can be placed the results of the primary analysis – this option has strong economic credentials under a plausible range of assumptions.

Table A35 Variables and Distribution used in Sensitivity Analysis of a National SunSmart Program

Variable	Primary analysis	Sensitivity analysis	Rationale for distribution
Increase in incidence	2.2%pa males 1.7%pa females	Risk Uniform (0,0.022) –males Risk Uniform (0,0.017) – females	The increase in incidence may taper off as cohorts age.
Survival rates	no change	Risk Uniform (-0.01,0.02)	Survival rates are more likely to improve
Dissemination ratio	no change	Risk Uniform (-0.01,0.02)	'No dissemination' group is more likely to increase
Lag time	10 years	Risk Uniform (5,15)	Working party suggested lag phase to be somewhere between 5 and 15 years.
Reduction in incidence of skin cancer	30.2%	Risk Triangulation (0.151,0.302,0.302	Reduction is predicted to be 30.2% (Carter 1999) but may be lower.
The costs of the program		Risk Uniform (0.9,1.1)	Cost estimate plus or minus 10%.

Table A36 Sensitivity Analysis Results

Variable			Including personal costs	
	Lower 95% CI level	Upper 95% CI level	Lower 95% CI level	Upper 95% CI level
Health benefit				
YLL	3,459	6,677	3,459	6,677
DALY	4,842	9,148	4,842	9,148
Costs				
Program costs ($million)	2.2	2.8	135.6	170.2
Costs offsets (savings) ($million)	(22.5)	(44.3)	(22.5)	(44.3)
Net costs ($million)	(20.0)	(41.7)	99.2	139.8
Cost/U or C/E				
$/YLL no offsets	325	703	19,639	42,443
$/DALY no offsets	238	505	14,390	30,523
$/YLL including offsets			13,260	35,585
$/DALY including offsets			9,705	25,633

Note: Figures in brackets are savings

Comparison with other economic studies

The economic appraisal published by Carter and colleagues (*1999*) reached very similar conclusions to the present study in relation to the cost effectiveness of the intervention. The difference in methods between that micro economic evaluation study, however, and the macro economic evaluation methods adopted here (refer Appendix Six) make detailed comparison of the results difficult. The Carter et al (*1999*) study, for example, adopted a 20-year time horizon for running the program, a 5% discount rate, different lag assumptions and a different approach to estimating the size of the mortality benefit.

The Carter et al (*1999*) study also found the proposal to be "dominant" when offsets were included, and a slightly higher cost effectiveness ratio of $1,357 per PYLS when they were excluded. The univariate and multi-variate sensitivity analysis adopted in the Carter et al (*1999*) study generated variations in the C/E ratio (cost offsets excluded) from $1,202 per PLYS to $8,074 per PYLS. When costs to individuals were included, the C/E ratio rose to $25,134, a similar result to the current study.

Discussion of the Results

Equity

Melanoma incidence varies in a direct relationship to intensity of and exposure to ultraviolet radiation (UVR). There is limited information on melanoma in indigenous Australians, however it is thought that the rate will be low because of the higher concentrations of melanin in their skin. Australian-born populations have significantly higher mortality rates than most migrant groups, except for males born in New Zealand and females born in Malaysia (*Giles, 1995*). The main population grouping where equity considerations arise concerns those living in rural/remote areas.

A second area of potential concern is the financial impact on individuals in complying with the SunSmart recommendations. The economic analysis identified these costs as an important influence on the C/E ratios. While in aggregate these costs are substantial, for individuals the cost of a hat or sunscreen is not substantial. It also needs to be noted that Australian primary prevention programs have relegated sunscreen use to second priority now for some years. This has been done for a variety of reasons, including cost, risk of short and long-term side effects and adequacy of application. Natural

protection in the use of shade, avoidance of sunlight around the middle of the day and clothing remain the first priorities in the program.

On balance, the equity filter is largely neutral on this intervention.

The public health significance of the problem

Australia has the highest incidence of skin cancer of any country in the world. The incidence and mortality rates for melanoma in Australia are matched only by New Zealand. There is a tenfold difference in incidence between Australia and England and Wales, but it is known that this ranges up to 150-fold compared with other countries (*AIHW & AACR, 1999*).

Melanoma:

In 1996 melanoma was the fourth most common cancer affecting both men (4,313 new cases) and third most common cancer in women (3,448 new cases) with 903 deaths overall. In terms of YLL (13,114) and DALY (20,010) it ranks among the top ten cancers.

Melanoma is more common in men than in women. Incidence trends are increasing for males and females (2.2%, 1.7% per annum) but mortality rates, which were increasing (0.3%, 2.2%), are now tending to be relatively stable. (*NHPA-AIHW1997*).

In terms of total health system costs, melanoma was the tenth highest costing neoplasm, with direct costs of $65.6 million in 1993/94 (*AIHW 1998*).

Non melanotic skin cancer (NMSC):

NMSC is the most commonly diagnosed cancer in Australia. Cancer registries do not routinely collect incidence data for this cancer, but the numbers per annum are estimated at 270,000, or 78% of all cancers (*AIHW & AACR, Staples 1998*). NMSC has a low mortality rate when compared with other cancers (the deaths mainly occurring from squamous cell carcinoma). Mortality has, nonetheless, been increasing since the late 1980s (*NHPA-AIHW1997*).

In terms of total health system costs, it was the highest costing neoplasm in Australia, with direct costs of $232.3 million in 1993/94. (*AIHW 1998*)

Consideration of this filter greatly enhances the importance and merit of this intervention.

Level of evidence

Sunlight is a major risk factor both as an initiator and as a promoter of skin cancer development. Sunburn is a measure of the biologically active sunlight reaching the skin (reflects skin type and degree of protection). Good evidence exists that educational campaigns can impact on behaviour. Extensive evaluation of the Victorian SunSmart campaign has shown a reduction in the crude proportion of sunburn in the Victorian population from 11% to 7% over three years. The reduction in sunburn (reduction in UVR) is modeled using known levels of biologically active UVR at different latitudes and the incidence rates of melanoma and NMSC at these latitudes.

A complex chain of events is nonetheless assumed between behaviour and disease reduction. While a conclusion of "limited evidence of effectiveness" is appropriate, in the context of this public health issue, that is an acceptable level of evidence.

Acceptability and feasibility

This intervention is comparatively low cost and requires little development. It involves little system inertia (ie it can be increased and decreased easily) and high community acceptance can be anticipated. This filter strongly supports the intervention.

Option: Psychosocial Care: Introduce Breast Care Nurses (BCNs) (Increment)

The Intervention

The need for initiatives to address psychosocial care was flagged in the NCCI (*1998*) and raised at the Cancer Strategy Development Workshop (*DHAC, 1999a*). The specific initiative evaluated in the PBMA trial (i.e. provision of support by breast cancer nurses (BSCN) to each newly diagnosed patient with breast cancer) was raised by the Working Party itself.

The NHMRC (*1999*) recently published relevant guidelines entitled: "Psychosocial clinical practice guidelines: Providing information, support and counselling to women with breast cancer". This document provides guidelines for generic psychosocial support provided by a number of different health professionals, including the medical team, psychologists, psychiatrists, counsellors and others. The NHMRC guidelines (*1999*) define the role of a specialist breast nurse as:

> *"... to provide ongoing counselling, information and support relating to all aspects of breast care for women with breast cancer, and clarify or reinforce information and provide continuity of care throughout the treatment process".*

Psychosocial problems are present in a significant proportion of women diagnosed with breast cancer. The provision of BCNs is a strategy thought to potentially improve the psychosocial care of women. The families of these women, as well as other members of the treatment team may also benefit (*National Breast Cancer Centre, 1999*). Recent Australian and overseas evidence suggests that BCNs are effective in reducing mild to moderate levels of such morbidity. Given that women are more likely to experience such problems during key transition points in the course of the diagnosis and treatment of breast cancer, the Anti-Cancer Council of Victoria (ACCV) has recommended that BCNs have contact with women at eight key points. These include the time of diagnosis, pre-surgery, post-surgery and 1 week, 1 month, 3 months, 6 months and 12 months post-discharge.

The current evaluation assumes that BCNs have contact with all newly diagnosed cases of breast cancer (approximately 10,000 per annum) during the 8 key points specified above. The provision of such nurses is compared to the "status quo" in which it is assumed that no BCNs are available.

The Health Benefit

Overview

The health benefit is measured in DALYs, as with the other interventions being evaluated in the PMBA trial. The introduction of BCNs has the potential to reduce the morbidity component (YLDs) during illness stages where there is mild to moderate levels of psychosocial morbidity (particularly anxiety and depression). BCNs are not expected, however, to reduce the mortality (YLLs) associated with breast cancer. In this respect, the proposed initiative is different to most of the other interventions being evaluated.

Effectiveness of BCNs

Previous literature (*NHMRC, 1999*) has suggested that the key outcomes associated with the introduction of BCNs include:

- information and satisfaction with care;
- psychological outcomes (eg. anxiety/depression/interpersonal problems); and
- social functioning – practical and financial support to women with breast cancer – particularly those from rural/remote areas.

It is still unclear as to whether psychosocial interventions affect the medical manifestation of cancer in terms of survival rates or duration in remission (*Meyer & Lark 1995*)[36]. Therefore a reasonable assumption for the purposes of the current study is that psychosocial interventions will only be expected to impact on the disability component of the DALY (ie the YLDs).

In a recent review Burke and Kissane (*1998*) found that the provision of BCNs is potentially beneficial in terms of reducing psychosocial morbidity throughout the continuum of care. Further, in a randomised study spanning one year post-surgery for breast cancer McArdle, George et al (*1996*) found that BCNs were more effective than routine care[37]. McArdle et al. found that on each of the self-rating scales (including the GHQ and hospital based depression/anxiety scales) psychological morbidity fell over a 12 month period. Significant differences were found for the GHQ score, and the anxiety/insomnia sub-scale and hospital depression.

A recent Australian study investigating the effectiveness of BCNs found less impressive results however (*NBCC, 1999*). In this study the BCNs were effective in dealing with mild distress, but were not able to reduce overall levels of morbidity in comparison to the control group. The study also suggested that BCNs may be effective in reducing the clinical time spent with patients by other members of the treatment staff (such as oncologists), but the perceived differences were not statistically significant.

Quantifying the change in the YLD

The disability weighting system utilised in the derivation of DALYs defines each disease stage in terms of a standardised health state description using a variant of the EuroQol 5D classification (EQ5D+) (*Mathers, Vos & Stevenson, 1999*). The Australian BOD studies used severity weights from a Dutch BOD study (*Southard et al 1997*). Each of the health states valued in the Dutch study is accompanied by a EuroQol 5D description (EQ5D+). If no Dutch weights were available, weights from the Global Burden of Disease (GBD) study (*Murray & Lopez 1996*) were used instead. For some health states there were no GBD weights or Dutch weights. Therefore a regression model of the Dutch weights and EQ5D+ descriptions was created to allow weights for new health states to be predicted given a EQ5D+ description. This regression model is used in the analyses below to model the impact of interventions on disease severity.

The 6 dimensions covered in the EQ5D+ scale include:

- Mobility;
- Self-Care;
- Usual activities;
- Pain/discomfort;
- Anxiety/Depression; and
- Cognition

[36] For example in a recent meta-analysis of psychosocial interventions Meyer & Mark (1995) state that psychosocial interventions (including BCN) do not impact on the medical status of cancer (including leukocyte activity, tumour response to chemotherapy and physician rating of disease progression).

[37] "Routine care" included care from ward staff, routine care plus support from voluntary organisations and routine care plus nurses plus voluntary care.

A rating of "1" on this scale means that there are no problems in this dimension, a "2" means that there are some problems and a "3" means that there are extreme problems. The specific weights for breast cancer are shown in Table 38. The ordering of the dimensions in the table is the same as listed above.

Table A37 EQ 5D+ Score Profile and Disability Weights for Breast Cancer used in the BOD Study (*Mathers, Vos, Stevenson, 1999*)

Disease Stage	EQ 5D+ score*	Disability weight
Diagnostic phase & primary therapy for non-invasive breast cancer or tumour <2cm	111221	0.260
Diagnostic phase & primary therapy for breast tumour 2-5cm &/or lymph node dissemination	112321	0.690
Diagnostic phase and primary therapy for locally advanced breast cancer (tumour >5cm)	113331	0.810
Clinically disease free after the first year	111221	0.260
Disseminated	212331	0.790
Terminal	323332	0.930

Notes: * These numbers refer to the score given to each of the above dimensions on the EQ 5D+ in the Dutch disability weights

Ideally, the individual EQ 5D+ scores of women with and without anxiety and depression should be considered and ultimately only changes in mild to moderate anxiety/depressive symptomatology altered[38]. However, the EQ 5D+ scores in the BOD model are reflective of the "average" case at each disease stage and make no allowance for differing levels of symptomatology in sub populations of women at each disease stage. As the DALY methodology currently stands, therefore, it is not possible to incorporate individual variation in the model. In order to derive a surrogate measure of the benefit of BCNs, an informed judgement needs to be made, drawing on the available evidence with respect to how the EQ 5D+ profiles for the "average" patient at each disease stage may change. Having regard to the fact that BCNs will see all women with breast cancer, the assumption was made that only half the women receiving care would experience the benefit of reduced anxiety/depression. Table 39 contains information on how the disability weights (DW) in the BOD model were altered.

