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There is nothing new about the task of making difficult choices in healthcare, but policy makers in a number of countries are now addressing the issue of priority setting with renewed interest [1–8]. Three main reasons are discussed in the international literature:

- The growing evidence that the deployment of current resources is far from optimal [9–14];
- The continued growth in healthcare expenditures [15];
- Doubts about the ‘free market’ as the mechanism of choice to allocate health sector resources and to determine access to services [16].

Of these, the increasing cost of healthcare in particular is making it difficult for governments to provide comprehensive high-quality healthcare to all citizens, irrespective of their ability to pay. The need to bring growing community aspirations and the scarcity of resources closer together is a common theme in the literature.

While the importance of priority setting or rationing is clearly recognized (following Ham and Coulter [7] we use these terms interchangeably), the central question of how priority setting is to be achieved remains strongly contested. There is a variety of priority setting approaches and models available. There have been several attempts to set priorities in public health systems; most noticeably in Oregon in the USA, The Netherlands, Sweden, Norway, New Zealand, Israel and the UK [1,7,17–19]. Each of these countries adopted a different approach and most continue to amend their processes as they strive to find satisfactory solutions. Some jurisdictions attempted to specify ‘core services’ (The Netherlands, Oregon, Israel and New Zealand’s initial approach); some identified broad principles but provided little guidance to agencies on how...
to implement them (Norway and Sweden); while some focused on the development of evidence-based guidelines to ration access to healthcare (New Zealand and the UK). Several lessons can be drawn from these experiences and we return to this theme later.

In addition to this international experience, which has been reviewed by a number of authors [15,7], there is no shortage of normative advice offered from a range of disciplines and researchers on how to make the difficult choices on what services to provide and who to provide them to. There are models offered by behavioral scientists based on achieving consensus [20–22], by epidemiologists/clinicians based on needs assessment [23], by philosophers based on notions of social justice [24–27], by economists based on achieving efficiency [28–35], and there are the approaches adopted by administrators based on feasibility (such as historical allocation) that are commonly applied in real-life settings [4]. How does the interested decision-maker choose between these well-intentioned offerings? A useful first step, not often taken, is to reflect on what constitutes an ‘ideal’ approach to priority setting. It is with this important question that the history of the Australian ‘Assessing Cost–Effectiveness’ (ACE) approach to priority setting started.

**Checklist for evaluating priority setting approaches**

The checklist (Box 1) involves ten criteria and is based on four underlying rationales – ‘economic theory’, ‘ethics’, ‘empirical evidence’ and ‘user considerations’. Economic theory is central as it is the discipline designed to offer guidance on choices in the presence of resource scarcity. Ethics is important because it provides a reference standard for judging societal welfare. Empirical evidence and user considerations are important to ensure relevance for decision-makers. Key conclusions on these rationales are summarized below and in Box 2, and are cross-referenced to the criteria in Box 1. The checklist is seen as an important contribution to the literature on priority setting, because it is the first time, to our knowledge, that criteria from such a broad range of considerations have been brought together to develop a framework that endeavors to be both realistic and theoretically sound.

**Rationale one: guidance from economic theory**

Normative economic theories provide the theoretical rationale for ranking from better to worse the policies, interventions and associated resource allocations under consideration. For normative theories, validity rests on the realism and relevance of their factual and ethical assumptions. Accordingly, the assessment of allocative efficiency (‘value-for-money’) should be based on evaluation frameworks that reflect what society truly values [36]. There is inevitably some overlap between ethics and economics because of the place of ethics in providing a reference standard for judging societal welfare (refer to rationale two).

The decision-making approach as the preferred normative foundation

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 [29,36]. A newer framework, the decision-making approach (DMA), has been put forward in recent years [37]. Welfarism and extra-welfarism derive from two distinct conceptual foundations: welfare economics gives primacy to individual preferences and the role of the market, while the dominant form of extrawelfarism (Culyer’s ‘healthism’) [38] is health-based and is conducive to a stronger government presence and third-party judgment on access by health professionals. 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.

There exist alternative ways to define and assess ‘value’ within the key economic notion of allocative efficiency [39–47]. Within the orthodox welfarist approach value is assessed using individual utility; within extrawelfarism value is assessed using a measure of health gain. While the DMA does not in theory preclude either a welfarist or extrawelfarist approach to what constitutes value (as the objective function is determined by the decision-maker), in practice it has been closely associated with the extrawelfarist framework. The DMA framework also allows the inclusion of social justice issues, provided the values involved are endorsed by the decision-makers.

The orthodox economic concepts of Pareto 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 [16,29,36,41]. 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 [41–47]. Healthism also provides a well-developed theoretical framework that has been widely applied by health economists, but can be criticized for its neglect of societal values other than maximizing health status.

Rejection of the welfarist approach and limitations of the extra-welfarist approach focus attention on the DMA as the theoretical framework that potentially enables most concerns to be addressed [29]. While intuitively appealing, it must be acknowledged that this framework has been subject to limited intellectual development and debate. The challenge for normative economics is to develop an evaluative framework with enough rigor 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 nonwelfarist 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 extrawelfarism, provided the values involved are endorsed by the decision-makers.

The choice of economic evaluation technique

The various economic evaluation techniques available either derive from, or can be related to, the three normative frameworks discussed. 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 the selection of evaluation technique. But there are also important similarities
Box 1. Priority setting model checklist.

Criterion 1: is there a well-defined research question? (T, P, U)
- Does the model specify a well-defined research question in answerable form? 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?

Criterion 2: is there a clear concept of benefit? (T, E, U)
- Does the model have a mechanism or process to define benefit in a way that captures the perspective and objectives of the decision-maker? 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?

Criterion 3: is there an acceptable process for generating the options for change? (T, P, U)
- Does the model have an explicit mechanism for generating options for change? Does 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)?

Criterion 4: is marginal analysis an integral component? (T)
- Does the model utilize incremental analysis in comparing the options for change? Does it operationalize the measurement and analysis of costs and benefits associated with the options for change through marginal analysis? Does the marginal analysis cover the scale and scope of the interventions, the target/user groups or mode of service delivery?

Criterion 5: are the decision rules clearly specified? (T, E)
- Does the model clearly articulate the decision rules by which the options for change are ranked (e.g., maximization through equating marginal cost and marginal benefit; maximization with equity weights; maximization subject to constraints; two-staged decision process)? 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?

Criterion 6: is the role of judgment recognized? (E, P, U)
- Does the model check the need for judgment in the specification, application and interpretation of the technical analysis, particularly in relation to underlying assumptions and values? Does the model make explicit the basis on which judgment impacts on the technical results?

Criterion 7: are the data needs tractable? (P, U)
- Does the model have a mechanism for making the data needs of the evaluation process tractable?

Criterion 8: is the need for due process recognized? (T, E, P, U)
- 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 and their acceptability to stakeholders? Is this process characterized 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?

Criterion 9: do the measurement methods demonstrate appropriate rigor? (T, E, P, U)
- Does the model involve a clearly specified evaluation protocol and standardized evaluation methods appropriate to the research question? Does the measurement of costs and benefits strike a reasonable balance between expense, difficulty and timeliness? Is there sensitivity analysis of key design parameters and evaluation assumptions? Is there rigor in the implementation of both efficiency and equity objectives; recognition that the choice of outcome measures has important ethical implications?

Criterion 10: reporting/implementation (E, P, U)
- Does the reporting address issues of likely concern to decision-makers, including ethical implications, feasibility of implementation, acceptability to stakeholders, importance of the problem addressed and financial implications? Is the reporting format designed to assist with judgments on what weight might be placed on the results, including generalizability to other settings and contexts, consultation processes adopted, strengths and weaknesses of the technical analysis, including comparison with similar evaluation studies in the literature?

For each criterion the letters in parenthesis indicate the relevant rationale: economic theory (T), ethical rationale (E), pragmatic rationale (P) and user considerations (U).

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 [29,34,35]. Similarly, at a more applied level, rigor 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 [34,35].

There would be debate, however, concerning 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 (allocative efficiency) from the question of how best to pursue a chosen objective (technical and/or productive efficiency). Three key techniques form the foundation of economic evaluation: cost–benefit analysis (CBA), cost–utility analysis (CUA) and cost–effectiveness
Box 2. Key findings from the four rationales on which the checklist is based.

Conclusions on economic theory:

- The Decision-Making School (DMA) is our preferred normative foundation, although it is less developed than orthodox welfarism or extra-welfarism.
- Cost Utility Analysis (CUA) is the preferred technique of economic appraisal, however, final selection of technique cannot be divorced from the decision context.

Lessons from literature on ethics and social justice:

- Ethical reasoning supports an explicit approach to priority setting (underlies a number of criteria, particularly Criterion 10: reporting).
- Ethical reasoning offers no decision rules to choose between conflicting ethical theories or principles. (Criterion 2: concept of benefit; Criterion 6: role of judgment and Criterion 8: due process).
- There is no logical way of resolving divergent ethical views other than through structured discussion and recognition of the legitimacy of alternative viewpoints. (Criterion 8: due process).
- While the various ethical concepts are useful to decide whether a “need” exists, they are less useful in deciding how much healthcare 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.

Lessons from empirical experience with priority setting:

- 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 8: due process).
- 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 2: concept of benefit).
- Economic evaluation has been regarded as useful and fundamental to the priority setting process, but within a restricted role (Criterion 1: the research question).
- The empirical experience raises important issues about what constitutes “adequate” data and how the data requirements of technical approaches can be made tractable (Criterion 7: data needs).
- Ultimately, priority setting rests on judgment informed by evidence (Criterion 6: role of judgement).

Needs of decision-makers:

- Specifying a core set of services to be funded has proven difficult (Criterion 1: the research question).
- Developing guidelines (rather than service exclusion) has attracted widespread support (Criterion 1: the research question).
- The importance of a strategic approach to deal with the inherent complexity and ongoing nature of priority setting (associated policy/infrastructure issue).
- Priority setting has important management and organizational dimensions (Relevant to criteria 1, 3 and 6–10).

analysis (CEA). Program Budgeting and Marginal Analysis (PBMA) is also significant (4), but more from a priority setting perspective, than from an evaluation techniques perspective. This judgment reflects PBMA’s role in providing an appropriate decision-making process, as well as its ability to incorporate various techniques for assessing value (such as CBA, CUA and CBA or options appraisal).

Orthodox welfarists see CBA as the gold standard of economic evaluation, because in principle, with both costs and benefits measured in dollar terms, CBA can determine whether a particular project is ‘worthwhile’. Both CEA and CUA were embraced by extrawelfarists because of the difficulties (conceptual, ethical and practical) in placing a dollar value on life. 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 (QALYs); (for CUA). CEA can be quite powerful where the policy question is how best to provide a given intervention (technical efficiency), but the lack of a common metric that picks up both mortality and morbidity impacts limits it’s role in allocative efficiency. CUA lies somewhere between CEA and CBA in terms of the problems it can address, but exactly where is an issue of some debate (29). It can be seen as either a form of CEA that can cope with more than one form of output (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.

While there are certainly important conceptual and practical questions associated with CUA, the technique is our 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.

Rationale two: lessons from the literature on social justice & ethics

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. Most would accept the proposition that the starting point for judgments about whether society is better or 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 opposed to community preferences (25–27). Richardson’s view (41,42) 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 precede, particularly if combined with a concern for procedural justice.

It is important to recognize that while ethical reasoning involves a rational approach to problem analysis, it offers no decision rules to choose between alternative ethical approaches. Deontology and consequentialism, together with distributive justice, stand out amongst the ethical issues of relevance to priority setting in healthcare [29]. Deontology focuses on duty, process and the rights of the individual; consequentialism 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 activities 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. There is no logical way of resolving divergent ethical views other than a convergence of thinking through structured discussion and recognition of the legitimacy of alternative viewpoints. In our ACE methods, therefore, specific provision is made for stakeholder involvement, with deliberative discussion based on best available information and consensus decision-making.

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. Concepts of equity that have received the most sustained attention are:

- Allocation according to need
- Allocation according to health status
- Allocation to ensure equality of health access

The principle that healthcare resources should be prioritized 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 defined clearly, 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), by disease severity and by the existence of an effective intervention (often combined with capacity-to-benefit). Under the principle of allocation according to need, horizontal and vertical equity call for equal treatment for equal need (‘horizontal equity’) and unequal (but fair) treatment in proportion to unequal need (‘vertical equity’). While these various concepts are useful to decide when a need exists, they are less useful in deciding how much healthcare is required to meet that need [6].

Given that healthcare 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 minimizing inequalities in health status. The question of differential aggregation weights to implement this equity principle has received considerable attention in the literature, particularly in the context of weights to adjust health outcomes in economic evaluation. To the extent that distributive concerns can be linked to the characteristics of people (such as age, ethnicity/Aboriginality, rurality/remoteness and 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 [27–44].

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 [29]. The choice of equity concept 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. Judgment is required having regard to policy objectives, decision context, community values and the theories of social justice held to be the most appropriate. It is important to note that the three approaches to distributive justice outlined will generally lead to different answers for the allocation of resources. Nowhere is this more apparent, for example, than in the ‘fair chances versus best health outcomes’ trade-off. When general principles of distributive justice fail to provide clear-cut answers, then the focus of social justice shifts to the legitimacy provided by a just process for making decisions. The issue of legitimacy of priority setting decisions in the eyes of stakeholders leads on to what has worked in practice and to the pragmatic concerns of decision-makers.

Rationale three: lessons from empirical experience
The experience of Oregon in the USA, The Netherlands, New Zealand, Sweden, Israel and the Nordic countries over the last decade or so exemplify the emergence of explicit priority setting as a national initiative [1,7,29]. In each of these countries priority setting entered the national health policy agenda as the scope of publicly financed health services came 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 [17–19,48–50].

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. The role of economic evaluation in the countries reviewed has reflected the significance afforded efficiency as an objective of their healthcare 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 (e.g., effectiveness, solidarity/fairness, severity and efficiency). All countries have come to recognize that if their decisions were to have legitimacy for patients, providers and 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 [1,7,29].

In relation to evaluation techniques, most countries recognized that the broader the priority setting task attempted, the more likely economic evaluation would encounter technical problems. Several countries (New Zealand and the Nordic countries) preferred to focus economic evaluation on vertical priority setting (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 the decisions of the Australian Pharmaceutical Benefits Advisory Committee (PBAC) or the Medical Services Advisory Committee (MSAC), has been well regarded. Experienced evaluators have questioned the suitability of available economic evaluation techniques in application to entire domains of healthcare. Those initiatives that have sought a much broader application (such as Oregon [7], the Health Benefits Group/Health Resource Group approach [30], and the Health Sector Wide Disease Model [31]), have encountered significant data problems that have limited their usefulness [29]. These approaches have sought to make the task more tractable by either limiting the scope of the research question, restricting the role of economic evaluation, or by withdrawing from priority setting to a more general planning and scenario assessment role. Techniques such as PBMA that provide a structure in which evidence and values can be brought together are growing in popularity [4,48–50]. In Australia, the early appeal of the consensus-based approaches reflected their focus on due process, particularly the effective involvement of participants in the decision-making process [20–22].

Finally, priority setting is not just about making one set of decisions, but recognizing ‘the complex interaction of multiple decisions, taken at various levels’ [51,52]. In New Zealand, for example, it is not clear whether recommendations coming out of their guidelines development process will match up with the purchasing recommendation that come from their PBMA process [53]. In the UK, NICE has been criticized for not taking into account the cost of its recommendations on regional bodies that are meant to implement them. There are concerns that NICE recommendations will distort efforts to establish priorities at the local level [54]. The empirical evidence thus highlights the reality that explicit rationing at all levels involves both the use of techniques and the application of judgment. The empirical experience also 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.

### Rationale four: user considerations

Criteria with a user rationale stem from an effort to ensure that models of priority setting respond to the particular needs of healthcare decision-makers. 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. Quite apart from the empirical evidence, the ‘exclusion’ approach is inconsistent with the importance placed on marginal analysis in finding ‘efficient’ solutions in economic theory. Reliance on average cost–effectiveness results ignores the variation in cost–effectiveness ratios with patient needs, population sub-groups, program size, program design and health service setting. 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. 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) [29].

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.

### How do existing approaches perform against the checklist?

#### Noneconomic approaches

Surveys across a number of countries suggest that probably the most common approach to resource allocation in health is to base funding decisions on what has been funded in previous years [4]. This historical allocation approach can be made a little more rigorous by pro rating allocations up or down based on changes in health service costs and/or demographic changes. As a lack of explicit priority setting activity is characteristic of this type of approach, it is common for local politics to enter into the process. Mitton calls this latter mechanism the ‘decibel approach’ [4]. While commonplace, this approach fails most of the checklist; particularly a clear concept of benefit, a process for generating options for change, clear decision rules and marginal analysis. Importantly, neither history nor decibels provide a mechanism for maximizing policy objectives (including health gain) within a given budget. Interestingly, while the simplest to administer, there is growing evidence that managers and clinicians find little satisfaction with approaches where implicit values and politics dominate, rather than evidence of effectiveness, sound judgment and explicit decision-making processes [4]. It is no
Origins, description & application of the Australian ACE initiative

Box 3: Needs-based models of priority setting.