Table A38 Alteration to Disability Weights (DW)

Disease Stage	New EQ 5D+ Profile*	Prop'n of population**	Weighted average ***	Prop change #	Dutch weight ##	New DW ###
Diagnosis <2cm	111221	0.5			0.26	0.159
	111211	0.5	0.153	1.633		
Diagnosis 2-5cm	112321	0.5			0.69	0.583
	112311	0.5	0.486	1.184		
Diagnosis >5cm	113331	1				
	No change					
Disease free	111221	0.5			0.26	0.159
	111211	0.5	0.153	1.633		
Disseminated	212331	1				
	No change					
Terminal	333332	1				
	No change					

Notes:

[38] Since recent Australian evidence suggests that BCN impact predominantly on mild to moderate cases and have little impact on more severe cases.

* These numbers refer to the score given to each of the EQ 5D+ dimensions. The first row refers to the profile as present in the Dutch DW and the second row refers to the researcher-imposed change to the DW.

** This column refers to the proportion of women expected to exhibit the specified EQ 5D+ profile

*** This column displays the weighted average of the two DWs relevant to each of the specified EQ 5D+ profiles.

\# This column refers to the proportional change in the new weighted average compared to the original DW profile.

This column specifies the Dutch DW as are present in the base case of the BOD model

###- This column is the product of the proportional change and the original weights. It is these weights that have been used to determine the net benefit.

The DW alterations may under-estimate the improvement for four reasons. First, they ignore interdependencies that may exist between the EQ 5D dimensions[39]; second, they focus only on benefits experienced by the patient (and not their families or the treatment team); third, they include only changes in mild to moderate levels of anxiety/depression; and fourth; they assume that the improvement in depression/anxiety is experienced by only half the women receiving BCN care.

On the other hand, it is possible that the anxiety/depression state associated with a cancer diagnosis is inherent to the health state and a move from 2 to 1 on the EQ5D+ scale is optimistic. Variations to the benefit assumptions in the primary analysis are tested in the sensitivity analysis. This is important because the dimension of anxiety/depression in the EQ 5D+ seems to be the key driver in the weights that have been altered. The DWs were reduced by nearly 5-fold by simply changing the anxiety/depression dimension score from 2 to1 (eg. the weight falls from 0.260 to 0.056 for the diagnostic stage and primary therapy for tumours >2cm). If the pain/discomfort dimension score is similarly changed from 2 to 1, while leaving anxiety/depression unchanged at 2, the weight reduces much less to (ie from 0.260 to 0.204). In the stages of the disease where it is thought that the BCN intervention would have most benefit, the anxiety/depression dimension is the key determinant of the DW.

By altering the disease weights in this fashion for moderate level depression, BCNs can potentially save 5,186 YLDs. That is, the incremental benefit of introducing BCNs is estimated to be 5,186 DALYs.

The Health Service Costs

In order to determine the cost of this intervention two main pieces of information are necessary. First, the number of nurses required to deliver the intervention as specified (ie all breast cancer cases to be seen at 8 key contact points); and second, the cost per BCN.

It is assumed that 10,000 new cases of breast cancer will be diagnosed each year. If all patients are seen at each of the 8 key contact points, this entails 80,000 contacts per annum. It is assumed that each BCN is capable of having 5 significant patient contacts each day[40], or 25 contacts per week. If it is assumed that a full-time BCN works 48 weeks in a year, then 1,200 (48*25) annual contacts may be expected. To cater for an expected 80,000 contacts, approximately 67 full-time BCNs would be required (80,000/1,200)[41].

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[39] For example, moderate to severe levels of depression and anxiety affect all areas of functioning including mobility, self-care and usual activities. Therefore reducing depression/anxiety can impact on the other dimensions of the EQ 5D+ as well. For the purposes of the current study such inter-dependencies were not considered and only changes in the variable of interest (i.e. depression/anxiety) were included. If such changes were also considered, then the impact would be to reduce the DW even further.

[40] This assumes an eight hour work day, with the remainder of the time made up in preparation, administration, attending meetings, staff development etc.

[41] It should be noted that this annual number of contacts is probably a fairly conservative estimate considering an actual BCN at the Peter McCallum hospital managed to have 8000 contacts.

The salary of a BCN is approximately $46,900 (not including salary oncosts) per annum (*Personal Communication, Doreen Ackerman, ACCV, 2000*). If 15% salary oncosts are also factored into the cost the annual cost becomes $53,935. Therefore the annual salary cost of the required full-time BCNs is approximately $3.6 million ($53,935*67).

This cost does not include any other costs associated with the employment of a BCN within an organisation (such as office costs, computer equipment, incidentals). Within health care services generally, the salary component of the total service costs comprises approximately 60-70%. If an allowance for such costs are is imputed, then the total cost of the 67 BCNs becomes approximately $5 million (assuming salaries constitute 60% of the total cost).

As previously stated, the recent NBCC study (*1999*) suggested that BCNs might also save clinician time (though the differences were not statistically significant). The current study does not include any provision for such cost offsets, nor for any broader health care system offsets that may occur due to the early intervention for patients with anxiety/depression. On the other hand, no provision has been made for any on-going training needs of BCNs or for any quality control mechanisms that may be considered appropriate.

Cost Effectiveness Results

The cost and outcome assumptions set out above yield a cost effectiveness ratio $935 per DALY saved. This result suggests that the introduction of BCNs is potentially a very cost effective intervention. Given that the level of evidence (see below) is in the "limited evidence of effectiveness" category, pilot testing may be a prudent next step.

Sensitivity testing

To test the robustness of the assumptions built into the economic analysis, sensitivity testing was undertaken in a number of ways.

First, the technique of "threshold analysis" was utilised.[42] On the benefit side (costs held constant) the smallest amount of benefit necessary to achieve an acceptable cost effectiveness ratio was addressed. Only 162 YLDs need to be averted to achieve a cost effectiveness ratio of $30,000 per DALY. On the cost side (benefits held constant) the cost of the BCN intervention would have to be over $155 million for a cost effectiveness ratio of $30,000 per annum to be achieved. This amounts to the provision of nearly 2140 BCNs ~ 31 times the proposed number of 67.

Second, a key variation in the application of the disability weight was considered. If the disability weight is only altered for the diagnostic and treatment phase (and not for the disease-free period following treatment) then the cost effectiveness ratio increases to $1,712 (in this instance there are 3,813 DALYs averted). This variation excludes the largest potential YLD contribution, because the diagnostic and treatment period varies from 11 to 35 weeks (depending on the size of the diagnosed tumor) while the disease-free period is defined as 5 years in the DALY disease model. While very conservative[43], this variation still yields a robust result.

The robustness of these results was also tested utilising the @Risk software package. Table 40 contains details on which parameters of the model were simultaneously varied.

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[42] This technique is useful to analyse the size of cost and outcome variations that still yield an acceptable cost effectiveness result.

[43] If BCNs are successful in reducing at least moderate levels of anxiety and depression during the highly stressful time of diagnosis and treatment, then it is unlikely that anxiety and depression levels will increase after this period.

Table A39 Uncertainty Parameters in the @Risk Modeling Simulations for Breast Care Nurses

Model Parameter	Base Value in original model	Range of possible values modeled
Benefit		
Proportion of women thought to benefit from intervention	50%	25% - 75%
Costs		
Incidence numbers of newly diagnosed cases	10,000	8,600 – 10,000*
Percentage of total costs attributable to admin/office costs	40%	30% - 50%
Number of annual contacts a BCN is expected to have	1200	1000-2000
Number of contacts per case	8	4-12

Notes:

* The incidence number of cases was varied considering the original BOD model received from the AIHW estimated 8,600 newly diagnosed cases in 1996, not 10,000. Modeling the costs on 10,000 cases over-estimated the number of nurses required.

It should be appreciated that the original version of the model was developed to represent an ideal situation in terms of the intervention design. While reasonably conservative assumptions were applied in terms of the estimated benefits, the reality may be quite different. For example, many women may not want nor need ongoing contact with BCNs and it is possible that as few as 25% of the women will benefit. A range of 25% – 75% in the proportion of women benefiting was assigned to test this uncertainty. Similarly, there may be variation in the number of contacts per case and a range of 4 – 12 was assigned.

The model was simulated 2000 times utilising the above uncertainty parameters. The mean benefit calculated was 3,659 YLDs (uncertainty interval: 2,089 – 5,228 YLDs) and the mean cost was $4.0 million (uncertainty interval: $1.3 - $6.6 million). The mean cost effectiveness ratio is $1,139 per DALY (uncertainty interval: $208 - $2,070 per DALY).

Even in the face of quite conservative uncertainty estimates, the intervention retains strong economic credentials on the first filter.

Discussion of Results

Assessment of the BCN intervention in terms of the second stage filters is set out below.

Equity

The BCN intervention is unlikely to worsen any existing inequalities for breast cancer patients. Rather, it provides a potential for special needs groups to receive tailored care more appropriate to their needs[44]. In this regard it useful to note that some 12% of women with breast cancer come from NESB

[44] The NCCI (*1997*) has suggested the use of telemedicine to ensure women in rural/remote areas access appropriate care. Hordern (*1999*) states that rural women face particular difficulties in accessing multidisciplinary care and that accessing such care often means travelling (sometimes quite significant distances) to regional centres. A recent parliamentary report (*cited in Hordern, 1999*) stated that women need to:

- be financially assisted to attend multidisciplinary teams or to access a team which has an outreach component;
- women who require radiotherapy need to be financially assisted to attend such therapy;
- women should be provided with financial assistance to enable them to attend a general practitioner within their geographic area;
- women should be provided with childcare while absent from home for breast care treatment; and

backgrounds and 30% are from rural areas (*NCCI, 1998*). There is also the broader issue of whether it is equitable to propose what appears to be a generic type of intervention only for one type of cancer – albeit a major one.

An equity filter should not unduly trouble any BCN initiative, but additional resources may be required to meet special needs. Access to BCNs in rural/remote areas may become part of the broader issues facing rural women (see footnote 79).

Size of the problem

There is general agreement that breast cancer is a very significant disease. The potential impact on breast cancer morbidity of this intervention is substantial. The impact on health care system costs was not assessed in the analysis, but is likely to be far less significant than the health status implications.

There is increasing recognition of the importance of including measures of morbidity in evaluation and priority setting activities. Devoting resources to ameliorating major morbidity associated with breast cancer and its treatment is acceptable on this filter.

Levels of evidence

The epidemiological evidence is summarised above in Section 5.6.2. . There have been very few well-designed randomised trials of this intervention and a recent Australian study suggests that BCNs are not effective in reducing overall levels of psychosocial morbidity. However this study was not a randomised study and the control group was not a true control. The majority of overseas studies have demonstrated that BCN are effective.

The evidence to support the efficacy/effectiveness of this intervention is therefore rated as "*limited evidence of effectiveness*", that is, effectiveness is demonstrated by limited evidence from studies of varying quality.

Caution is appropriate as to the next steps in implementation of the BCN intervention.

Acceptability and feasibility

The proposed intervention is likely to be acceptable to key stakeholders (ie funders, providers, the general community and politicians) if its efficacy credentials can be established more firmly. It is a low cost intervention ($5 million per annum) with the potential for significant morbidity improvements for breast cancer patients.

There may be an issue as to whether the necessary number of BCNs would be available outside Victoria/ New South Wales, but this should not prove too troublesome to overcome.

The BCN intervention is unlikely to be rejected on acceptability or feasibility grounds.

- if a woman has to travel away from home to receive treatment for her breast cancer she should be entitled to receive financial travel assistance towards having a support person accompany her.

Option: Psychosocial Care: Introduce Psychologists for Cancer Patients (Increment)

The Intervention

Background

The need for initiatives to address psychosocial care was flagged in the NCCI (*1998*) and raised at the Cancer Strategy Development Workshop (*DHAC, 1999*). The specific initiative evaluated in the PBMA trial (i.e. provision of psychologists for cancer patients in cancer treatment centres) was raised by the Working Party itself.

Moderate to severe levels of psychosocial problems are present in a significant proportion of people diagnosed with cancer. A number of randomised control studies (as well as three recent meta-analyses) have shown psychosocial interventions, including psychological therapy, to be effective in reducing such morbidity. "Psychosocial interventions" include a number of quite different types of intervention. Cognitive Behavioural Therapy (CBT), however, developed and primarily practiced by psychologists, has been shown to be highly effective in reducing affective disorders such as depression and anxiety, particularly in the acute phases of illness. Longer-term supportive psychotherapies are more effective in disseminated and terminal cases of cancer.

Description

The current study models the cost effectiveness of short-term CBT for patients in the acute phase of diagnosis and treatment and longer-term supportive psychotherapy for patients with disseminated and terminal cancers. The short-term CBT intervention entails 12 sessions of CBT either in an individual or group setting (50% of patients are assumed to have individual therapy and 50% are assumed to have group therapy in groups of 6 patients). Supportive psychotherapy entails individual weekly contacts up until the time of death. Further details are specified in the briefing paper available separately (refer Section 3.2).

The current study assumes a psychologist will assess all patients at the times of initial therapy, recurrence and disseminated/terminal phases and provide further therapy to a proportion of patients exhibiting moderate to severe levels of morbidity.

The Health Benefit

As with the other interventions being evaluated, the health benefit is measured in DALYs. The introduction of psychologists will not effect the YLLs associated with cancer, but will reduce the YLDs during illness stages where there is moderate to severe levels of psychosocial morbidity (particularly anxiety and depression). Two methods were employed to model the anticipated impact of psychologists on YLDs. In the first method the anxiety/depression dimension in the DWs was reduced by one level and the resulting new DWs run through the BOD model. This method is similar to the methodology utilised in the BCN intervention explained above.

In the second method additional dimensions of the DW were utilised. It was assumed that incremental changes attributable to a psychosocial intervention would occur in only 12% of people (*Meyer & Mark, 1995*[45]) but that in these instances the depression/anxiety dimension, the usual activities dimension and the pain/discomfort dimension of the DWs would all change.