Criterion 1: 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 WHO global burden of disease study [GBD] and associated national disability-adjusted life-year [DALY] or ‘avoidable mortality/morbidity’ studies), while others focus on specific diseases and particular health service sectors. Well-defined research question is achievable within context of clear model objectives.

Criterion 2: Clear concept of benefit
- Few of the needs-based approaches explicitly consider priority setting objectives and what these mean 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 are rarely canvassed, although their descriptive nature does allow equity issues to be explored.

Criterion 3: 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. ‘Healthcare needs’ studies take into account whether efficacious interventions exist, but rarely provide advice on option generation/selection matched to specific decision contexts.

Criterion 4: Marginal analysis
- Needs-based models are not based on economic principles and do not involve marginal analysis or opportunity cost principles.

Criterion 5: Clear decision rules
- Fail to incorporate decision rules for priority setting in a situation of resource scarcity. Needs-based models generally contain no mechanism to adjust health service mix towards the optimal (such as the ‘marginal benefit = marginal cost’ rule of economics).

Criterion 6: Role of judgment noted and clearly specified
- Performance would vary between models and studies. The better studies would make explicit the role of judgment in specification, application and interpretation of the technical analysis.

Criterion 7: 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 are often employed.

Criterion 8: Due process
- Needs-based models, like most technical approaches, rarely give consideration to issues of procedural justice. Most studies endeavor to make their methods explicit. Involvement of stakeholders varies between models.

Criterion 9: Rigorous approach to measurement
- Performance varies from study to study. A rigorous and balanced approach to measurement is achievable.

Criterion 10: Reporting issues of concern to decision-makers
- Some issues of concern to decision-makers not covered by approach (financial cost; allocative and technical efficiency). Coverage of other issues (e.g., ethical values, feasibility and acceptability to stakeholders) would vary from study to study.

Overall assessment
- Needs-based models have been useful in distributing regional budgets (Resource allocation formula), in prioritizing 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 utilized to provide need/severity classification systems and as an input to decision-making where decision rules are introduced from efficiency-based models.

surprise that the priority setting literature is dominated by discussion of the relative merits of explicit versus implicit approaches and of how explicitness should be achieved [5,7,17,18].

Another commonly used means of setting priorities is through the assessment of ‘need’ employing various epidemiological techniques. One approach to needs assessment is to define need either at the individual or population level, and then set a minimum standard of care (or set of services) to meet that need. Needs assessment, for example, was given a pivotal role in the development of purchasing in the National Health Service internal market reforms of the early 1990s in the UK and is utilized by many public health units in various states of Australia [29]. Need, however, as discussed earlier, is a complex concept, with many different definitions provided in the literature. The crucial distinction is between defining need as the extent and/or severity of illness (‘health needs’) and defining need as the capacity-to-benefit (‘healthcare needs’). Early enthusiasm for needs assessment by purchasers in the UK and elsewhere waned, largely because of its limited relevance for specific purchasing decisions, coupled with the size of the research task. Without intervention-specific cost data and the decision rules offered by economic appraisal, there are formidable difficulties in trying to set priorities from needs data. This poor performance is reflected in failure to meet key criteria from the checklist – particularly marginal analysis, decision rules and data tractability (Box 3).

Even when there have been attempts to explicitly link needs assessment with expenditure, such as with resource allocation formulae (RAF), such formulae have been helpful with the equitable distribution of regional budgets, but have not assisted specific purchasing decisions. This reflects their 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). All this is not to say that needs assessments are not important or that descriptive data sets on the burden of disease or cost of illness cannot be helpful as an input to priority setting. Such data can be useful in identifying unmet need, in flagging societal inequalities and when linked to economic evaluation, in assessing cost offsets and potential health gains. However, needs assessments alone are not useful for promoting the efficient use of resources and are not best used as a primary mechanism for setting priorities.

Interesting endeavors at explicit consensus-based approaches to priority setting have also been conducted in Australia [20–22]. The ACE case study presented later resulted from perceived deficiencies of one important example of the consensus approach, involving the development of a national cancer strategy in Australia. Another interesting example in Australia [20] involved the development of priority areas for health promotion for women in the Hunter region of New South Wales. In this approach epidemiological data on disease incidence and distribution, views from the community and advice from experts were synthesized using a nominal group approach. This consensus model clearly had advantages in terms of its potential to achieve legitimacy in the eyes of stakeholders. There were also, however, some important weaknesses that compromised its potential to guide resource allocation decisions. These related principally to the type of information provided (e.g., no resource cost information), the omission of economic appraisal, the lack of precision in how criteria were to be used for ranking options and the primary focus on the size of the problem rather than on health gain (Box 4).

Carter reviewed a wide range of noneconomic models and concluded that while several had innovative aspects and demonstrated merit in relation to some of the criteria on the checklist, none performed well against all of the criteria [29]. All the models proposed by noneconomists had serious weaknesses that compromised their credentials as stand-alone guides to resource allocation, particularly as guides to purchasing decisions. They are best utilized in combination with an economic approach that provides guidance on efficiency.
Box 5. League table model of priority setting.

**Criterion 1. 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.

**Criterion 2. 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.

**Criterion 3. 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.

**Criterion 4. 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 maximize community benefit. This is more a criticism of current practice than intrinsic to method.

**Criterion 5. 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 (such as $50,000 per QALY). Opinion varies about appropriateness and practicality of using shadow price of societal willingness-to-pay for health gains.

**Criterion 6. Role of judgment noted and clearly specified**
- Performance varies between tables. The better studies would make explicit the role of judgment in specification, application and interpretation of the technical analysis. Many league tables have substantive implicit elements, as evidenced by PBAC and Oregon. Ethical issues are rarely made explicit.

**Criterion 7. 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).

**Criterion 8. 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.

**Criterion 9. 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.

**Criterion 10. 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 (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 judgments. League tables are more likely to make a positive contribution if utilized 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.


**Economic approaches**

There are a number of economic approaches to priority setting. Two common approaches are selected here to illustrate the deficiencies of current approaches, the use of league tables (Box 5), and program budgeting and marginal analysis (Box 6).

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. While this approach has intrinsic appeal, economists have urged caution in using league tables to set priorities for three key reasons. 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. The aim is to ensure that the economic merit of the interventions evaluated is not confounded by differences in 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 the economic and epidemiological data may not be easily transferable from one setting to another. 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 [29,34,35].
Box 6. Program budgeting and marginal analysis model of priority setting.

Criterion 1. Well-defined research question. Adaptable to decision context and setting
- Most PBMA studies have been undertaken at a regional or organizational 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 one-off study or institutionalized as ongoing planning process. Study perspective will vary between applications in accordance with context and setting.

Criterion 2. 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-staged approach.

Criterion 3. 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 formalized process, involving a research team assisting the Working Party, is an important way of improving the comprehensiveness and rigor 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.

Criterion 4. 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 (e.g., that equate average and marginal changes for subgroups) are not uncommon, but this is true for most applied economic evaluation work. PBMA can embody the full range of economic evaluation techniques.

Criterion 5. Clear decision rules
- PBMA applies standard optimization rules of economics, although they may be subject to adjustment to reflect broader objectives. Particular rules will depend on evaluation technique utilized (CEA, CUA, CBA, options appraisal). Any modification of standard decision rules should be clearly specified.

Criterion 6. Role of judgment noted and clearly specified
- Performance on this criterion would vary between studies. The better studies would make explicit the role of judgment 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.

Criterion 7. 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. 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 macroevaluation protocol and in-built mechanism for resolving data needs. Institutionalizing PBMA at organizational level will require linkage with existing financial and statistical collections.

Criterion 8. Due process
- PBMA provides a mechanism, through the Working Party, to give consideration to issues of procedural justice. Most studies endeavor to make their methods explicit. Nature and degree of involvement of stakeholders varies between studies.

Criterion 9. Rigorous approach to measurement
- Has been a point of major criticism of early PBMA studies, which relied on judgment rather than evidence for assessing intervention performance. Rigorous and balanced approach to measurement is potentially achievable, however, with PBMA approach.

Criterion 10. 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 that addressing organizational and managerial issues will be central to successful implementation.

Overall assessment
- Capable of providing both a valid and practical approach to priority setting in many contexts. Criticisms reflect more ‘growing pains’ of evolving technique than fatal flaws in underlying structure or rationale. Criticisms such as lack of measurement rigor, inadequacies in option selection, narrow perspective and poorly developed marginal analysis are all resolvable within PBMA approach, as evidenced by recent developments. 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 data tractability, organizational and managerial issues will be central to successful implementation.


In addition to these technical concerns raised by economists, there are also concerns stemming from the social justice and empirical experience rationales reviewed earlier. It is clear that irrespective of technical merit, policy makers and the communities they represent do not wish to see automated decision-making based on cost–effectiveness ratios. Program Budgeting and Marginal Analysis 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 current activities, through comparison
across or within programs. 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 5–10% around the current level.

It is clear from a growing literature on PBMA [4,29] that substantially different evaluation approaches have emerged within this overarching framework. While the steps in conducting a PBMA are broadly similar between studies, rigor in the selection of options, in the consultation/bargaining process, in the measurement of costs and benefits, and in the level of evidence demanded, all vary substantially. Most attempts at PBMA have relied on local subjective judgments for assessing the effectiveness of options for change, and for some observers this, together with the possibility of ‘gaming’ and/or reinforcement of the status quo, has undermined their credibility [55,59]. Other researchers, however, including the ACE team, have sought to improve the evidence base of PBMA [56–58] in line with the growing acceptance of the evidence-based medicine movement.

In Box 6 we conclude that the PBMA technique is capable of providing a valid and practical approach to priority setting, but requires development. Many of the criticisms reflect more the ‘growing pains’ of an evolving technique, than fatal flaws in its underlying structure or rationale. Criticisms, such as lack of measurement rigor, inadequacies in option selection, narrow perspective and poorly developed marginal analysis [55,59], are all resolvable as evidenced by the ACE work, which sits arguably within the PBMA genre.

**Description of the ACE model & its unique features**

The ACE approach, summarized in Figures 1 & 2, reflects our endeavors to develop an approach that satisfies the checklist, particularly the challenge of finding an appropriate balance between technical rigor and due process. We tested and refined this balance through a series of case studies that are summarized in Table 1. We are reassured by the fact that the ACE approach has appealed to both our academic peers across a range of disciplines (reflected in competitive grants) and to decision-makers in government and provider organizations (reflected in commissioned work). The decision context for most ACE evaluations has been the possible adoption Australia-wide of options to improve the efficiency of current health services and to inform policy makers about the best bundle of interventions, given alternative levels of budget availability.

On the technical side, the ACE approach applies the key economic concepts of ‘opportunity cost’, ‘marginal analysis’ and a ‘clear concept of benefit’ using standardized evaluation methods clearly documented in an evaluation protocol. Undertaking the economic evaluations as part of the priority setting exercise addresses the reservations expressed by many economists regarding the simplistic use of league tables, where economic studies are assembled from the literature with little regard to differences in methods, context and setting. The key characteristics of the ACE evaluation methods are:

- The rationale for the selection of interventions is discussed and clearly specified;
- The evaluation methods are standardized, documented and open to scrutiny;
- The CUA is used to develop incremental cost–effectiveness ratios (ICERs) based on economic/epidemiological modeling techniques that utilize best-available data;
- The ICERs, total costs and disability-adjusted life years (DALYs) are reported as a range (around point estimates) reflecting explicitly the uncertainty of cost, process, outcome and value estimates;
- The setting, context and comparator are common to all interventions;
- Country-specific data are used, wherever possible, for health system costs and demographic and epidemiological disease parameters;
- Data needs are made tractable by utilizing Australian DALY data as the primary measure of health outcomes (adjusted for application within an evaluation context) [60], together with the Australian Disease Costs and Impacts data (DCIS) to assist with cost offset estimates [61];
- The ICERs are placed within a broader decision-making framework that includes ‘equity’, ‘strength of evidence’, ‘feasibility of implementation’, ‘acceptability to stakeholders’ and other study-specific considerations, which we have our called ‘second-stage filter’ analysis;
- Information is assembled by a multidisciplinary research team, preparing briefing papers to a standardized format agreed by a Working Group of stakeholders who are involved throughout the study.
ACE Working Groups generally consist of stakeholders recruited from topic experts, clinicians and practitioners, relevant community organizations and policy makers. The Working Group in ACE studies has an important role in selecting the interventions for evaluation, as well as achieving balance between the technical analyses and due process (Figure 2). On the technical side, members contribute in areas of their expertise and discuss issues of method and evidence. On the ‘due process’ side, members ensure stakeholder interests and views are articulated, facilitate sensible interpretation of the technical analysis, assist with ‘value’ judgment aspects of the second-stage filter analysis and help ensure transparency throughout the project and assist in the promulgation of the results to policy makers.

In applying the second-stage filter criteria the Working Group considers a common core of filters (Table 1), but the individual decision context can give rise to variations (such as the selection of ‘cultural security’ in the indigenous component of ACE: Prevention). The main outcome of the second-stage filter analysis is a table for each intervention in which these broader issues are flagged and a qualitative judgment made explicit about each of the criterion and its impact. Issues raised under the ‘equity filter’ or the ‘acceptability to stakeholders’ filter, for example, are briefly described and then a summary entry made under a ‘Decision point’ heading (such as ‘not a key issue’; ‘possible concerns, needs attention’), which are then all brought together under a ‘Policy considerations’ heading that combines both the ICER and second-stage filter information (Table 2). The second-stage filter analysis can lead to recommendations about the need for pilots prior to widespread implementation, about the need for intervention redesign to address equity concerns and/or the need for ongoing evaluation/research to improve the evidence base.

**Case study of the ACE approach: ACE–Cancer Background to the ACE–Cancer Study**

When ACE-Cancer was undertaken in 2000, Australia Health Ministers were advised on strategies to manage nominated priority areas by the National Health Priority Action Council (NHPAC). The Cancer Strategies Group (CSG) was a standing Subcommittee of NHPAC and oversaw the development of the National Cancer Strategy. A key element of CSG’s approach to its task was a transparent systematic decision-making process for priority setting and strategy development. Earlier in 1997 the National Cancer Control Initiative (NCCI) had been 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 had undertaken an extensive consultation process of unprecedented breath, which included a questionnaire to every organization with interests in cancer control in Australia, as well as workshops in each State/Territory to discuss and rank 30 proposed actions given priority in the questionnaire responses. 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 (‘size of the problem’, ‘efficacy of the action within a 5-year time frame’, ‘likelihood of successful implementation’, ‘cost and cost–effectiveness’ and ‘equity’).

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 judgments 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 criticized (whether participants had a common understanding of the ranking criteria provided, whether they gave them similar weight in arriving at their ratings, had a common understanding of the ranking criteria provided, whether they gave them similar weight in arriving at their ratings, 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); the 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 healthcare 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 judgments on resource allocation issues. Arguably, the more central issues for resource allocation are information on the effectiveness of the various interventions in reducing the disease burden, the net cost of the interventions 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 judgments on resource allocation issues. Arguably, the more central issues for resource allocation are information on the effectiveness of the various interventions in reducing the disease burden, the net cost of the interventions and whether the interventions represented value-for-money. 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.
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 utilized as part of the decision-making process for developing cancer control priorities in the future. In particular, the discussion focused on the clarity of the criteria and associated decision rules, and whether the efficiency objective had been satisfactorily addressed. In mid 1999, the CSG resolved to trial the use of an economic approach as part of its review of the priorities determined in the ‘Cancer Control Towards 2000’ report’ [22]. The trial was to address whether 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. Note that at this time we had not coined the term ‘ACE’ to describe our approach to priority setting, which arguably belongs within the PBMA genre.

Overview of the approach adopted
A nine-member Working Party was constituted to cover key stakeholder interests and take key decisions concerning conduct of the study (concerning option selection, concept of benefit, ranking of options for change and judgments about the impact of the second-stage filter). The Working party agreed that there would be:

- 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 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 (economic decision rule based on ‘cost per DALY’ preferably weighted for distributive justice) and ‘judgment’ aspects as the second-stage filter (level of evidence, equity, size of the problem, acceptability to stakeholders, and feasibility of implementation);
- An economic protocol specifically developed for a priority setting context.

The focus on marginal analysis (without any program budget component) reflected the decision context, a national strategy involving multiple jurisdictions and organizations. Along with the attention to rigor in the economic modeling, the absence of the program budget element distinguishes ACE from other PBMA-based approaches to priority setting. The focus on marginal analysis in the case study also allowed the Working Party to assess key issues within the time available, such as:

- The potential of ACE 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 traditional economics with 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.

Selection of the options for change
The Working Party reviewed 21 action areas (involving over 40 individual interventions and/or activities) based on the earlier NCCI exercise and classified them into one of five groups using a number of criteria:

- That a clear and concrete intervention could be specified;
- That there was sufficient evidence to make an assessment of effectiveness possible;
- That both increments (options that involve additional expenditure) and decrements (options that involve reduced expenditure) be included;
- That options from across the complete disease pathway be included;
- That options be included that test the assessment of both mortality and/or morbidity impacts on health status.