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[45] The Mark and Meyer study was a meta-analysis of 45 published randomised trials and is the preferred review from the perspective of methodological rigour. Their study found that psychosocial interventions improved emotional outcomes in 56% of cases compared to 44% in the control groups not exposed to the intervention (i.e. an improvement for 12% of cases).

The second method is more conservative method than the first, but is considered a more realistic estimate. As with the BCN intervention, it is important to be conservative in estimating potential benefit. Anxiety/depression may be inherent in the health state of cancer. Overall, method 1 suggested that 28,913 YLDs could be averted in the top 5 cancers, while method 2 suggested that 4,839 YLDs could be averted. Table 41 summarises estimates for the number of YLDs averted or saved by the implementation of a psychologist.

Table A40 YLDs Averted by Psychologist Intervention Utilising the Two Methods of Altering the DWs

Cancer Type	Original YLDs	New YLDs Method 1	New YLDs Method 2	Incremental Difference (M1)	Incremental Difference (M2)
Colorectal	11,579	4,257	10,373	7322	1,207
Prostate	9,974	4,588	8,940	5,386	1,034
Breast	13,425	5,720	12,072	7,705	1,352
Melanoma	6,896	403	6,114	6,494	782
Lung	7,375	5,369	6,901	2,006	474
TOTALS	49,249	20,336	44,400	28,913	4,849

The Health Service Costs

Overview

The estimated cost of the intervention to the Government as the funder and provider of the program is approximately $25.7 million. The bulk of this cost is the salary and associated oncosts for 286 full time equivalent level 3 psychologists. Other costs associated with the employment of psychologists within an organisation, such as administration, office costs, computer equipment and incidentals have been factored into the overall cost. The cost estimate does not include any recruitment or training costs that may be associated with the acquisition of the psychologists, nor any extra costs associated with the provision of psychological services in rural/remote areas. No provision has been included for downstream cost offsets that might accompany early intervention by the psychologists.

Resource utilisation

The intervention to be costed is the provision of a psychologist in each "cancer unit/centre." The definition of a "cancer unit/centre," however, is somewhat nebulous and the approach taken was to estimate the number of full-time psychologists required to meet the psychosocial needs of cancer patients. Firstly, it was assumed that the psychologists would assess all patients at least once upon diagnosis, as well as at each key transition point, such as relapse. This is necessary as previous research has suggested that members of the direct treatment team are not particularly skilled in detecting psychosocial problems and because patients are reluctant to accept referrals from members of the direct treatment team (*Burke & Kissane, 1998; NBCC, 1999*). It was assumed that 25% of patients in the diagnostic and treatment phases of the disease, as well as at recurrence, would require further intervention. In the dissemination and terminal phases[46] 50% of patients were assumed to display such symptomatology. Once the prevalence was determined, the ideal scenario of all these patients receiving the recommended intensity of the intervention was modeled.

[46] Even though the meta-analysis by Van't Spijker et al, suggests that the prevalence does not change according to disease phase, this result may be due to the way time was defined in this study. Most studies defined time in terms of weeks post diagnosis and not upon disease stage – therefore other studies which suggest a much higher proportion (approximately 50%) of such morbidity at these stages (eg. *Burke & Kissane, 1998*) is probably more appropriate.

For terminal cases, a longer-term psychotherapeutic intervention was modeled. This involved mostly weekly meetings until the time of death (the duration of time modeled was derived from the BOD model duration in the disseminated and terminal stages of each of the five cancers). Prostate and breast cancers have quite lengthy dissemination stages. In these instances it was assumed that fortnightly contacts took place during the dissemination stages and weekly contacts during the terminal stages.

Table 42 contains information on how the resource utilisation, in terms of number of contacts required to meet the psychosocial needs of cancer patients, was modeled.

Table A41 Summary of Service Utilisation Assumptions

Cancer type & Disease Stage	No of people at each time point	No with significant morbidity[1]	No of psychologist contacts[2]
Colorectal Cancer (CRC)			
Stage of diagnosis and primary therapy	11,203	2801	30,808
State of intentionally curative primary therapy/In remission	5090		
In remission	6112	1528	16,808
Irradically removed or disseminated carcinoma/terminal (duration 4 months)	6112	3056	55,008
Total			102,624
Prostate Cancer			
Accidentally located localised prostate cancer, follow up without active intervention (watchful waiting)			
Diagnostic phase and primary therapy for localised prostate cancer	10,444	2611	28,721
Clinically disease free after primary therapy	7599		
In remission	2846	712	5692
Disseminated – hormone refractory cancer/terminal (duration: 19 months)[3]	2846	1423	59,766
Total			94,179
Breast Cancer			
Diagnostic phase & primary therapy for non-invasive breast cancer or tumour <2cm	4603	1151	9206
Diagnostic phase & primary therapy for breast tumour 2-5cm &/or lymph node dissemination	3686	922	7372
Diagnostic phase and primary therapy for locally advanced breast cancer (tumour >5cm)	342	86	684
Diagnostic phase and primary therapy for locally advanced breast cancer (tumour >5cm)	6005		
In remission	2626	657	5252
Disseminated/Terminal (duration: 13 months)[3]	2626	1313	42016
Total			64530
Melanoma			
Primary Treatment, no evidence of dissemination	7005	1751	14010
No evidence of dissemination after initial treatment	6291		
Primary treatment, lymph node but no distant dissemination	792	198	1584
In remission	1506	377	3012
Disseminated/Terminal melanoma (4 months)	1506	753	13554
Total			32160
Lung Cancer			
Diagnosis and primary therapy for operable non-small cell cancer	1103	276	2206
Disease free after therapy for non-small cell cancer	573		
Diagnosis and primary therapy for non operable non-small cell cancer	5538	1385	11076
Disseminated non-small cell cancer	6073	3037	30365
Terminal stage non small cell cancer	6073		
Diagnosis and chemotherapy small cell cancer	1242	311	2484
Disease free after primary therapy for small cell cancer	55		
Small cell cancer in remission	1187	297	2374

Relapse/terminal stage small cell cancer (2 months duration)	1187	594	5935
Total			54440

Notes:

1. This assumes that 25% of people at diagnosis and remission have significant psychological/ psychiatric morbidity, and 50% of people have such morbidity at the disseminated/terminal phase of illness.
2. This assumes **all** people are assessed at diagnosis, during recurrence (defined in the above model as during remission), and when people enter the disseminated/terminal phase. For the 25% of people assumed to have significant morbidity at diagnosis/treatment and recurrence half will have individual therapy lasting on average for 12 sessions and the other half will attend group therapy, again for 12 session with the assumption of 6 people per group. For the people in the disseminated/ terminal phase it is assumed that 50% of these people will have significant morbidity requiring psychotherapy on a weekly basis, until the point of death. The duration of psychotherapy is determined by the duration of time spent in this disease stage. For example 4 months would equate to 4*4 = 16 sessions.
3. This assumes that during the dissemination phase (lasting 18 months for prostate cancer and 12 months for breast cancer) fortnightly contacts were made.

To determine the number of psychologists required it is assumed that each psychologist has 5 patient contacts per day lasting 45 minutes to an hour, with the remainder of the working day used for preparation, administration, professional development etc. *(Lisa Henry, clinical psychologist, personal communication)*. As such, each psychologist is assumed to have 1200 contacts per annum. Therefore the numbers of psychologists required for each cancer is approximately:

- Colorectal Cancer – 82
- Prostate Cancer – 78
- Breast Cancer – 54
- Melanoma – 27
- Lung Cancer – 45
- Total - 286

Unit cost

Considering the psychologists will sit within the multidisciplinary oncology treatment team it is assumed that a fairly senior level psychologist, able to work autonomously would be required. The weekly salary of a level 3 psychologist[47] in the Victorian public service (in 1996 dollars) is:

PL1 – $933.65 (level 3 year 1)
PL2 - $967.60 (level 3 year 2)
PL3 - $1002.89 (level 3 year 3)
PL4 – $1048.61 (level 3 year 4)
(Source: Mark Henry, administrative manager, Mental Services for Kids and Youth[48]).

If a 15% loading for salary oncosts is factored into the cost then the annual salary cost of a PL2 psychologist is $57,862 (deflated to 1996 prices). The annual salary cost of the required full-time psychologists to provide assessment and psychological interventions to the top five cancers is approximately $16.5 million ($57,862 * 286).

This cost does not include any other costs associated with the employment of a psychologist within an organisation, such as office costs, computer equipment, incidentals, etc. Within health care services generally the salary component of total service costs is approximately 60-70%. Therefore, if non-salary costs are included on a pro rata basis, the total cost of the required psychologists is in the order

[47] Level 3 psychologists are senior clinicians with considerable experience able to work independently with no supervision.
[48] Weekly salary rates received from Mark Henry were in 1999 dollars. The costs reported have been deflated utilising a health deflator from the AIHW (*1998*) to the base year of 1996.

of $25.7 million (assuming salaries constitute 60% of the total cost). The costs attributable to each cancer type are:

- Colorectal Cancer – $7,327,358
- Prostate Cancer – $7,038,789
- Breast Cancer – $4,822,328
- Melanoma – $2,403,587
- Lung Cancer – $4,068,135
- Total - $25,660,198

It is not inconceivable that some downstream cost savings may arise from the early involvement of psychologists, including less time required from treating clinicians. However there is no evidence documenting such potential cost savings and therefore these have not been included in the current study. On the other hand, no provision has been made for any on-going training needs or quality control/monitoring that may be thought necessary for this option.

The Cost Effectiveness Results

The overall C/U ratio utilising method 1 for the DW changes is **$887 per DALY** ($25,660,198 / 28913). For method 2 the C/U ratio is **$5,292 per DALY** ($25,660,198 / 4849). The cost effectiveness of the intervention within each of the 5 major cancers is detailed in Table 43.

Table A42 C/U Ratios of the 5 Major Cancers for Psychologist Intervention Using Two Methods of Altering the DW

Cancer Type	C/U per DALY Method 1 ($)	C/U per DALY Method 2 ($)
Colorectal	951	$6,072
Prostate	1173	$6,807
Breast	567	$3,566
Melanoma	337	$3,075
Lung	1817	$8,576

Interestingly, the C/U ratio of the intervention changes according to cancer type. Melanomas are the most cost effective, followed by breast, colorectal, prostate and finally lung cancer. This ordering is probably a function of the mortality associated with each type of cancer. Cancers with fairly low early mortality would have a greater proportion of YLDs than cancers with a high early mortality. Therefore, there is greater scope to save potential YLDs in cancers with low mortality in comparison to cancers with high mortality.

Sensitivity analysis

To test the robustness of the assumptions set out above, sensitivity testing was undertaken in number of ways. Firstly, the technique of threshold analysis was applied. On the benefit side, only 855 YLDs need to be averted to achieve a cost effectiveness ratio of $30,000 per DALY. With respect to each of the top 5 cancers, the following YLDs need to be averted to achieve a threshold ratio of $30,000 per DALY:

- Colorectal Cancer – 244 YLDs
- Prostate Cancer – 234 YLDs
- Breast Cancer – 161 YLDs
- Melanoma – 80 YLDs
- Lung Cancer – 136 YLDs

In contrast if the cost side of the equation is considered, then the cost of psychologists would have to be $146.7 million for a cost effectiveness ratio of $30,000 per annum to be achieved. This is equivalent to the provision of nearly 1635 psychologists.

The robustness of these results was also tested utilising the @Risk software package. Table 44 contains details on which parameters of the model were simultaneously varied.

Table A43 Uncertainty Parameters in the @Risk Modeling Simulations for Evaluation of Psychologist Intervention

Model Parameter	Base Value in original model	Range of possible values modeled
Benefit		
Proportion of people thought to benefit from intervention	12%	8%-16%
Compliance rate[1]	70%	50%-90%
Costs		
Proportion of people in diagnosis/remission phases requiring intervention	25%	10%-40%
Proportion of people in terminal phase requiring intervention	50%	25%-60%
Proportion of people undergoing individual therapy	50%	30%-70%
Individual therapy sessions	12	6 – 12
Group therapy sessions[2]	12	6 – 12
Number of annual contacts a psychologist is expected to have	1200	1000-2000
Percentage of total costs attributable to admin/office costs	40%	30% - 50%

Notes:

1. The original version of the model does not include a compliance rate – it is assumed that all people eligible and offered therapy will undertake it. During the sensitivity testing runs of the model it was assumed that only 70% of people offered the therapy would undertake it. Uncertainty parameters around this 70% value were determined. Furthermore, the compliance and the proportion of people thought to benefit from the intervention were linked. The number of people thought to benefit from the intervention was determined from the number of people who actually undertook the intervention. For example, if the total number of people eligible for the intervention was 100, and the compliance rate was 70%, this means that only 70 people underwent therapy. If the benefit rate is 12% then only, 8 people are assumed to benefit from the intervention (70*12%).
2. The proportion of people undergoing group therapy is determined by subtracting the proportion of people undergoing individual therapy from 1.

The model was simulated 2000 times utilising the above uncertainty parameters. The mean benefit calculated was 4769 YLDs (uncertainty interval, 2,453 – 7,084) and the mean cost was $16,159,350 (uncertainty interval, $8,786,498 - $23,532,202). The mean cost utility ratio is $3,533 per DALY (uncertainty interval, $1,612 - $5,453).

It is not surprising that the mean costs and benefits in the uncertainty run of the model were less than the original version of the model. Both of these parameters were influenced by the newly introduced compliance rate. In terms of the costs, the compliance rate had the effect of reducing the number of psychologists required and in terms of the benefit this parameter had the effect of reducing the number of people who could ultimately benefit from the intervention.

Table 45 contains the sensitivity results of each of the top 5 cancers. Even in the face of quite conservative uncertainty estimates the intervention still remains a highly cost effective intervention.