The five groups were:

- Options for change – defined as interventions where sufficient evidence existed 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;
- Possible options for change – defined as interventions where some evidence existed 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;
- Monitor developments/liaison – defined as interventions that are currently being worked on and/or implemented in another context and where it was too early or inappropriate to perform an economic evaluation at present;
- 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 could not be specified;
- 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).
Table 1. Summary of selected Assessing Cost–Effectiveness studies.

<table>
<thead>
<tr>
<th>ACE study</th>
<th>Research question and context</th>
<th>Funding source</th>
<th>Impact</th>
<th>Second-stage filters selected</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE–Cancer</td>
<td>To investigate the feasibility of including economic analysis in the cancer strategy. To undertake the research in a time scale that allowed inclusion of results. Evaluated 7 cancer control interventions</td>
<td>Australian government through its National Health Priority Action Committee</td>
<td>Published as part of the national cancer strategy: “Priorities for Action in Cancer Control 2001 2003”. Well received by broader cancer community</td>
<td>Strength of the evidence Equity Acceptability to stakeholders Feasibility of implementation Size of the problem</td>
<td>Well received at the time, but not repeated when the cancer strategy was updated. Reflected change in institutional arrangements, changing government personnel and need for prior planning/commitment before strategy update due</td>
</tr>
<tr>
<td>ACE–Heart disease</td>
<td>Academic setting. Evaluated over 20 interventions</td>
<td>Competitive grant funding from the NHMRC</td>
<td>Articles published in academic press but not integrated in any policy documents</td>
<td>Strength of the evidence Equity Acceptability to stakeholders Feasibility of implementation</td>
<td>Important academic contribution, but little impact on policy</td>
</tr>
<tr>
<td>ACE–Mental health</td>
<td>Funded as intelligence-gathering exercise, not to resolve specific policy question. Evaluated over 20 interventions</td>
<td>Joint funding from: Commonwealth and Victorian departments of health</td>
<td>Published in series of 12 articles. Received favorable review from WHO. No direct impact on government policy</td>
<td>Strength of the evidence Equity Acceptability to stakeholders Feasibility of implementation</td>
<td>Generated considerable interest, but only minor impact on policy. WG rejected ‘duty of essential care’ and ‘severity’ as filters</td>
</tr>
<tr>
<td>ACE–Obesity</td>
<td>Funded as intelligence-gathering exercise, not to resolve specific policy question. Evaluated 12 interventions</td>
<td>Funding from Victorian Department of Human Services</td>
<td>Published by Victorian Department of Human Services on its website. Journal articles being disseminated. To date only indirect impact on government policy</td>
<td>Strength of the evidence Equity Acceptability to stakeholders Feasibility of implementation Potential for side-effects Sustainability</td>
<td>Generated considerable interest, but only minor impact on policy</td>
</tr>
<tr>
<td>ACE–Prevention</td>
<td>Academic setting. To evaluate approximately 150 interventions in the area of noncommunicable disease for both nonindigenous and indigenous populations. 100 prevention interventions plus 50 reference interventions in care/cure and communicable disease</td>
<td>Competitive grant funding from the NHMRC</td>
<td>Still in progress. Strong interest being shown by governments in forthcoming results</td>
<td>Strength of the evidence Equity Acceptability to stakeholders Feasibility of implementation For Indigenous component, cultural security and healthy community</td>
<td>Still in progress and complemented by additional NHMRC Capacity Building Grant</td>
</tr>
</tbody>
</table>

ACE: Assessing Cost–Effectiveness; NHMRC: National Health and Medical Research Council; WG: Working group.
### Table 2. Example of cost per DALY results and impact of second-stage filters.

<table>
<thead>
<tr>
<th>Options (increments and decrements)</th>
<th>First stage filter: cost per DALY</th>
<th>Second-stage filter: equity implications</th>
<th>Second-stage filter: levels of evidence</th>
<th>Second-stage filter: size of the health problem</th>
<th>Second-stage filter: acceptability and feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRC screening (increment)</td>
<td>Biennial 55–69 years age group: $12,000 per DALY recovered (net cost) Biennial 55–74 years age group: $10,000 per DALY recovered (net cost) Annual 55–69 years age group: $16,000 per DALY recovered (net cost) Addition to biennial program of: 70–74 years age group: $5300 per DALY 75+ years age group: $6000 per DALY 50–54 years age group: $23,000 per DALY 45–49 years age group: $33,000 per DALY</td>
<td>There are existing inequities in the incidence and mortality for low SES, rural/remote and indigenous Australians Introduction of a national screening program is likely to increase existing inequities (due to likely utilization patterns) unless specific action is taken to address equity issues in design and implementation of program</td>
<td>‘Sufficient well-designed research’ Major international trials (four of six) reported a reduction in mortality of 12–21% for biennial screening Only one RCT available for annual screening</td>
<td>High on health burden and health system costs. CRC is second most common cancer affecting both men and women. Medium on potential reduction in the disease burden (11% fall in DALYs with biennial screening; 17% with annual) High on potential costs of screening program and potential cost offsets</td>
<td>Large cost variation depending on design option ($38 million to over $180 million). Acceptability issues for participants include availability of counseling and adequate information on cost, benefit and 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</td>
</tr>
<tr>
<td>Decision points</td>
<td>Important design features to be tested, with significant cost implications (age; interval; attendance; positivity rate; equity issues). Introducing another national screening program requires very careful consideration due to health system inertia</td>
<td>Consideration of this filter raises important issues for program design</td>
<td>Consideration of this filter increases the weight to be given to a successful intervention</td>
<td>Consideration of this filter increases the weight to be given to a successful intervention</td>
<td>Consideration of this filter suggests caution and need for careful planning</td>
</tr>
</tbody>
</table>

CRC: Colorectal cancer; DALY: Disability-adjusted life year; RCT: Randomized controlled trial; SES: Socioeconomic status.
The five groups provided a useful way of classifying the large number of potential interventions into policy-relevant groupings. The intention was to include all those strategies classified as 'Options for change,' together with some of the 'Possible options for change.' Briefing papers to guide the Working Party in its assessment were prepared by the research team. The briefing papers were quite detailed assessments that summarized the available evidence on each option. The options chosen for evaluation are listed in Table 3.

The concept of benefit
An important dimension to the ACE approach is its potential to broaden the concept of benefit to reflect the underlying goals, objectives and principles of an organization or program wishing to employ the technique. The Working Party adopted seven broad criteria that integrated the objectives of Australia’s cancer policy [62] into the measurement of benefit, namely the:

• Size of the problem (where can the biggest difference be made?);
• Effectiveness (what is the quality of the evidence that the intervention works and what health status improvement can be anticipated?);
• Equity (what is the capacity of the intervention to reduce inequity in health status and the healthcare system);
• Efficiency (is the option value for money as reflected by the cost–effectiveness ratio?)
• Cost (is the intervention affordable?);
• Acceptability (acceptance by stakeholders, particularly the general community);
• Likelihood of successful implementation (because of availability of relevant expertise and/or infrastructure, timing considerations or other feasibility issues).

It was agreed by the Working Party that these seven criteria would be utilized in a two-stage approach to ranking the options. 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 epidemiological and ‘technical’ considerations). In the second stage, the ranking of options would include the more pragmatic acceptability/feasibility issues. The first stage is characterized 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 judgment and due process. In its initial consideration of this approach, the Working Party included criteria one to five 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 at the specific approach to calculating the cost–effectiveness ratio, criteria were moved between the two stages. It was decided that the measure of health gain should be the DALY and that the DALY should be weighted, if possible, to reflect equity concerns. The availability of Australian DALY data [60,63] meant that a common unit of measurement was available that captured both morbidity and mortality effects across a wide range of diseases and intervention types. This decision meant that criteria two (effectiveness) and three (equity) provided the theoretical measure of ‘health gain’ and the denominator in the cost–effectiveness ratio. Criterion five (cost of the cancer control option) provided the numerator in the PBMA cost–effectiveness ratio. Criterion four (efficiency) was picked up automatically by the cost–effectiveness ratio (efficiency is a relationship between cost and benefits). Two dimensions of health benefit previously placed in stage one (‘size of the problem’ and the quality of evidence component of ‘effectiveness’) were transferred to the second stage of the ranking process during these discussions. In relation to the size of the problem, this reflected the Working Party’s concern that there might be overlap between this dimension and the health gain dimension (because the size of the 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.

The Working Party’s initial intention was for the DALY score attributed to each intervention to be weighted for the equity implications for four target groups: socioeconomic status, Aboriginality, rurality and ethnicity. As a consequence of not being able to fully develop and apply equity weights in the time available for the study, the Working Party agreed to include equity in the second-stage filter. Two dimensions of equity were considered. The first was the extent to which the intervention might redress any existing health status inequity. 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.