Table A44 Probabilistic Sensitivity Testing of the Top 5 Cancers for Psychologist Intervention

		Colorectal	Prostate	Breast	Melanoma	Lung
Benefit	Mean U.I.	1104 554-1654	1040 582-1498	1361 683-2039	787 395-1179	477 240-714
Cost	Mean U.I.	$4,762,984 $2,763,370 - $6,762,598	$4,500,281 $2,527,986- $6,472,576	$2,886,149 $1,391,235- $4,381,063	$1,419,167 $587,877- $2,250,457	$2,590,773 $1,425,280- $3,756,266
C/E ratio	Mean U.I.	$4,521 $2092-$6950	$4,472 $2,224- $6,721	$2,210 $917-$3,503	$1,880 $664-$3,097	$5,674 $2,559-$8,790

Notes: U.I. refers to the uncertainty interval

It should also be noted that potential benefits to family and friends of patients diagnosed with cancer are not considered in the current study and their inclusion would further enhance the potential cost effectiveness of the intervention. On the cost side, however, the additional cost associated with placing psychologists in rural and/or remote areas has not been included.

Discussion of Results

Equity

This intervention is unlikely to worsen any existing inequalities for cancer patients, although it needs to be acknowledged that our target groups are likely to be less amenable to assistance from psychologists. In this context, the intervention provides an opportunity for the psychosocial needs of our target groups to be specifically addressed in ways they are likely to find more acceptable.

Size of the problem

An intervention that addresses the major cancers is clearly addressing a significant health problem. The potential impact on cancer morbidity of this intervention is substantial. Devoting resources to ameliorating morbidity associated with the major cancers and their treatment is acceptable on this filter.

The impact on health system costs has not been addressed in the evaluation due to lack of data. It is likely to be far less significant, however, than the health status implications.

Level of evidence

A number of randomised control studies (as well as three recent meta-analyses) have shown psychosocial interventions, including psychological therapy, to be effective in reducing morbidity. "Psychosocial interventions" include a number of quite different types of intervention. CBT, however, developed and primarily practiced by psychologists, has been shown to be highly effective in reducing affective disorders such as depression and anxiety, particularly in the acute phases of illness. Longer-term supportive psychotherapies are more effective in disseminated and terminal cases of cancer.

The efficacy of the intervention described in this evaluation is established *by "sufficient well-designed research".*

Acceptability and feasibility

It is a little difficult, a priori, to judge the acceptability of this intervention to key stakeholders - that is, to third-party funders; medical providers; the community; and politicians. This being said, however, it is not likely that this intervention would be ruled out on this filter.

The intervention appears to be quite feasible, particularly as the intention is to locate the psychologists in cancer treatment centres. The availability of suitably trained psychologists with the required skills would need to be considered.

Option: Tobacco Control (Increment)

The Intervention

Background

Interventions targeted at the control of tobacco were considered in NCCI (*1998*) as well as discussed at the National Cancer Strategy Development Workshop (*DHAC, 1999*). The Working Party was also aware that the National Expert Advisory Committee on Tobacco (NEACT) was developing a National Tobacco Control Strategy. NEACT was invited to suggest options for change that would accord with the Working Party's inclusion criteria set out under Section 3.1 and which could be completed in the short timeframe available.

Dr Hill, Chair of NEACT, suggested that the most appropriate option to evaluate would be the National Tobacco Campaign (NTC). Efficacy data for the NTC had been published (*Hassard, 1999*), a conventional economic appraisal had just been completed (*Carter & Scollo, 2000*) and the continuation of cessation based national tobacco media campaigns was an important strategic decision for NEACT. Inclusion of the NTC within the PBMA trial would provide useful supplementary information for NEACT. It would also allow the Working Party to compare the cost per DALY results from the macro evaluation approach adopted in the PBMA trial, with results from the Carter and Scollo study (*2000*).

The National Tobacco Campaign (NTC)

In Australia anti-tobacco campaigns are developed and implemented within each State and Territory as part of a tobacco control program within each jurisdiction. In addition to this the Federal Government and a range of non-government organisations also undertake campaign activity. Although cooperation had occurred prior to the NTC, the full potential had not been realised. The NTC represented the first real pooling of knowledge and resources for a collaborative national anti-tobacco campaign.

The following extract captures the key features of the NTC:

> *"Although largely funded by the Commonwealth, the campaign involved a high degree of collaboration with Quit programs in all jurisdictions and with non-government organisations. It provided a stimulus and an "umbrella" for existing state-based tobacco control activities. The campaign involved mass media advertising and a range of promotional activities intended to extend the reach of the key advertising messages. Letters and Quit resources were sent to all Australian GP's and pharmacists to encourage their participation in providing assistance to smokers to quit. While most smokers quit without formal assistance, many do seek help and therefore, additional elements of the campaign involved distribution of Quit smoking resources, and provision*

of professional cessation services, principally the telephone Quitline. These are services demonstrated as increasing smoker's chances of quitting successfully." (CBRC, 1998, p 4).

In the Carter and Scollo (*2000*) study the research question was specified as:

> *"What is the cost effectiveness of the first phase of the National Tobacco Campaign (NTC) as an additional 'umbrella' initiative to the ongoing State/Territory based tobacco control activities, from the perspective of: i) the Commonwealth government; and ii) the Commonwealth Government plus the State/Territory Quit campaigns and partner organisations?"*

This question and perspective(s) is consistent with the evaluation methods adopted in the PBMA pilot (refer Appendix Six) and enables meaningful comparison between the micro and macro economic evaluation approaches. Note that in evaluating the NTC option, a detailed description of the current or ongoing tobacco control activities at the National and State/Territory levels is not required. The NTC was a complementary activity, not a replacement activity to current practice. What is required, however, is to be able to ascertain the additional State/Territory resource commitment and additional quitters attributable to the NTC.

The Health Benefit

"*Australia's National Tobacco Campaign: Evaluation Report No. One*" (*Hassard, 1999*) provided detailed evidence on the effectiveness of the NTC in influencing smokers' beliefs, attitudes and awareness; reported quit rates and quit attempts; together with data on the change in smoking prevalence. A follow-up survey of quit rates in November 1998 (that will be published in Volume Two of the NTC Evaluation) confirmed the accuracy of the prevalence estimates. The same efficacy data on the NTC utilised in the Carter and Scollo (*2000*) study was utilised in the PBMA trial. The outcome measure varies between the two approaches, however, with the Carter and Scollo (*2000*) study using 'Potential Years of Life Saved to age 75' ($PYLS^{75}$), while the PBMA trial uses the DALY.

The Carter and Scollo Approach

A full explanation of the Carter and Scollo (*2000*) evaluation approach will not be reproduced here. It is however summarised below, together with the key differences involved in using DALYs as the outcome measure.

Using the NTC benchmark and follow-up survey data (*Hassard, 1999*) estimates were made by Carter and Scollo (*2000*) of the reduction in the number of smokers that could be attributed to the NTC. This reduction in the prevalence of smoking (approximately 190,000 people) was then translated into a reduction in the number of new cases of selected diseases that could be anticipated[49]. The diseases chosen were lung cancer, chronic obstructive pulmonary disease (COPD), various cardiovascular diseases (CVD) and stroke. The delay between a fall in the prevalence of the risk factor (ie smoking) and a reduction in disease incidence was built into the analysis, together with the relative risks for "smokers," "ex smokers" and "non smokers." The time lags incorporated were based on the literature, but erred on the side of caution (eg. 20 years for lung cancer; 10 years for COPD; and 5 years for CVD). A discount rate of 5% was used to express key variables in PV terms.

Benefits from the estimated reduction in disease incidence were measured in a number of ways and related to the reference year 1997. Firstly, as the number of premature deaths that would be prevented; secondly, as the potential years of life saved to age 75 ($PYLS^{75}$); and thirdly, as the cost offsets in terms of the direct health care costs associated with these preventable diseases.

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[49] Using formulae based on population attributable fractions (*English et al, 1995*).

Carter and Scollo (*2000*) evaluated the NTC as a once-off total package, fully implemented in the year 1997[50]. The time period for the calculation of costs and benefits associated with the NTC was dictated by when those events occur. The "quitter" benefit, for example, was assumed to occur in the year of the project, while the reduction in disease incidence effects due to those quitters, were lagged according to the individual disease causality.

Approach used in PBMA trial

Use of the DALY as the outcome measure facilitates comparison with conventional micro economic studies that use either a mortality measure (ie deaths; life years saved; or years of life lost before a specified age) or a combined mortality/ morbidity measure (such as quality adjusted life years ~ or QALYs). This is because the YLL and YLD components of the DALY can be unpacked and because the DALY can also be calculated to specified ages (ie DALYs to age 75). Thus the PBMA results (cost per YLL ^{75}) can be compared directly with the Carter and Scollo (*2000*) results (cost per PYLS ^{75}), and any differences examined in terms of the assumptions behind the estimates and/or the strengths/ weaknesses of the methods.

The key assumptions of the Carter and Scollo (*2000*) study in terms of the effectiveness of the NTC (i.e. the change in smoking prevalence; the study perspective; the lag periods between risk factor and disease onset[51]; and the health care system cost estimates for preventable disease) were all maintained. The key differences between the two approaches related to:

- the use of a 3% discount rate by the PBMA trial (applied via an exponential function) rather than 5% (applied using the standard discount tables);
- an increase in the number of smoking-related diseases from 7 to 25 in the PBMA trial, through the addition of 9 extra cancers (i.e. cancers of the mouth, oesophagus, larynx, pancreas, bladder, kidney, stomach, cervix and uterus) and 9 other diseases (i.e. Parkinson's disease, low birth weight, sudden infant death syndrome, fire injuries, inflammatory bowel syndrome, asthma, otitis media and vision disorders); and
- incorporation in the PBMA trial of the impact of the downward trend in smoking prevalence witnessed in the past decades, particularly in males, on the future disease burden and health care system costs.

Adjustment for the differences in the discount rate and number of smoking-related diseases included can be accommodated quite readily, particularly since the sensitivity analysis in the Carter and Scollo (*2000*) study included these variations. Adjustment for the impact of the prevalence trend on the health burden and health system costs attributable to smoking is more difficult and needs to be kept in mind in comparing the two sets of results (ie one would expect the Carter and Scollo (*2000*) estimate of benefit, all other things being equal, to be higher than the PBMA estimate).

The Health Service Costs

With the exception of the health care offsets (which are affected by the number of diseases included in the analysis and choice of discount rate) the cost estimates are taken directly from the Carter and Scollo study. In accordance with the research question, the focus is on those costs impacting on the Commonwealth government and State/Territory Quit campaigns. More specifically, the costs include:

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[50] Carter & Scollo commented that evaluation of the NTC as an ongoing annual program could also be undertaken, but would involve more sophisticated cohort modeling.

[51] The lag period for the additional cancers was set the same as lung cancer (i.e. 20 years); while the lag period for the additional diseases was set at 5 yrs or no lag as follows: 5 yrs ~ Parkinson's disease; LRTI; inflammatory bowel disease; & vision disorders. No lag for ~ low birth weight; SIDS; fire injuries; asthma; & otitis media.

1 expenditure by the Commonwealth Government on the 1997 first phase of the NTC (advertising; payments to Quit programs; et al.); plus
2 additional expenditure by the State/Territory Quit campaigns and partner organisations that can be attributed directly to the NTC (ie over and above the expenditures they would have incurred without the NTC initiative); minus
3 any cost offsets in the management of tobacco related disease that can be attributed to the NTC.

Expenditure by the Commonwealth

Between 1 April and 30 November 1997, the DHAC spent a total of $7.1 million on the NTC. This comprised approximately $5.4 million on media advertising, including approximately $754,000 on production of advertising materials; $238,000 on activities to attract unpaid media coverage about smoking and quitting; $595,000 on educational materials for smokers; $487,000 on research and evaluation; and $464,500 on administration and national coordination (*Carter &Scollo, in press*).

Cost impact on States/Territories

During the same period, organisations such as the National Heart Foundation, state cancer councils and State Government funded Quit campaigns also conducted numerous activities aimed at encouraging and assisting experimenting and established smokers to quit. These included:

- advertising in the media, predominantly using advertising materials produced for the National Campaign;
- public relations activities aimed at attracting coverage in local, state-wide or national media;
- telephone counselling and courses to assist people to quit; and
- distribution of materials through newsletters, community and workplace displays and through health professionals.

Based on a survey of State/Territory organisations involved, expenditure on these activities and related administrative costs over this period totalled $3.7 million. Expenditure over the period was thought to be roughly equal to that in previous years. (Precise details on expenditure between April and November in previous years were not available.) However, in 1997 a much greater proportion of expenditure than in previous years would have been spent on advertising broadcast and smoker counselling as opposed to production of materials, and staff and other administrative costs. This resulted both from the greater use of national advertising and educational resources, and the more efficient utilisation of services. Local telephone counselling staff for instance reported spending more time handling calls, and waited less time between callers than in previous state-based campaigns. Carter and Scollo (*2000*) were not able to quantify precisely the additional broadcasts and the service utilisation attributable to the NTC. They assumed that the value of such activities was around $1.85m or 50% of total expenditure. They believed this to be a (conservatively) high figure that is an over-estimate the cost of these resources. Their estimate has been used in the PBMA calculations.

Cost offsets

As with the estimates for the DALY and PYLS[75], the calculation of the cost offsets is based on the reduction in disease incidence predicted from the fall in smoking prevalence. The same percentage fall in new cases is used and applied on this occasion to the estimated health care costs attributed to the selected diseases. The methodologies used in the Carter and Scollo (*2000*) study and the PBMA trial to estimate cost offsets were the same, except for the choice of discount rate; the number of diseases included; and adjustment for the impact of the smoking prevalence trend on cases attributable to smoking.

The estimate of health care costs attributed to the specified diseases is taken from the "*Disease Costs and Impact Study*" (DCIS) (*Mathers et. al., 1998a; 1998b; 1999a; 1999b*). The health sector costs are

based on 'direct costs' only (i.e. expenditure on hospital services, medical services, pharmaceuticals, allied health services and nursing homes) and do not include 'indirect costs' (ie production losses due to ill health) or any dollar valuation of pain and suffering. The 1989/90 estimates were chosen, as this was the year for which data on all the diseases of interest was available. DCIS data for some of the diseases is available for a later reference year (1993/94) and confirmed the validity of the 1989/90 estimates for the purposes of this evaluation.[52]

The disease cost estimates for the year 1989/90 were inflated to our 1996 reference year using the health care deflator (*AIHW, 1998*). The cost offset is then calculated by applying the percentage reduction in new cases for the specified diseases in 2001 (diseases with a 5 year lag); 2006 (diseases with a 10 year lag) and 2016 (diseases with a 20 year lag) to the corresponding 1996 disease cost estimates. This calculation uses the estimate of the current average cost of care to compute future cost offsets. This assumes that the current relationship between cost and incident cases does not change through time. It also assumes that the "average cost" is representative of the costs of care for the prevented cases. The cost offset is then expressed in present value terms utilising a 3% discount rate.

The disease cost estimates utilised are likely to be a conservative estimate for two reasons. First, because the reference year probably involves lower real costs of care than might be expected in the future when the savings will be realised due to changes in demography (population growth and ageing), and more expensive technology. Second, because the DCIS methodology used for the 1989/90 estimates provides a conservative estimate of current disease management costs, incorporating approximately 70% of recurrent health care expenditure (*AIHW, 1996*).

Countering these conservative effects, the cost offset estimates based on the DCIS data may be overstated for two reasons. First, DCIS is based on a 'prevalence approach' (i.e. total expenditure in 1989/90 on all *existing* cases in 1989/90) rather than an 'incidence' approach (present value of total expenditure- in 1989/90 and beyond- for complete care of all *new* cases in 1989/90). The prevalence/incidence distinction is relevant because health promotion programs like the NTC typically prevent new cases from occurring, rather than impact on existing disease. To the extent that disease episodes are of a short duration, prevalence-based costings give similar estimates to the incidence-based costings. In the case of our selected diseases, this will vary from disease to disease. Second, the disease cost estimates cover expenditures by the public sector (ie the Commonwealth and State/Local Governments) as well as the private sector (ie private health insurance, individuals, workers compensation and motor vehicle insurance). Depending on the perspective of the study, not all of the estimated cost offset might be deemed relevant for inclusion. The Government share[53] of health sector expenditure is typically around 68%, with the Commonwealth Government funding two-thirds of this. From a strict "Commonwealth" perspective, therefore, it could be argued that only 45% of total offsets is relevant, that is, will impact on Commonwealth Government expenditures.

It is difficult to predict with any certainty the net effect of these offsetting biases. For this reason the cost offset is reported separately so that its impact under alternative assumptions can be examined.

Cost Effectiveness Results

The cost, outcome and cost effectiveness results for the NTC from the two studies are shown in Table 46. The PBMA trial results and the adjusted Carter and Scollo (*2000*) results (adjusted for discount rate and number of diseases included) are very similar, suggesting that the DALY outcome measure has performed soundly in estimating expected benefit. The DALY measure also allows morbidity

[52]For example, the 1989/90 estimate for lung cancer (inflated to 1993/94 prices) was $92.3M compared to the 1993/94 estimate of $98.9M. The 1989/90 estimate for stroke was $578.7M (inflated to 1993/94 prices) compared to the 1993/94 estimate of $595.5M and the 1989/90 estimate for coronary heart disease was $1138.7M (inflated) compared to the 1993/94 estimate of $1462.4M.

[53] Of the one-third non-government share, private health insurance covers approximately 35%, direct patient contributions 51% and workers compensation/ transport accident insurance 14%.

benefits to be estimated, enabling cost utility results (ie cost per quality adjusted life year (QALY) to be provided. The adjusted Carter and Scollo (*2000*) measure of "years of life saved (YLS) to age 75" is, as expected, larger than the PBMA estimate, as it does not include an adjustment for the impact of the downward trend in the prevalence of smoking on future disease incidence attributable to smoking.

The message from both studies is very similar – the NTC represented a very good buy. On the basis of the assumptions used, the 1997 first phase of the NTC should prevent approximately 920 premature deaths; achieve over 3,000 additional years of life prior to age 75 (discounted at 3%); and yield cost offsets of approximately $35 million (PV).

These results suggest that the first phase of the NTC should achieve substantial health status improvements and pay for itself more than twice over. Because the project case in this study (ie the NTC) is "dominant" over the comparator (ie no NTC), meaningful cost effectiveness ratios can only be expressed if the cost offsets are excluded. Ignoring the cost offsets, the incremental cost effectiveness ratios for the NTC from the Commonwealth perspective are approximately $7,700 per premature death averted and $2,160 per $PLYS^{75}$ (discounted). From the broader health sector (public) perspective – that is including the resource commitment by the State/Territory Quit campaigns and partner organisations, the incremental cost effectiveness ratios are approximately $9,700 per premature death averted and $2,700 per $PYLS^{75}$ (discounted at 3%).

Note that these results are presented in cost per outcome terms appropriate for comparing the Carter and Scollo (*2000*) study and the PBMA result. To compare the PBMA result for the NTC with other interventions evaluated in the PBMA trial, the cost per DALY (all ages) would need to be used, that is, $844 per DALY (cost offsets excluded).

Even with the substantial cost offsets excluded, these are still impressive results. In the sensitivity analysis of the Carter and Scollo study, the results were robust to pessimistic cost and outcome variations. In the PBMA trial the @RISK simulation package was used to place upper and lower bounds on the cost, outcome and cost effectiveness results. The simulation results are reported in Table 47, together with the variations tested. The cost per YLS to age 75 varies between $1,711 and $3,879 (cost offsets excluded) for the broader health sector (public) perspective, confirming the strong economic credentials of the NTC.

Table A45 Comparison of Cost Effectiveness Results from the PBMA Trial and the Carter and Scollo (*2000*) Study

	PBMA Trial	Carter & Scollo (2000) (unadjusted)	Carter & Scollo (2000) (adjusted)[1]
Costs:			
To Commonwealth	$7.1 million	$7.1 million	$7.1 million
To States et al	$1.85 million	$1.85 million	$1.85 million
Cost Offsets	$39.07 million	$24.2 million	$37.8 million
Benefits:			
Years of Life Saved (to Age 75)	3,280	2,287	3,685
DALYs (to age 75)	5,562	n/a	n/a
DALYs (all ages)	10,599	n/a	n/a
Cost Effectiveness Ratios (cost offsets excluded):			
Cost per YLS[75]	$2,725 ($2,165 C'wealth only)	$3,913 ($2,287 C'wealth only)	$2,429 ($1,926 C'wealth only)
Cost per DALY[75]	$1,609	n/a	n/a
Cost per DALY (all ages)	$844	n/a	n/a

Notes:

1. Adjusted using the sensitivity analysis in the Carter & Scollo (2000) study to reflect a 3% discount rate and inclusion of all smoking-related diseases

Table A46 Sensitivity Results for the PBMA Trial Analysis Using the @RISK Simulation Package

Study Parameter	Point Estimate	Lower Bound	Upper Bound
Benefits:			
DALYs (all ages)	10,599	7,583	13,626
YLL (all ages)	7,136	5,036	9,243
DALY (to age 75)	5,562	3,954	7,178
YLL (to age 75)	3,280	2,273	4,292
Costs of NTC			
To Commonwealth	$7.1 million	$5.5 million	$8.7 million
To States et al	$1.85 million	$1.43 million	$2.2 million
Cost Offsets	$39.1 million	$27.4 million	$53.4 million
Cost Effectiveness Ratio (Cost Offsets Excluded)			
Cost per DALY (to age 75)	$1,609	$1,032	$2,255
Cost per YLL (to age 75)	$2,729	$1,711	$3,879
Cost per DALY (all ages)	$844	$544	$1,180

Notes: The @RISK uncertainty analysis assumes:

- uniform variation in lag times of: cancers (10-20 yrs); CVD & other 5 year lag diseases (2-8 yrs); COPD (5-15 yrs);
- uncertainty RR estimates: 1 + (RR-1)*risknormal (1,0.05);
- uniform variation in costs of +/- 20%
- uniform variation in impact on smoking prevalence of 1.2-2.4% for men and 0.67-1.33% for women.

Discussion of Results

The cost per DALY results confirms the economic credentials of the NTC in terms of the first stage health benefit. Assessment of the NTC in terms of the second stage filters is set out below.

Equity

The results of the surveys on the impact of the NTC indicated that the positive effects applied to males and females, to older and younger smokers and to all levels of educational attainment and occupational status. Where relative differences in change were observed, these mainly served to minimise the differences between sub-groups, which had previously existed at benchmark. A similar pattern of findings was observed in each State (*Hassard, 1999*).

While not the subject of the 1997 NTC evaluated, it is worthy of note that the ongoing NTC program has made specific attempts to address the appropriate communication strategy for non-English speaking peoples. In February 1998, for example, a specific strategy was launched in recognition of the particular characteristics of smoking prevalence among different ethnic groups (*Hassard, 1999*). Similarly, attempts are being made to develop a National Indigenous Smoking Strategy and to address the effectiveness of the NTC for indigenous communities. Given the importance placed on equity in this and other evaluations, these initiatives aimed at addressing specific target groups seem appropriate should be encouraged.

In summary, consideration of the equity filter does not impact adversely on the ranking of the NTC and current efforts to fine-tune the NTC for the needs of specific disadvantaged groups.

Size of the problem

Smoking, both active and passive exposure is commonly acknowledged as the most important source of preventable disease and health care expenditure in Australia. It is difficult to think of a more important risk factor from a public health perspective. Consideration of the size of the problem filter increases the weight that would be given to a successful intervention to modify smoking as a risk factor.

Level of evidence

The causal links between smoking and disease is now firmly established by "sufficient well-designed research". Effectiveness of the NTC in modifying smoking behaviour is demonstrated by evidence from behavioural pre and post campaign survey research.

Consideration of the level of evidence filter does not impact adversely on the ranking of the NTC initiative.

Acceptability to stakeholders

Continuation and development of the NTC is likely to be widely acceptable to a broad range of stakeholder groups concerned with public health in Australia. Smoking cessation initiatives are strongly supported by medical providers, the anticipated cost offsets are substantial (releasing health care resources for the treatment of non preventable disease) and the general community is more appreciative of efforts to discourage smoking.

The appraisals reported here were undertaken from the perspective of the Commonwealth government, as well as from a broader perspective that includes the State/Territory Quit campaigns and their partner organisations. This "funder / provider" perspective excludes costs impacting on

individual smokers in seeking to quit. The impact of costs falling on individuals on the cost effectiveness of the NTC is, however, approximated in the sensitivity analysis of the Carter and Scollo (*2000*) study. This specification also eliminates consideration of significant benefits accruing to individuals (eg. cost of cigarettes; gap payments on health services; dry cleaning) and to the business sector (eg. absenteeism; special provisions for smokers). A broader societal perspective is likely to yield a stronger cost effectiveness result for the NTC than that indicated by this study.

Consideration of the acceptability filter reinforces the importance of maintaining the NTC.

Feasibility

As an existing intervention, the NTC is clearly a feasible intervention. One of the more outstanding aspects of the campaign concerns the value of cooperative partnerships between the Federal and State/Territory jurisdictions and the interested non-government organisations. A timely injection of Commonwealth funds, combined with the cooperative partnerships helped to forge a truly "National" effort in tobacco control.

Option: Encourage Consumption of Fruit and Vegetables (Increment)

The Intervention

Background

There is increasing evidence that high consumption of fresh fruit and vegetables offers protection against many forms of cancer and coronary heart disease (*Ziegler, 1991; Block et al., 1992; Tavani and La Vecchia, 1995; Rimm et al., 1996; Steinmetz and Potter, 1996; Miller et al., 1997; NZMOH, 1999; Baghurst et al., 1999*). It is generally recommended that adults consume between 5 and 9 servings of fruit and vegetables daily. Dietary surveys in Australia indicate that a high proportion of Australian adults and children do not consume these amounts (*Baghurst et al., 1987; McLennan W & Podger A, 1999*) and thus may be at increased risk of developing cancer, ischaemic heart disease and stroke over their lifetime.

While increased fruit and vegetable intake is not a National Health Priority, the recent National and Victorian burden of disease studies reported that approximately 10% of all cancers and 2.8% of the total burden of disease are attributable to insufficient intake of fruit and vegetables (*Mathers et al., 1999; Vos & Begg, 1999a,b*). These reports highlight the important impact that this risk factor has on the health of the population. There are important differences between the intake of fruit and vegetables by both gender and age. In general, women[54] consume more serves of fruit and vegetables than males and younger males consume less than older males.

There have been two major fruit and vegetable interventions in Australia – the Western Australia "*2 Fruit 'n' 5 Veg*" campaign and the Victorian "*2 Fruit 'n' 5 Veg Every Day*" campaign. The Victorian campaign was modeled on the Western Australian intervention. Both campaigns used multiple strategies, including mass media and community-based consumer education to encourage an increase in fruit and vegetable intake. The evaluations of both campaigns focused on changes in consumer knowledge, attitudes and consumption of fruit and vegetables. Economic appraisals were not undertaken.