The ACE-Cancer results
The results of ACE-Cancer were integrated into the proposed National Cancer Strategy, and were distributed for comment and feedback by the CSG [62]. They were well received and were included in the subsequent National Cancer Strategy. The detailed results have also been published separately [48]. Table 3 provides a summary of the cost per DALY results. The interventions are ranked on the basis of the ICERs – either by their level of ‘dominance’ or the net cost per DALY ratio. The net cost per DALY estimates provided include the point estimate (the result from the primary economic analysis) together
Table 3. Ranking of the interventions on the basis of the degree of dominance and net cost per DALY results.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Cost (savings) $ millions</th>
<th>DALYs recovered (lost)</th>
<th>Cost per DALY (point estimate) $</th>
<th>Cost per DALY (lower bound) $</th>
<th>Cost per DALY (upper bound) $</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Increments</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tobacco control: National Tobacco Campaign</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross costs (no offsets)</td>
<td>9.0</td>
<td>16,000</td>
<td>840</td>
<td>540</td>
<td>1200</td>
</tr>
<tr>
<td>Net costs (or net saving)</td>
<td>(39)</td>
<td></td>
<td>Dominant</td>
<td>Dominant</td>
<td>Dominant</td>
</tr>
<tr>
<td>Primary prevention of skin cancer (SunSmart on National Basis)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross costs (no offsets)</td>
<td>2.5</td>
<td>10,000</td>
<td>250</td>
<td>240</td>
<td>510</td>
</tr>
<tr>
<td>Net costs (or net saving)</td>
<td>(37)</td>
<td></td>
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<td>Dominant</td>
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<tr>
<td>Fruit &amp; Vegetables Media Campaign</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Gross costs (no offsets)</td>
<td>2.5</td>
<td>3600</td>
<td>680</td>
<td>510</td>
<td>16,000</td>
</tr>
<tr>
<td>Net costs (or net saving)</td>
<td>(12)</td>
<td></td>
<td>Dominant</td>
<td>Dominant</td>
<td>Dominant</td>
</tr>
<tr>
<td>Psychosocial care: breast care nurses</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Gross Costs (no offsets)</td>
<td>4.9</td>
<td>5200</td>
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<td></td>
<td>Offsets not estimated</td>
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<td></td>
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<tr>
<td>Psychosocial care: psychologists for cancer treatment centers</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Gross costs (no offsets)</td>
<td>26</td>
<td>4800</td>
<td>5300</td>
<td>1600</td>
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</tr>
<tr>
<td>Net costs (or net saving)</td>
<td></td>
<td></td>
<td>Offsets not estimated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National Colorectal Cancer Screening Program (Biennial: ages 55–69 years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross costs (no offsets)</td>
<td>53</td>
<td>3200</td>
<td>17,000</td>
<td>12,500</td>
<td>45,000</td>
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<td>Net costs (or net saving)</td>
<td>38</td>
<td></td>
<td>12,000</td>
<td>10,300</td>
<td>40,000</td>
</tr>
<tr>
<td>National Colorectal Cancer Screening Program (Biennial: ages 55–74 years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gross costs (no offsets)</td>
<td>66</td>
<td>4300</td>
<td>15,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Net costs (or net saving)</td>
<td>44</td>
<td></td>
<td>10,000</td>
<td></td>
<td></td>
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<tr>
<td><strong>Decrements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationalize the National Cervical Cancer Screening Program: change screening interval from 2 to 3 years (net saving)</td>
<td>(51)</td>
<td>(98)</td>
<td>520,000</td>
<td>160,000</td>
<td>960,000</td>
</tr>
<tr>
<td>Rationalize the National Cervical Cancer Screening Program: increase age of commencement from 18 to 25 years (net saving)</td>
<td>(24)</td>
<td>(30)</td>
<td>790,000</td>
<td>620,000</td>
<td>960,000</td>
</tr>
</tbody>
</table>

Results presented rounded to two significant figures.

*The ICERs for decrements can be hard to interpret. Because they are often a combination of potential cost savings, but with potential health loss, the larger the $ per DALY, the better the result – you want to see large cost savings but with small health losses. Desirably you want to see dominance – that is, cost savings with no health loss.*

Impact of the second-stage filter analysis

Table 2 provides an example 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 ranged from simple ‘hand-sorting’ of the results by the Working Party along the lines adopted by the Commissioners in the Oregon
process to approaches based on decision theory (such as those adopted in some PBMA studies [49,50]). In the event, the filters were treated as dichotomous constraints (‘pass’ or ‘fail’) and none of the interventions was ruled-out by them. There were, nonetheless, some important issues raised that the Working Party emphasized should not be ignored. These included attention to the design of the interventions to offset equity concerns (e.g., colorectal cancer screening), the need to strengthen the evidence base (e.g., psychosocial care by breast care nurses, fruit and vegetables) and the way in which proposals might be implemented (e.g., cervical cancer screening). The application of the second-stage filters clearly involved a judgment process that the Working Party endeavored to make as explicit as possible by documenting both the process and the content of their judgments.

Comparison of the case study & the checklist

**Criterion 1: is there clarity in the research question?**

A focus on the research question and the objectives of the decision-maker is a distinctive characteristic of the ACE approach and its normative foundation in the Decision-Making School. It was given effect through the care taken in defining the study perspective, concept of benefit and choice of comparators with the Working Group and in the full specification of a study protocol. Criterion 1 also covers the recognition given decision context and setting, and whether models clarify their relative strengths and weaknesses in different choice problems. In this regard, the role and limitations of ACE–Cancer were clearly specified in both technical and policy reports. More generally, the ACE approach is intended to aid decision-making at the macro and meso levels within the healthcare system. At these levels, the marginal analysis possible with the DALY and DCIS databases that make ACE tractable, offer quite reasonable guidance. While potentially quite adaptable to variations in decision context at the macro and meso levels, its suitability for decisions at the micro level would have to be carefully considered.

Conclusion: the ACE approach actively seeks a well-defined research question and is clear about those decision contexts to which it is suited.

**Criterion 2: is there a clear concept of benefit?**

A key component of Criterion 2 is whether the priority setting approach has a mechanism or process to define the concept of benefit in a way that captures the perspective and objectives of the decision-makers. ACE–Cancer illustrates that this criterion is met through careful discussion in the Working Party. A key task of the ACE research team is to assist the Working Party to establish clear connections between their policy objectives, research question and the concept of benefit. Once the various dimensions of benefit are clarified, the ACE team then takes the Working Party through the various steps in defining and measuring the first stage ‘cost per DALY’ results and the second-stage filters selected.

Conclusion: the pursuit of a clear concept of benefit is a distinguishing characteristic of the ACE approach, reflecting the adoption of the best features of PBMA.

**Criterion 3: is there an acceptable process for generating options for change?**

Criterion 3 is an important aspect of giving practical effect to the economic principle of opportunity cost. 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, 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 ACE emphasizes:

- A clear process for the development and selection of options
- Clear specification of an evaluation protocol specifically developed for the priority setting context

ACE–Cancer demonstrated two key aspects of the ACE process for generating options for change, namely:

- Clarity regarding the steps necessary to generate the options for change, having regard to the specific decision context;
- Clarity about the principles that guide the selection process.

Conclusion: ACE 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.

**Criterion 4: 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 ACE since its inception. ACE–Cancer illustrates that in addition to incremental analysis comparing the intervention with its ‘current practice’ comparator (‘allocative efficiency’), marginal analysis of intervention design features (‘technical efficiency’) is also quite feasible. The evaluations of the colorectal and cervical cancer screening programs, for example, both illustrated that marginal analysis of intervention scale/scope (in this case screening frequency) and target/user characteristics (age group) is not only tractable, but produces accurate results in comparison with existing micro studies.

Conclusion: for decision-making at the macro and meso levels, ACE has demonstrated a capacity for both sound incremental analysis (allocative efficiency) and marginal analysis across several dimensions (technical efficiency).

**Criterion 5: are the decision rules clearly specified?**

As a general principle, the ACE approach features clear specification of the ranking process and associated decision rules, including the definition of ‘evidence’. ACE–Cancer illustrates that the ACE first-stage ranking adopts conventional cost-effectiveness decision rules, complemented by probabilistic analysis; while the second stage, which captures the broader considerations, is more subjective, but still explicit. The choice of how the second-stage filters are handled is one for the Working Party, having regard to the decision context. In ACE–Cancer this took the form of a simple dichotomous
variable (‘pass’, ‘fail’); combined with the specification of decision points and policy action to correct specified shortcomings. It is worth noting that while the ACE approach places importance on clarifying the decision rules, it does not place total reliance on them. Due regard has been paid to evidence from empirical experience that ritualistic adoption of technical rules simply does not 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 utilized in the overall ranking process are clearly specified in the ACE approach.