In this study, cost-utility and cost effectiveness analysis is undertaken comparing the anticipated impact of a *National* "*Fruit 'n' Veg*" campaign with the status quo. The analysis is based on a number of simplifying assumptions (reflecting the state of available data) and should be regarded as generally indicative of the likely economic credentials of this intervention, rather than as a rigorous estimate.

Description

The strategy for evaluation is a broadly based, multi-level, National "*Fruit 'n' Veg*" promotion modeled on the Victorian campaign. The Victorian campaign was jointly funded by public sector health agencies and the food industry and represented the first coordinated approach to the promotion of fruit and vegetables in Victoria. Table 48 summarises the promotional strategies of the campaign across the 4 phases of its operation.

[54] The accuracy of this statement is subject to challenge. Women may eat more serves than men, but in terms of total quantity men may eat more. A different picture emerges depending on whether researchers use food frequency questionnaires; verses 24-hour recall; verses weighted records.

Table A47 Summary of Strategies for Victorian "*2 Fruit n 5 Veg*" Campaign

Promotional activity	Phase 1 (1992)	Phase 2 (1993)	Phase 3 (1994)	Phase 4 (1995)
Television advertising	X	X	X	
Radio advertising		X		
Print advertising	X	X		
Transit advertising	X			
Sports/arts sponsorships	X	X		
Point of sale promotions	X	X	X	
Other/public relations	X	X	X	X

Source: Adapted from Dixon et al., 1998

A central feature of the campaign was a short, intensive burst of television advertising, conducted over a 3 week period in the first 2 phases and for 1 week in the third phase. In addition to targeting of consumers directly[55] through television advertising, community-based health and education professionals, food retailers and food service providers were also targeted as potential vehicles to influence the population's consumption of fruit and vegetables. A variety of point-of-sale materials, which included cookbooks, recipe cards and posters were distributed through food retailers across the state. Health and education professionals were notified of the campaign via mail-outs summarising the campaign and suggesting ideas for community level promotional strategies.

The evaluation of the campaign was based on an annual post-campaign survey of consumer responses, which included questions designed to examine public awareness and reactions to the "*2 Fruit 'n' 5 Veg*" campaign, beliefs about desirable eating habits for fruit and vegetables, and reported consumption of fruit and vegetables (*Dixon et al., 1998*). A commercial research centre conducted the surveys using a computer-assisted telephone interviewing system. Approximately 500 persons were approached each year with annual response rates varying between 64% (Phase 1) and 44% (Phase 4).

The Health Benefit

The health benefit is measured in DALYs to ensure consistency with the other interventions assessed in the PBMA trial. The DALYs associated with inadequate intake of fruit and vegetables and the change after implementation of the campaign have been derived by adapting the methodology from "*The Burden of Disease and Injury in Australia*" (Mathers, Vos and Stevenson, 1999) and "*The Victorian Burden of Disease Study: Mortality*" (*Vos and Begg, 1999*). In addition to health benefits, cost offsets associated with a reduction in future disease were calculated (refer 5.8.3).

The health benefit was estimated for Victoria and prorated up for Australia. The estimates should be regarded as preliminary and indicative. The calculation involved the following steps:

- estimation of the BOD associated with inadequate intake of fruit and vegetables by age and gender after the implementation of the fruit and vegetable campaign (the "with intervention" scenario);

- estimation of the BOD associated with inadequate fruit and vegetable intake by age and gender under the assumption that the observed change in the prevalence of fruit and vegetable intake had not taken place (the "without intervention scenario"); and

[55] Phase 1 of the program focused on women with children, Phase 2 on adults aged 16 to 54 years with Phase 3 targeting men aged between 18 and 34 years of age.

- calculation of the resulting net health benefit attributable to the intervention.

The diseases causally related to inadequate fruit and vegetable intake were defined as "all cancers"; "ischaemic heart disease" and "stroke." The impact of the campaign on fruit and vegetable intake was assumed to occur in the year of the campaign (1996), with the reduction in disease incidence lagged according to the individual disease causality. For the purposes of this indicative study it was assumed that the time lags for all forms of cancer was 15 years (with a range of 10 to 20 years used in sensitivity analysis) and 5 years (range 2 to 8 years) for ischaemic heart disease and stroke.

Because there are considerable secular changes in incidence and mortality of cancers and cardiovascular diseases, the BOD estimates were estimated for the years when the incidence impact was anticipated. Thus the impact on cancer is derived from the projected burden of disease figures for the year 2011[56] and the impact on cardiovascular disease (CVD) from the projections for 2001[57]. The change in the burden attributable to inadequate intake of fruits and vegetables was then discounted back to the reference year for the PBMA pilot (1996) to obtain the value of the health benefits in the baseline year of analysis.

Estimating the impact of the "*Fruit n Vegetable*" campaign on intake

The target groups for the Victorian "*2 Fruit 'n' 5 Veg Every Day*" campaign varied across the 3 phases of the program. The analysis provided by Helen Dixon of the Centre for Behavioural Research in Cancer (CBRC) of the ACCV provided changes in fruit and vegetable intake based on the 20-24, 35-34, 35-49, 50 years and over age groups (see Table 49). From these figures, sex specific estimates of change in fruit and vegetable intake were estimated for the age categories used in the BOD study (15-24, 25-34 ...75+) by linear extrapolation (Table 49). Prevalence estimates for the "with intervention" scenario were obtained by a linear extrapolation of the change in baseline results from the *'2 Fruit 'n' 5 Veg Every Day'* campaign. Of note is the higher prevalence in males and that males between ages 25 and 44 years of age consume the least serves. For both genders, inadequate intake decreases with increasing age.

Table A48 Summary of Change in % of Persons with Inadequate Intake of Fruit and Vegetables Phases 1 to IV of Victorian '*2 Fruit 'n' 5 Veg Every Day*' Campaign

Gender	Ph I	Ph IV	% Change
Males	74%	66%	12%
Females	50%	47%	6%
Age	Ph I	Ph IV	% change
20-24	72%	68%	6%
25-34	64%	61%	5%
35-49	59%	57%	4%
50+	55%	50%	10%

Table 50 summarises the estimates of the prevalence of inadequate fruit and vegetable intake prevalence for the 'with' and 'without' intervention scenarios.

[56] Incorporating the estimated lag time of 15 years after the base line year 1996, together with a 3 year survival factor.
[57] Incorporating the estimated lag time of 5 years after the base line year of 1996, together with a 2 year survival factor.

Table A49 Prevalence of Inadequate Intake of Fruit and Vegetables in Victoria (from 1995 National Nutritional Survey) and Estimates of the Prevalence in the "Without Intervention Scenario"

Age Group	Males			Females		
	1995	"without intervention"	Difference	1995	"without intervention"	Difference
25-34	67.5%	71.8%	4.3%	60.5%	62.6%	2.1%
35-44	70.0%	73.2%	3.2%	56.0%	57.4%	1.4%
45-54	58.0%	61.9%	3.9%	54.0%	55.9%	1.9%
55-64	55.0%	62.2%	7.2%	46.0%	49.2%	3.2%
65-74	56.0%	63.3%	7.3%	47.0%	50.2%	3.2%
75+	59.0%	66.7%	7.7%	50.0%	53.4%	3.4%

Note: Inadequate intake is defined as consuming less than 5 serves in total of fruit and vegetables (not including juices)

The original published analysis for this campaign (*Dixon et al., 1998*) was based on the change in consumption from baseline using a threshold acceptable fruit and vegetable intake of 2 or more serves and 5 or more serves respectively. To ensure consistency with the epidemiological evidence attributing risk of disease with inadequate fruit and vegetable intake, Dixon (*1998*) re-analysed baseline and post campaign intake of fruit and vegetables (not including juices) for us to use five serves of fruit and vegetables in total as the threshold of acceptable intake. This definition of an adequate intake is also in line with the BOD studies that constitute the basis for our DALY estimates.

Estimation of the BOD associated with intake of fruit and vegetables

Table 51 summarises relative risk estimates for cancer, ischaemic heart disease and stroke related to an inadequate intake of fruit and vegetables. These estimates were based on the New Zealand Ministry of Health (*NZMOH*) review of relevant epidemiological studies.

Table A50 Relative Risk Estimates for Disease Associated with Inadequate Intake of Fruit and Vegetables by Age

Relative risks	<45	45-64	65-74	75+
All cancers	1.40	1.30	1.20	1.10
Ischaemic heart disease	1.18	1.18	1.10	1.00
Stroke	1.18	1.18	1.10	1.00

Source: NZMOH, 1999

The relative risk estimates together with prevalence estimates of inadequate intake of fruit and vegetables consumption based on the 1995 National Nutrition Survey were used to derive attributable fractions for these conditions for the "without" intervention scenario. Prevalence estimates for the "with intervention" scenario were obtained by a linear extrapolation of the change in baseline results from the "*2 Fruit 'n' 5 Veg Every Day*" campaign.

Table 52 provides estimates of attributable fractions for 1996 in Victoria (the "with intervention scenario") and the hypothetical "without intervention scenario" in 1996 if the campaign had not taken place. In line with prevalence data, the attributable fractions are higher for males than females at each age category. For example, in males aged 25-34, 21.3% of all cancers are directly attributable to an inadequate intake of fruit and vegetables. The corresponding figure for females is 19.5%.

To estimate the proportion of disease directly attributable to an inadequate intake of fruit and vegetables, the total burden of a specific disease is multiplied by the attributable fraction associated

with either the "with intervention" and "without intervention" scenarios. The health benefit of a screening program is derived from the difference between the BOD with and without a fruit and vegetable campaign program. Tables 53 and 54 summarise the results. The resulting health benefit was estimated to be 222 deaths averted, 2,640 YLS and 3,626 DALYs averted. An inadequate intake of fruit and vegetables was estimated to be responsible for 3.1% of total deaths and 2.8% of total DALYs in Victoria for 1996.

Table A51 Attributable Fraction by Age, Gender and Disease in the "with intervention" and "without intervention" scenarios

	"With intervention Scenario"		"Without intervention" Scenario		Change in attributable fraction	
Age and Disease	**Males**	**Females**	**Males**	**Females**	**Males**	**Females**
All cancers						
25-34	0.213	0.195	0.223	0.200	0.011	0.005
35-44	0.219	0.183	0.227	0.187	0.008	0.004
45-54	0.148	0.139	0.157	0.144	0.008	0.004
55-64	0.142	0.121	0.157	0.129	0.016	0.007
65-74	0.101	0.086	0.112	0.091	0.012	0.005
75+	0.056	0.048	0.063	0.051	0.007	0.003
Ischaemic heart disease and stroke						
25-34	0.108	0.098	0.115	0.101	0.006	0.003
35-44	0.112	0.092	0.116	0.094	0.005	0.002
45-54	0.095	0.089	0.100	0.091	0.006	0.003
55-64	0.090	0.076	0.101	0.081	0.011	0.005
65-74	0.053	0.045	0.060	0.048	0.007	0.003
75+	0.000	0.000	0.000	0.000	0.000	0.000

Table A52 Difference in BOD Comparing "with intervention" and "without intervention" Scenarios

Disease	Deaths	YLL	YLD	DALY
Cancer				
Males	135	1486	467	1966
Females	48	624	177	805
Persons	183	2109	644	2771
Ischaemic heart disease				
Males	27	364	136	506
Females	4	65	27	94
Persons	32	430	163	600
Stroke				
Males	6	78	109	196
Females	1	23	34	60
Persons	7	101	143	256
Total				
Males	168	1928	711	2668
Females	54	712	239	959
Persons	222	2640	950	3626

Table A53 Difference in BOD by Age and Gender Comparing "with intervention" and "without intervention" scenarios

Age Group	Deaths	YLL	YLD	DALY
Males				
25-34	1	26	10	37
35-44	3	66	13	79
45-54	8	161	55	218
55-64	45	692	258	960
65-74	66	709	272	993
75+	45	274	102	380
Total	168	1928	711	2668
Females				
25-34	1	16	6	22
35-44	1	37	10	47
45-54	4	82	28	110
55-64	14	245	81	329
65-74	17	214	82	299
75+	17	118	32	151
Total	54	712	239	959
Persons				
25-34	2	42	16	59
35-44	4	103	24	127
45-54	12	243	83	329
55-64	59	937	339	1289
65-74	83	923	354	1292
75+	62	392	134	531
Total	222	2640	950	3626

The Health Service Costs

Cost of the intervention

Little information is available on the full cost of the implementation and operation of the Victorian "*Fruit 'n' Vegetable*" campaign. The only published costing data was for TV advertising - $163,480, $163,064 and $50,000 for Phases 1-3 respectively – a total of $376, 544. Estimates of the cost of the Western Australia campaign are $840,0000 over 5 years, excluding the costs of staff. Discussions with persons involved in the Victorian and Western Australia campaigns indicate that the additional costs of staff and other related costs would amount to at least twice the cost of the media buy.

In 1999 it was estimated that the cost of developing and implementing a campaign to promote fruit and vegetables in New South Wales was between $592,620 and $1,113,100 depending upon whether the materials were developed from scratch or whether strategies and materials already developed in Western Australia and Victoria were used. A breakdown of the estimates for individual component costs is shown in Table 55.

Table A54 Estimated Cost of Conducting a Fruit and Vegetable Campaign in New South Wales: Generic Campaign Versus '2 *Fruit and 5 Veg*' Campaign.

Cost Components	Annual Cost ($1999) generic fruit & vegetable campaign	Annual Cost ($1999) "2 Fruit 'n' 5 Veg Every Day"
Production	525,000	$10,000 - $50,000 depending on numbers printed
• TV advertisements	280,000	Supplied
• Radio advertisements	8,000	Supplied
• NESB pamphlets (10 language versions)	38,000	Printing costs only
• Cook book	110,000	Printing costs only
• Point of sale	56,000	Printing costs only
• Qualitative research (TV ads and other resources)	33,000	Printing costs only
PR	25,000	25,000
Media	407,600	407,600
• State TV	330,000	330,000
• SBS	12,600	12,600
• Regional radio	33,000	33,000
• NESB Newspapers	19,000	19,000
• NESB Radio-2UE	13,000	13,000
Campaign analysis, research and evaluation	55,000	30,000
Staff @ 2 FTE	100,000	100,000
CAMPAIGN TOTAL	**1,113,100**	**592,620**

For the purposes of this preliminary analysis, it was assumed that the annual cost of a national campaign, including staff, would be between $3.2 million and $1.71 million (depending upon whether a generic campaign or a campaign based on the Victorian and Western Australia campaigns was undertaken). The New South Wales estimate was adjusted by a factor of 2.94 to reflect the size of the Australian population relative to the New South Wales population. A price deflator was also used to adjust prices from 1999 to 1996 values.

Calculation of the cost offsets

As with the estimates for the DALY and YLL, the calculation of the cost offsets was based on the reduction in disease incidence predicted from the reduction in the proportion of persons who consumed an inadequate amount of fruit and vegetables. The same percentage fall in new cases of disease (refer Table 52) and time lags are utilised -- this time applied to the estimated health care costs attributed to the selected diseases. The estimate of the healthcare costs attributed to specified diseases is taken from the Disease Costs and Impact Study (*Mathers et al., 1998a; 1999a*). The health sector costs are based on 'direct' costs only (ie expenditure on hospital services, medical services, pharmaceuticals, allied health services and nursing homes) and do not include 'indirect' costs (i.e. production losses due to ill health) or any dollar valuation of pain and suffering. The future cost savings were discounted by 3% per annum to present value using an exponential function consistent with the DALY estimates.

The results are set out in Table 56. The estimated cost offset from the introduction of a National "*Fruit 'n' Veg*" campaign is $14.6 million (PV: 1996). The intervention should, therefore, more than pay for itself in terms of preventable disease costs. The difficulty is to determine with any precision by how

much health care costs change after the provision of a primary prevention program. The best case scenario is that costs change in the same proportion as the estimated fall in incidence. This is the assumption behind the estimates in Table 56.

Table A55 Health Care Cost Offsets Attributable to National "*Fruit 'n' Veg*" Campaign

Disease and specified age groups	Health Sector Costs[1] $ Millions	Saving (Gross) $ Millions	Discount factor	Saving (Discounted) $ Millions
All Cancers				
Male	835.4	9.76	0.638	6.23
Female	948.7	4.89	0.638	3.12
All Persons	1784.1	14.65	0.638	9.35
IHD & Stroke				
Male	838.5	4.64	0.934	4.34
Female	682.7	0.98	0.934	0.92
All Persons	1521.2	5.62	0.934	5.26
Total				
Male	1673.9	14.40		10.57
Female	1631.4	5.87		4.04
All Persons	3305.3	20.27		14.61

Key:

[1] Health Sector Costs are based on the *year 1993/94 and are taken from Table 6 of "Health System Costs of Cancer in Australia: 1993/94" (Mathers et al., 1998)* and Table C12 & C20 of *"Health System Costs of Cardiovascular Diseases and Diabetes in Australia 1993/94" (Mathers & Penm, 1999)*. In this indicative study the estimates were not inflated to 1996 values (the reference year), but the inflator involved (1.09) would make little difference to the estimates.

The Cost Effectiveness Results

Table 57 summarises the health gain, cost and average C/U and C/E ratios for a National "*Fruit 'n' Veg*" campaign compared to the status quo.

Table A56 The Incremental Benefits, Costs and Cost Utility/Effectiveness Results for the Introduction of a National "*Fruit 'n' Veg*" Campaign

Variable	Result
Health Benefit	
YLL	2,640
YLD	950
DALY	3,626
Deaths averted	122
Costs	
Program costs ($millions)	$2.46 (mid-point of range)
Cost Offsets ($ millions)	$14.61
Net Cost of Intervention ($millions)	$12.15 (saving)
Cost Utility/Effectiveness Result	
$/YLL (no offsets)	$930
$/DALY (no offsets)	$677
$/death averted (no offsets)	$11,607
$/YLL (with offsets)	Dominant
$/DALY (with offsets)	Dominant

The mid-point of the cost estimate range ($2.46 million) was used to derive the base case cost effectiveness ratios. From the Government perspective, the program is highly cost effective. With cost offsets included the intervention is "dominant", that is, it both saves money and reduces the health burden. With the cost offsets excluded, the option still yields very strong cost effectiveness results with $930 per YLL and $677 per DALY.

Sensitivity analysis

A probabilistic sensitivity analysis was performed using the @RISK software. Results are presented in Table 58, taking into account key sources of uncertainty in terms of both program costs and effectiveness. The cost offsets were not included in this analysis. Estimates of the mean score as well as lower and upper estimates of the uncertainty interval are presented. The major sources of uncertainty for simulation were specified as:

1. uncertainty about the impact on prevalence of people eating 5 or more serves a day: assumed a uniform distribution between 0% and impact measured between phase I and IV of Victorian campaign[58];
2. uncertainty around costs of a National campaign: ranging from a lower estimate of $1.71 million to a high estimate of 3.2 million;
3. uncertainty about the relative risk estimates of health impact: assumed a triangular distribution +/- 25%; and
4. uncertainty about lag times: assumed a uniform distribution between 10-20 years to onset of cancer (add 3 years average survival for cancer death) and 2-8 years for ischaemic Heart Disease (IHD) and stroke (add 2 years average survival for deaths).

[58] This variation adequately covers concern stemming from the fact that the Victorian result went against the national trend indicated by the ABS food disappearance data for fruit and vegetables over that time.

Table A57 Sensitivity Analysis: Incremental Cost effectiveness Ratios (cost offsets excluded)

Outcome Measure	Mean estimate	Uncertainty interval	
		Lower limit	Upper limit
Cost per DALY	$8,308	$513	$16,392
Cost per YLL	$11,447	$700	$22,524

The cost effectiveness ratios are most sensitive to the assumption of uncertainty around the measure of impact on the prevalence of Fruit & Veg intake, with a rank correlation coefficient of -0.94. The results are much less sensitive to the assumptions about the uncertainty in costs with a rank correlation coefficient of 0.26 and the uncertainty modeled around the estimates of relative risk with a correlation coefficient of -0.13.

Discussion of Results

The cost per DALY results confirms the economic potential of a National "*Fruit 'n' Veg*" campaign in terms of the first stage health benefit. Assessment of the intervention in terms of the second stage filters is set out below.

Equity

There are important differences between the intake of fruit and vegetables by both gender and age. In general, women consume more serves of fruit and vegetables than males and younger males consume less than older males. Analysis in terms of the four equity target groups was not readily available. Analysis of the behavioural changes in the Victorian population suggest that both men and women respond to the campaign, with larger improvements in adequate fruit and vegetable intake occurring in men (i.e. 12% improvement in men compared to 6% in women). Similarly, all age groups respond to the campaign, but the improvements are larger in persons aged 50 and over. The Victorian results suggest that a National campaign should have the impact of lessening existing inequities in the distribution of "inadequate fruit and vegetable intake" as a risk factor.

In summary, consideration of the equity filter does not impact adversely on the ranking of this intervention.

Size of the problem

The diseases causally related to inadequate fruit and vegetable intake are major causes of premature mortality and morbidity. The recent National and Victorian burden of disease studies reported that approximately 10% of all cancers and 2.8% of the total burden of disease are attributable to insufficient intake of fruit and vegetables (*Mathers et al., 1999; Vos & Begg, 1999*). These reports highlight the important impact that this risk factor has on the health of the population.

Consideration of this filter endorses the significance of action in this area.

Level of evidence

The causal links between inadequate intake of fruit and vegetables with cancer and IHD/stroke is established by "sufficient well-designed research." There is "limited evidence of effectiveness" to support the "*Fruit 'n' Veg*" campaign in modifying behaviour. Given the potential significance of an effective national campaign and its anticipated economic credentials, the available evidence is

considered sufficient to sustain the proposed intervention.

Acceptability and feasibility

The proposed intervention is likely to be acceptable to key stakeholders. It is a low cost intervention for the Government, which does not impose significant expense on the community. A National program is certainly feasible, with two State campaigns to model a National intervention on.

A National "*Fruit 'n' Vegetable*" campaign is unlikely to be rejected on acceptability or feasibility grounds.

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Survey of Cancer Strategy Group Members

Please return the completed questionnaire in the reply-paid envelope to the Commonwealth Department of Health and Aged Care by no later than **Friday 10 September 1999**.

If you have any questions, please contact Mr. Steve Nerlich on telephone: (02) 6289 7359.

The example given on this page indicates how we wish you to mark your responses on the questionnaire.

Further instructions are provided on the next page also.

We really appreciate your help in completing this questionnaire.

1.1.1.1.1.1.1 Example

Score against eight criteria
Please provide a score between 1 and 5 for each cancer control action against each of the eight criteria where:
1 is the lowest score (i.e. the cancer control action scores poorly against this criterion), and;
5 is the highest score (i.e. the cancer control action scores well against this criterion).

	Effectiveness Size of problem	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	**Overall Importance**
System-wide changes							
1.1 Identify and reduce activities in cancer control that are harmful, useless or of unknown, but probably low, efficacy.	☐	☐	☐	☐	☐	☐	☐
1.2 Evaluate new technologies quickly before they become established in clinical practice	☐	☐	☐	☐	☐	☐	☐

Explanation of Criteria

You are asked to score proposed cancer control actions against eight criteria.

- **size of the problem** each action seeks to address
- ***effectiveness*** of the action (quality of the evidence basis, size of impact on the problem, capacity of the strategy to satisfy consumers)
- **cost** of the cancer control action
- **efficiency** of the cancer control action
- capacity to **reduce inequity**
- **acceptance** by the community
- likelihood of successful **implementation** (because of availability of relevant expertise, budget implications, political issues).
- **Overall Importance** (this criteria provides you with an opportunity to give each cancer control action an overall score)

Scoring

You are asked to place a number in each box that provides a score for each action with respect to each of the eight criteria. The number must be between 1 (lowest score) up to 5 (highest score). Please ensure that you place a number in every box and take advantage of the full range of scoring possible. Remember that:

1 is the lowest score (i.e. the cancer control action scores poorly against this criterion), and;
5 is the highest score (i.e. the cancer control action scores well against this criterion).

Score against the eight criteria

Please provide a core between 1 and 5 for each cancer control action against each of the eight criteria where 1 is lowest and 5 is highest score.
(Please refer to the full definition of each criteria provided on the previous page)

		Size of problem	Effectiveness	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	**Overall Importance**
1	**System-wide changes**								
1.1	Identify and reduce activities in cancer control that are harmful, useless or of unknown, but probably low, efficacy.	☐	☐	☐	☐	☐	☐	☐	☐
1.2	Evaluate new technologies quickly before they become established in clinical practice.	☐	☐	☐	☐	☐	☐	☐	☐
1.3	Develop incentives to reward evidence-based practice.	☐	☐	☐	☐	☐	☐	☐	☐
1.4	Improve the capacity of the system to provide equitable access to highly specialised services for people living in regional areas.	☐	☐	☐	☐	☐	☐	☐	☐
2	**Reducing Smoking Prevalence**								
2.1	Investigate ways to reduce inequalities in health status resulting from the socioeconomic gradient in smoking prevalence.	☐	☐	☐	☐	☐	☐	☐	☐
2.2	Take further regulatory steps to decrease pollution of indoor air with tobacco smoke; decrease uptake of smoking by children and teenagers; increase smoking cessation among adults; and eliminate residual advertising of tobacco products.	☐	☐	☐	☐	☐	☐	☐	☐
2.3	Continue to increase the real cost of tobacco smoking by fiscal means. Overall importance	☐	☐	☐	☐	☐	☐	☐	☐

	Size of problem	Effectiveness	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	**Overall Importance**
3 Increase consumption of fruit and vegetables								
3.1 Identify barriers to change in dietary behaviour.	☐	☐	☐	☐	☐	☐	☐	☐
3.2 Develop evidence-based programs for changing dietary behaviour in ways that will reduce cancer risk.	☐	☐	☐	☐	☐	☐	☐	☐
3.3 Develop economic and regulatory measures that will encourage increased intake of fruit and vegetables.	☐	☐	☐	☐	☐	☐	☐	☐
Where possible, integrate health promotion campaigns across cancer and other lifestyle-related diseases such as cardiovascular disease and diabetes.	☐	☐	☐	☐	☐	☐	☐	☐
4 Reduce the risk of skin cancer								
Develop a national SunSmart program through expansion of existing State and Territory programs.	☐	☐	☐	☐	☐	☐	☐	☐
5 Improve skills in diagnosing skin cancer								
5.1 Develop programs to increase the specificity of general practitioner diagnosis of skin cancer.	☐	☐	☐	☐	☐	☐	☐	☐
Support research into the efficacy of population screening for melanoma.	☐	☐	☐	☐	☐	☐	☐	☐
6. Improve efficiency of cervical screening								
6.1 Investigate the application of human papilloma virus (HPV) testing in cervical screening.	☐	☐	☐	☐	☐	☐	☐	☐
6.2 Review the national cervical screening program and consider:								
➢ increasing the screening interval from two to three years;	☐	☐	☐	☐	☐	☐	☐	☐
➢ reviewing starting to screen women at a later age than the current 20 years;	☐	☐	☐	☐	☐	☐	☐	☐
➢ determining a number of normal smears after which screening should stop.	☐	☐	☐	☐	☐	☐	☐	☐
7. Improve detection of colorectal cancer								
7.1 Develop a population-based screening program for colorectal cancer, based on faecal occult blood testing.	☐	☐	☐	☐	☐	☐	☐	☐
7.2 Research the acceptability and feasibility of such a screening program.	☐	☐	☐	☐	☐	☐	☐	☐