**Criterion 6: is the role of judgment clearly specified?**
There is clear recognition of the role of judgment in the ACE second-stage filter approach, together with acceptance that such judgment needs to be made explicit if priority setting is not to default back to implicit practices. A weakness in the ACE–Cancer study was the lack of in-depth discussion and teasing-out of ethical issues. To a large extent this reflected the tight time constraint, the established aims and objectives of the national 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 ACE approach, one suspects that practical constraints will always rear their head.

Conclusion: the need for judgment, as well as an explicit process for integrating technical information and issues of judgment, is clearly recognized in the ACE approach.

**Criterion 7: are the data needs tractable?**
Data limitations have played a major role in limiting the role and credibility of economic approaches to priority setting. The major innovation in data management under the ACE approach has been the development and/or use of ongoing descriptive databases on health expenditure and health status that facilitate incremental analysis between current practice and multiple options for change. The DALY database both assists with estimating the health gain (when combined with the efficacy data) and aids judgments about ‘size of the problem’ (when size is an agreed dimension of benefit). Similarly, the DCIS health expenditure database published by the Australian Institute of Health and Welfare assists with estimating any cost offsets and impact on health sector resource utilization. This makes priority setting across multiple interventions a viable proposition and limits the data needs of applying ACE to levels achievable with a small research team. More specifically, the context specific data needs for ACE are:

- **Effectiveness data on the options for change (the existence of which is a prerequisite for option selection);**
- **Resource utilization data associated with the options for change (based on specifying intervention activity pathways), together with routine unit cost assumptions;**
- **Data needs specific to broader notions of benefit (such as feasibility, acceptability and quality of the evidence base) with which the Working Party is expected to assist.**

Apart from the DALY/DCIS databases, the data needs of ACE are made tractable by a number of other features of the approach. These include:

- The focus on the development of an evaluation protocol that pays careful regard to the priority setting context;
- The use of a small research team to gather/develop the context specific databases (the case study was implemented with a small research team equivalent to two or three full-time research staff);
- The focus on option selection so that a comprehensive but manageable number of interventions are assessed at any one time;
- The potential for ACE to be institutionalized 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; manuals of resource unit costs and disease incidence/prevalence/risk factor data sets).

Conclusion: ACE provides an approach to priority setting in which the data needs are made tractable.

**Criterion 8: is the need for ‘due process’ recognized?**
The extensive involvement of stakeholders within the ACE Working Party potentially meets important aspects of this criterion. The extent and nature of this involvement separates the ACE Working Party from the more routine project-steering committees and/or advisory committees that are a common feature of the health sector. Key issues that arise, however, include:

- The extent to which all stakeholder interests are adequately represented (particularly the consumer perspective);
- The extent to which the decision-making processes adopted within the Working Party are regarded as ‘fair and reasonable’ (explicit, consistent, principled, democratic and based on relevant and credible information);
- 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 ACE–Cancer, clearly there is potential for the performance of the ACE model to vary from application to application.

One aspect of this complex issue is the way in which group decisions/scores are taken, particularly whether by seeking simple averages or by group consensus after informed discussion. While an issue of judgment, our clear preference after trialing both approaches in several ACE studies, is for the group consensus approach. Participants of ACE studies conducted to date support this view. Other difficult issues include how to facilitate
effective consumer representation and how to capture the difficult issues surrounding equity and ethics. While participants in the ACE–Cancer study were very supportive of the ACE approach and saw it as a ‘quantum’ improvement in the way in which decisions were taken, no member believed we yet had the process ‘just right’. Further work will be required to fine-tune the process, aided by empirical feedback by participants and those affected by the decisions.

Conclusion: the ACE approach has the potential to meet the due process criterion, but there is still room for improvement and careful ongoing monitoring of performance on this criterion is essential.

**Criterion 9: do the measurement methods demonstrate appropriate rigor?**

All ACE studies, including ACE–Cancer, are underpinned by a full economic protocol and publication of research methods. The evaluation protocol ensure that, wherever feasible, standardized evaluation methods are applied across all options assessed (with any exception clearly documented); that sensitivity analysis of key parameters is undertaken using multivariate probabilistic sensitivity analysis; that a standardized approach is taken to data collection and analysis and that careful regard is paid to the quality of evidence.

Conclusion: the ACE approach, both in design and application, demonstrates rigor in the measurement of costs and benefits.

**Criterion 10: reporting/implementation**

Criterion 10 asks whether priority setting models report results in a way that meet the concerns of decision-makers. The steps that underlie the ACE approach (particularly on focus on aims and objectives, on a clear concept of benefit, the second-stage filter analysis and on meaningful discussion of the results and their implementation) ensure that this criterion is taken very seriously. The full report of ACE–Cancer [48] illustrates the potential for reporting of a range of issues of concern to decision-makers. This includes guidance on what weight can be placed on the results in terms of the strength of evidence and rigor of the evaluation methods, as well as broader issues such as equity implications, feasibility of implementation, acceptability to stakeholders, importance of the problem addressed and financial implications.

Conclusion: the analysis and reporting of results under the ACE approach ensures that issues of concern to decision-makers are addressed.

**Overview of the ACE-Cancer performance**

The merit of the ACE approach was discussed on several occasions in the various meetings of the Working Party. The clear view that emerged from these discussions was that while there were aspects of the ACE methods and process that could be criticized and/or improved upon, the approach trialed represented a “quantum leap forward in the quality of information available for decision-making” [Pers. Comm. Mark Elwood. Working Party Member] [48]. Both the information base (the briefing papers) together with the process by which the deliberative judgments 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 and efficiency was strongly supported. The type and quality of information, the method of its collection and presentation and the clarity as to its intended use were viewed as important improvements over the NCCI priority setting process of 1997. The emphasis of the ACE approach on achieving a clear concept of benefit was also strongly supported. While members saw this discussion and its translation into clear measurement techniques as a challenging process, it was nonetheless accepted as an important task. Members of the Working Party concluded that the ACE process performed well and showed promise of being an important addition to the strategic planning process for cancer control in Australia.

This optimism was enhanced by three additional considerations. First, the feedback on the Draft National Cancer Strategy Report released for public consultation, included very positive feedback on the ACE input from senior members of the cancer research community (such as ‘should serve as a model for priority setting in other health areas’; ‘decision-making and priority setting techniques are impressive’ and ‘inclusion of economic analysis very valuable’). Second, a positive assessment of the cancer control case study by an independent review of priority setting models for health [59] and third, the funding of additional major applications of the ACE approach in cardiovascular disease and mental health within a year after completion of the ACE–Cancer study.

**Other ACE work & reflections from the ACE experience**

Reflecting back across the ACE studies completed to date and/or currently in progress (Table 1), there are a number of observations to offer. We have grouped these under three headings:

- Observations regarding acceptability and impact of ACE
- Observations regarding the technical analysis component of ACE
- Observations regarding the due process component of ACE

We have also reflected on to what extent any difficulties encountered are resolvable.

Observations regarding acceptability & impact of ACE approach

- The use of an evidence-based approach, facilitated by a suitably qualified research team assembling information on effectiveness, cost-effectiveness and the second-stage filters, has been strongly supported by all ACE Working Groups;
- In all ACE studies, irrespective of decision context and funding source, there has also been strong endorsement of the relevance and usefulness of the second-stage filter analysis to complement findings based on the ICERs;
- While stakeholders support the second-stage filter analysis, they have still expected technical rigor in the ICERs in order to ‘trust the arithmetic’. Technical rigor and due process have been seen as complements, not substitutes;
• Where studies have been directly funded by government, policy impact was higher, particularly when undertaken to inform specific strategic plans (as with ACE–Cancer). The drawback of decision contexts involving direct use in government policy, however, was shorter timeframes with less scope for more rigorous methods. We do not see this situation changing in the near future;

• Where studies have been grant-funded over longer timeframes, technical sophistication has improved, but the policy impact is indirect and more diffuse, often reliant on dissemination through the literature and/or conference presentations (e.g., ACE–Heart disease; ACE–Prevention). Again this situation is unlikely to change;

• Government-funded studies that were only loosely connected to policy development (important information-gathering exercises but not undertaken to help resolve specific questions) also struggled to achieve visible direct policy or clinical impacts (e.g., ACE–Mental health), but their indirect impacts were more substantive. In ACE–Obesity, for example, the Departmental project leader has been asked to supply information for various policy processes that link back to the ACE–Obesity research. Examples include the banning of fizzy drinks in schools and informing the national debate about further restricting advertising to children. This is encouraging for future collaborations between government and ACE researchers.