	Size of problem	Effectiveness	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	**Overall Importance**
8 Increase efficiency of breast cancer screening								
8.1 Link the Medicare benefit for mammography outside BreastScreen Australia to referral from an accredited breast assessment or breast cancer treatment service.	☐	☐	☐	☐	☐	☐	☐	☐
8.2 Accredit breast assessment services and introduce appropriate financial benefits for care given by accredited services.	☐	☐	☐	☐	☐	☐	☐	☐
9. Improve outcomes from ovarian cancer								
9.1 Address variation in practice and emerging information on genetic risk, through the development of guidelines and a practice survey.	☐	☐	☐	☐	☐	☐	☐	☐
10. Rationalise prostate specific antigen testing								
10.1 Develop public education programs on the implications of a positive prostate specific antigen (PSA) test to reduce the demand for PSA testing in Australia.	☐	☐	☐	☐	☐	☐	☐	☐
11 Investigate treatment uncertainties in prostate cancer								
11.1 Improve the management of screen-detected prostate cancer through: a prospective audit where participation is linked to payment; monitoring of existing randomised trials comparing treatment with watchful waiting and considering the need for a similar trial in Australia.	☐	☐	☐	☐	☐	☐	☐	☐
11.2 Conduct research to define discriminators of cancer aggressiveness.	☐	☐	☐	☐	☐	☐	☐	☐

	Size of problem	Effectiveness	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	**Overall Importance**
12 Develop guidelines in areas of need								
12.1 Identify and resource the development of clinical guidelines for different cancers in potentially high impact areas.	☐	☐	☐	☐	☐	☐	☐	☐
12.2 Develop guidelines on follow-up of patients who have received potentially curative treatment and financial incentives for adherence to such guidelines	☐	☐	☐	☐	☐	☐	☐	☐
13 Evaluate and facilitate multidisciplinary care								
13.1 Further develop models of evidence-based multidisciplinary care	☐	☐	☐	☐	☐	☐	☐	☐
13.2 Conduct trials of shared care models to identify that will decrease patient travel and the cost of specialist services.	☐	☐	☐	☐	☐	☐	☐	☐
13.2 Conduct trials of shared care models to identify that will decrease patient travel and the cost of specialist services.	☐	☐	☐	☐	☐	☐	☐	☐
14. Improve palliative care								
14.1 Investigate ways to improve the quality of care for people dying from cancer.	☐	☐	☐	☐	☐	☐	☐	☐
14.2 Incorporate training in pain and other symptom control in the education of all health professionals involved in cancer control.	☐	☐	☐	☐	☐	☐	☐	☐
14.3 Develop a palliative care information and advisory network.	☐	☐	☐	☐	☐	☐	☐	☐
14.3 Coordinate activities with the national Palliative Care Strategy 1999-2003.	☐	☐	☐	☐	☐	☐	☐	☐
15. Define, implement and monitor psychosocial care								
15.1 Define elements of appropriate psychosocial care for cancer patients and develop strategies to implement these.	☐	☐	☐	☐	☐	☐	☐	☐

	Size of problem	Effectiveness	Cost	Efficiency	Reduces inequity	Acceptance	Implementation	Overall Importance
16 Promote participation in cancer control within general practice								
16.1 Include generic aspects of caring for patients with cancer in undergraduate medical training.	☐	☐	☐	☐	☐	☐	☐	☐
16.2 Promote general practitioner participation in early diagnosis of cancer through changes to reimbursement and accreditation.	☐	☐	☐	☐	☐	☐	☐	☐
17 Continue the national commitment to research								
17.1 Conduct research into high impact areas of ignorance identified through guideline development.	☐	☐	☐	☐	☐	☐	☐	☐
17.2 Ensure adequate ongoing infrastructure funding for an autonomous national clinical trials research program.	☐	☐	☐	☐	☐	☐	☐	☐
17.3 Monitor and evaluate the impact of advances in molecular genetics on cancer in Australia.	☐	☐	☐	☐	☐	☐	☐	☐
18 Organise education and resources for those with familial cancers								
18.1 Develop State/Territory-based resources for cancer-related genetic advice.	☐	☐	☐	☐	☐	☐	☐	☐
18.2 Ensure equitable provision of resources to reduce the impact of high penetrance familial cancers.	☐	☐	☐	☐	☐	☐	☐	☐
19 Facilitate the involvement of consumers								
19.1 Increase availability of cancer information and evidence-based guidelines for consumers.	☐	☐	☐	☐	☐	☐	☐	☐
19.2 Increase the proportion of the population who can make informed choices about cancer control	☐	☐	☐	☐	☐	☐	☐	☐
20 Meet urgent national needs in data collection								
20.1 Improve the availability of data for monitoring cancer control at all levels f the system, with feedback.	☐	☐	☐	☐	☐	☐	☐	☐
20.2 Improve data collection, particularly stage of presentation, treatment as related to guidelines, outcomes (survival, disease-free survival), on a population basis.	☐	☐	☐	☐	☐	☐	☐	☐
20.3 Conduct research into measurement of outcomes, including quality of life, and outcomes-based funding.	☐	☐	☐	☐	☐	☐	☐	☐
20.4 Collect data on new technologies through trials or prospective audit	☐	☐	☐	☐	☐	☐	☐	☐

Comparison of MEEM/PBMA Ranking with the Survey of the Cancer Strategies Group

Early on in the discussions of a possible MEEM/PBMA trial, CSG decided to survey its membership for a ranking of the interventions being considered for inclusion. The decision was taken as both a precautionary measure – in case the MEEM/PBMA trial could not be completed in the short time available – and to measure the contribution of an economic approach to the development of the revised National Cancer Strategy. The CSG ranking provides a broad "reality check" (while clearly not a gold standard) in evaluating the MEEM approach. A copy of the survey instrument is at Appendix Two of the thesis. Members were asked to score 46 possible cancer control actions against the following eight criteria[59]:

- **size of the problem** each action seeks to address;
- **effectiveness** of the action (quality of the evidence basis, size of impact on the problem, capacity of the strategy to satisfy consumers);
- **cost** of the cancer control action;
- **efficiency** of the cancer control action;
- capacity to **reduce inequity;**
- **acceptance** by the community;
- likelihood of successful **implementation** (because of availability of relevant expertise, budget implications, political issues); and
- **overall importance**.

For each intervention, CSG members were asked to score the eight criteria with a number between 1 (lowest score) and 5 (highest score). As with the NCCI survey instrument, members were left to weight the various criteria themselves in arriving at the "overall importance" score. Table A58 provides the summary results of the CSG survey for those interventions assessed in the trial, set alongside their corresponding PBMA/MEEM ranking. The CSG columns report the results for all eight dimensions combined, for the "overall importance" dimension only, and for the "efficiency" and "equity" dimensions combined. Table A59 provides the more detailed results for the CSG survey. With one exception (colorectal cancer screening) there is reasonable consistency between the CSG survey ranking based on "all eight dimensions combined" and the "overall importance" dimension. The "efficiency and equity combined" score gives a quite different ranking for a number of interventions, particularly tobacco control, colorectal cancer screening, rationalising cervical cancer screening and psychosocial care. Similarly, analysis of individual dimensions (refer Table A59) confirms that, as expected, interventions rank differently depending on the dimension selected. The CSG results confirm the concern that led to the PBMA/MEEM trial – i.e. that clarity as to the concept of benefit is important. Attaching different weights to the various dimensions scored would yield quite different rankings. Further analysis of the results is provided in Appendix Two

The ranking of tobacco control and skin cancer prevention as 1st and 2nd in the PBMA/MEEM trial and the NCCI is confirmed by the CSG results. A greater focus on skin cancer primary prevention seems widely accepted. The fruit and vegetables intervention is ranked quite differently in the CSG survey to the PBMA trial, even on the "efficiency and equity combined" criterion. The lack of specific economic evaluation data for CSG members would have contributed to this result. The high standard deviation result for this intervention suggests a divergence of views, possibly due to a perceived lack of reliable data. Psychosocial care is ranked similarly in both the PBMA/MEEM and CSG studies. The CSG gave this intervention a higher ranking than the NCCI respondents did (refer Section 13.6.2). As with the fruit and vegetables intervention, however, the width of the standard deviation suggests a divergence of views on the merit of this proposal. Colorectal cancer screening was judged to be important by the CSG (ranked 2nd on "overall importance" dimension) but ranked much lower when all dimensions were combined. Interestingly, it was

[59] These eight criteria were subsequently discussed and developed by the Working Party into the benefit measurement approach used in the PBMA/MEEM trial (refer Section 12.5).

given a low score on the "efficiency" dimension, even though the PBMA/MEEM evaluation suggests its efficiency credentials are better than existing screening programs.

Table A58: Comparison of the PBMA Ranking with the CSG Survey Results

Cancer Intervention	PBMA/MEEM Ranking	CSG Survey: Score for all 8 dimensions combined	CSG Survey: Score for "Overall Importance"	CSG Survey: Score for "Efficiency" & "Equity" combined
INCREMENTS:				
Tobacco Control	1st	1st (6 / 46)	1st	4th
Skin Cancer Prevention	2nd	2nd (8 / 46)	2nd (tie)	2nd
Encourage Fruit & Veg. Consumption (Note: cost per DALY result indicative only)	3rd	8th (26 / 46)	6th (tie)	7th
Psychosocial Care	4th & 5th	4th (17 / 46)	6th (tie)	3rd
Colorectal Cancer Screening	6th	7th (25 / 46)	2nd (tie)	6th
DECREMENTS:				
Rationalise Cervical Cancer Screening	Saving of $50.6 m & small DALY increase	5th (19 / 46)	5th	1st
Rationalise Prostate-Specific Antigen Testing	Results not yet available	3rd (14 / 46)	2nd (tie)	5th
Rationalise and Improve Skin Cancer Diagnosis Skills	Results not yet available	6th (23 / 46)	8th	8th

The comparison of the PBMA/MEEM results with the CSG survey (and with the earlier NCCI results presented in Section 13.6.2) confirms the importance of:

- clarity as to the concept of benefit;
- clarity as to the "decision rules" in ranking proposals and when such rules are modified by judgement reflecting broader criteria (Criteria Five and Six); and
- the provision of quality information on the cost, outcomes and efficiency of interventions.

The attention in the PBMA/MEEM process to these issues led to a clearer rationale for the results achieved (that could be subject to later scientific review and revision) and greater consensus between the participants. The range in the scores given and/or size of the standard deviations in the CSG survey suggests a lack of common understanding or consensus on the results. In this context the use of mean scores from such surveys could be quite misleading if they were used to imply a consensus view.

Table A59 Detailed Survey Results for Cancer Strategy Group Members

Cancer Control Action (15 responses)	Size of the Problem		'Effectiveness'		'Cost'		'Efficiency'		'Reduces Inequity'		'Acceptance'		'Implementation'		'Overall Importance'		All Eight	Criteria
	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)	Mean Score	SD (Mode)
(2.2) Tobacco Control (NTC)	4.27	0.93 (5)	3.60	0.88 (3)	3.53	1.09 (3)	3.73	1.00 (3)	2.93	1.24 (2)	3.00	0.52 (3)	3.07	0.68 (3)	4.13	0.88 (5)	28.87	4.24 (28)
(3.4) Fruit & Vegetables Campaign	3.33	1.19 (2)	3.33	0.94 (4)	3.40	1.14 (3)	3.33	1.30 (5)	3.07	1.29 (4)	3.53	0.88 (4)	3.27	1.06 (3)	3.47	1.09 (3)	26.73	6.64 .(30)
(4.1) Skin Cancer Prevention	3.93	1.18 (5)	3.60	1.02 (3)	3.53	1.15 (5)	3.47	0.88 (3)	3.53	1.15 (4)	3.40	1.14 (4)	3.53	0.88 (4)	3.73	1.00 (4)	28.73	6.06 (36)
(5.1) Skin Cancer Diagnosis	3.87	1.02 (4)	3.20	0.91 (3)	3.33	0.94 (3)	3.50	0.82 (3)	2.67	1.19 (2)	3.93	0.93 (5)	3.27	0.77 (3)	3.40	0.71 (4)	26.93	4.52 (31)
(6.2) Rationalise Cervical Cancer Screening	3.13	0.72 (3)	3.60	0.80 (3)	4.07	1.24 (5)	3.93	0.85 (4)	3.13	1.36 (4)	2.67	0.94 (2)	3.40	1.20 (2)	3.53	0.72 (4)	27.47	4.39 (29)
(7.1) Introduction Colorectal Cancer Screening	4.27	0.93 (5)	3.47	1.09 (3)	3.00	1.10 (3)	3.07	0.85 (3)	3.36	1.23 (3)	3.07	1.00 (3)	3.07	0.93 (3)	3.73	1.18 (5)	26.80	5.37 (32)
(10.1) Rationalise PSA testing	4.33	0.70 (5)	3.00	1.03 (3)	3.80	1.11 (5)	3.33	1.14 (3)	3.33	1.01 (4)	3.27	1.06 (4)	3.40	0.80 (3)	3.73	0.77 (4)	28.20	4.34 (30)
(15.1) Psychosocial Care	3.73	1.18 (5)	3.40	1.02 (4)	3.33	1.14 (2)	3.07	0.77 (3)	3.93	1.29 (5)	4.13	1.31 (5)	2.93	0.93 (2)	3.47	1.09 (4)	28.00	6.98 (19)