Observations regarding the technical analysis

• A key challenge has been to find a level of economic modeling that is sufficiently rigorous to achieve confidence in the results, achievable within the priority setting context where multiple interventions need to be assessed, while being transparent and easy-to-understand for policy makers. The ACE team is still resolving this challenge and will use case studies where different models are applied to the same decision context to further explore the issues and impacts;

• A second key challenge has been finding satisfactory ways of combining the ICERs into policy advice about intervention packages. While technical solutions are available that reflect the ICERs (such as expansion paths), resolving how to combine the ICERs with the second-stage filter information is more challenging. The ACE team is still researching this issue;

• The available evidence base in some research areas (such as obesity prevention) is also an issue. Evidence impacts on ACE methods at three points: first, at the point of selecting the interventions for assessment (there must be sufficient evidence to be able to clearly specify and model the effects of the intervention); second, in the sensitivity analysis (less evidence leads to wider and sometimes arbitrary uncertainty intervals) and third, at the policy conclusion stage in terms of what level of confidence can be placed in the ICERs and the trade-offs between ICERs and broader factors. For each application of the ACE approach, therefore, careful consideration has had to be given to clearly defining the concept of ‘evidence’ with stakeholders, including a classification system to grade additional sources of evidence, such as ‘indirect evidence’, ‘parallel evidence’ and ‘epidemiological modeling based on a range of evidence sources’;

• It has been easier, although still challenging, to apply our standardized methods in ACE studies that focused on a single disease or a single risk factor, than in those studies involving multiple diseases and/or risk factors, with disparate data sources. This supports the empirical evidence from a number of studies that vertical priority setting is easier to accomplish than horizontal priority setting;

• Related to this, data tractability remains a challenging problem for technical approaches that seek to analyze multiple diseases and risk factors. In Australia we are fortunate to be able to draw on existing databases that describe the epidemiology of diseases and summarize the disease burden and current healthcare expenditure. Such databases can be very useful in calculating the health benefit and potential cost offsets across multiple diseases/risk factors in a consistent way;

• Approaches like ACE that include rigorous technical analysis across multiple disciplines require skilled researchers in health economics and epidemiology. ACE has benefited from grant support in this regard (as opposed to reliance on commissioned work), because training and up-skilling of research staff (including PhD scholarships) can be specified as an important component of the grant program;

• Finally, agreeing clear criteria to underpin the selection of options of change has been important both in theoretical terms (focusing on ‘opportunity cost’) and in policy terms (to ensure relevance and commitment).

Observations regarding due process

• Stakeholders have always been strongly supportive of linking broad policy objectives to the assessment through the second-stage filters. Selecting the filters has worked well, although avoiding overlap has on occasions been challenging. Defining the filters clearly to avoid confusion in the discussions has been a little tougher (e.g., defining concepts such as ‘equity’ or ‘cultural security’), but never insurmountable. Finding data to inform the second-stage filter discussion has often proven difficult and this aspect of the analysis is inevitably reliant on the professional judgment of the stakeholders. This situation is not likely to change;

• While there are technical ways of incorporating the second-stage filters into the ICERs (using decision theory), most ACE Working Groups have not been attracted to this technical option and have preferred the clarity and simplicity of the two-step process;
• In ACE studies to date, game playing has not been a problem and consensus conclusions following deliberative discussion have been adopted in all studies. Confidential voting has not been requested or applied in any ACE study;

• While lay people have been involved in some of our studies (e.g., ACE–Cancer, ACE–Mental health and Community Health Centers study), this has always been a challenging issue owing to the steep learning curve involved for lay people to get across the technical component of the ACE work. This issue is likely to remain while ever priority setting exercises are run on tight budgets with tight timelines.

Expert commentary & five-year view

Despite some progress in recent times, explicit priority setting along the lines involved in ACE is not commonplace. 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 organizational 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 (e.g., program structure and associated cost centers); for current data collections (e.g., the collection of activity and outcome data); for research activity (e.g., establishing the evidence base) and the visibility of decisions. There needs to be recognition that explicit approaches to priority setting require infrastructure, a long-term commitment from senior management and the courage to confront vested interests. Decision-makers need to have confidence, therefore, not only in the technical results, but also that the policy recommendations include a consideration of the broader factors that impinge on them.

ACE has shown that there is 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 judgments on priorities. The key question will remain the extent to which the technical appraisal and due process is used and the respective emphasis on these different approaches. Key issues in finding this balance will include:

• Closer working with government to generate trust, maintain relevance and direct knowledge transfer;

• Finding the correct level of economic modeling, balancing rigor, timeliness and user friendliness;

• Finding the balance in reporting formats between declaring weaknesses in the methods and data sets and not undermining the whole endeavor (not letting ‘perfection’ become the enemy of the ‘simply good’);

• Achieving data tractability through large data bases that summarize the current health burden and health expenditure across all diseases/risk factors;

• Improving the surveys and routine data collection systems that underpin the epidemiological estimates of disease/risk factor incidence and prevalence (reducing the reliance on self-report in generic health surveys);

• Developing the evidence base on intervention efficacy/ effectiveness;

• Careful consideration of the definition of ‘evidence’ and its incorporation into all aspects of the analysis;

• Broading the appeal of studies in the health sector (to Departments of Finance and Treasury) by incorporating broader production effects in the general economy.

Many authors and reviewers of international experience endorse the call for multidisciplinary research. Australian experience has demonstrated that consensus approaches founded in behavioral science have been well regarded by participants. While these approaches have important limitations from an economic perspective, their success in consensus building highlights the potential for an interdisciplinary approach that draws on the respective strength of each discipline. Similarly there are a number of models that demonstrate the significant potential for cooperative research between economics and epidemiology. The nature of the collaboration and the disciplines involved will depend, of course, on the research issue.

Acknowledgements

Each of the ACE studies involved a Working Group of stakeholders and some also involved Steering Committees or Technical Advisory Panels. We are very appreciative of the input and contribution to the studies provided by these stakeholders and collaborators. Finally, but certainly not least, the ACE studies have relied upon dedicated research staff who have been an important part of the research program. We thank them for their vital contribution to the research endeavors.

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No writing assistance was utilized in the production of this manuscript.
Key issues

- There are no simple solutions to the challenges posed by priority setting. Complexity is inherent in the range of stakeholders involved, the various levels at which decisions are taken and the importance attached to ethical values and principles.
- There are a wide variety of approaches to priority setting available, offered from a range of disciplines (economics, epidemiology, behavioral science and philosophy). A useful step in assessing these various approaches is to reflect on the question of what constitutes an ‘ideal’ approach to priority setting.
- An important contribution of this article is to provide a broadly based checklist based on four rationales, namely: guidance from economic theory, the lessons from empirical experience with priority setting, guidance from ethics and social justice and the needs of decision-makers.
- The Assessing Cost–Effectiveness (ACE) approach to priority setting meets the ten criteria set out in the checklist better than any of the other approaches reviewed. ACE offers a credible way of achieving both technical rigor and the practical inclusion of broader issues of concern to decision-makers.

References

Papers of special note have been highlighted as:
• of interest
•• of considerable interest


• Excellent guide to program budgeting and marginal analysis and its use around the world.


• Excellent review of classical welfarism from a health economics perspective.

• Provides full explanation of the checklist presented to guide priority setting.


32. Mitton C, Donaldson C. Priority Setting in Regional Health Authorities: The Impact of Program Budgeting and Marginal Analysis. *International Health Economics Programs, University of Calgary, Canada* (2000).


• Excellent text on economic evaluation methods. Also provides a checklist to guide evaluation of individual interventions. Checklist can be compared with the Carter checklist reported in this article which incorporates broader factors relevant to priority setting.


• Excellent text on economic evaluation methods. Also provides a reference case to guide economic appraisals and associated recommendations. The guidance offered can be compared with the Carter checklist reported in this article which incorporates broader factors relevant to priority setting.


• Excellent coverage of normative economics from a health economics perspective.


• Provides a useful introduction to normative economics and the potential role of the Decision Making School (which is where the Assessing Cost–Effectiveness (ACE) approach logically sits).


• Provides a useful introduction to normative economics and the potential role of extra-welfarism and ‘healthism’ (as opposed to welfarism).


• Full report on the ACE-Cancer case study reported in the article.

49. Peacock S, Richardson J, Carter R. *Setting Priorities in South Australian Community Health II: Marginal Analysis in Mental Health Services.* Centre for Health Program Evaluation, Melbourne, Australia (1997).

• Good example of decision theory being used to combine multiple dimensions of benefit into a single score.


• Excellent example of ACE approach and associated methods.


• Excellent example of ACE approach written to inform decision-makers.


• Excellent example of ACE approach and associated methods.
Origins, description & application of the Australian ACE initiative

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