

Priority-setting methods to inform prioritisation: a rapid review

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An **Evidence Check** review brokered by the Sax Institute
for the NSW Treasury and the Agency for Clinical Innovation

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This rapid review was brokered by the Sax Institute.

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EXECUTIVE SUMMARY

This review seeks to provide guidance for the Agency for Clinical Innovation (ACI) as part of the NSW Ministry of Health's new governance arrangements on priority setting methods that support the key design principle of 'Efficient and appropriate allocation of resources where they can do most good on the basis of models of best practice which deliver best health outcomes'.

On the basis of a review of the main approaches both internationally and in Australia, it indicates the sort of priority-setting framework which is best suited for use in NSW. It does so on the basis of criteria developed for a sound 'best practice' framework with specific reference to NSW.

To supplement the review and to identify which priority setting methods implemented in various settings were perceived as successful, a targeted survey was conducted with 18 researchers in this field.

This review first sets out to identify the criteria that might apply to best practice to meet the terms of reference of the review. These criteria are of differing degrees of importance in providing the necessary guidelines for priority setting in NSW. They are set out below in four tranches.

Key criteria in priority setting frameworks

First there are general *background criteria*: those elements which, independent of the approach used, are needed if priority setting is to be implemented successfully. Second are those elements deemed to be *essential criteria* as, if these were missing, then the approach simply cannot succeed. Third are what are deemed to be *highly desirable criteria*. These cover items and issues which, in addition to those listed under essential, a good priority setting approach would ideally include. And finally there are *capacity criteria* which any approach may be capable of, but which some are more able to incorporate than others. These can be seen as desirable to successful priority setting but at the level of the capacity of an approach, as opposed necessarily to the actuality of the approach, to resolve certain questions.

Below, the *background criteria* are simply listed. They are required whatever priority setting approach is adopted, and no approach is better or worse in principle with respect to these criteria. In Table 1, each priority setting approach is judged in terms of the presence or absence of these *essential criteria* and the *highly desirable criteria*. An assessment is then made (not in table format) of the ability or capacity of each approach to meet the *capacity criteria*.

Background Criteria

- Acceptance of the need to prioritise: if those who have to do the prioritising in practice do not accept the need for it, progress will be difficult and perhaps impossible
- Incentives for change: as there needs to be some change in various actors' behaviour, consideration is needed to ensure that relevant incentives are in place to allow that change
- Leadership/championing: numerous studies of priority setting indicate that strong leadership or a 'champion' for prioritisation (especially among clinicians) makes the whole process more viable.

Essential Criteria

- Opportunity cost within health care: opportunity cost is a technical economic term which means simply the benefit foregone in the best alternative use of the resources in health care. In lay language 'robbing Peter to pay Paul' – at what cost to Peter?
- The concept of the margin: again economics terminology which is focused on the idea that priority setting is about getting a better balance in the use of resources or looking for best buys with additional resources. Priority setting is thus about changes 'on the margin' – a bit more of this at the expense of a bit less of that or, where the budget expands, the best buy for the extra money available
- Some set of acceptable principles or objectives: organisations can be differently structured; some based on principles (or values) which might include fairness, accountability, etc.; and others focused on what they seek to achieve i.e. objectives such as health maximisation. Such principles can be more or less acceptable to those in the system and to those the system serves
- Having the capacity to be understood and acted upon by clinicians in health services and networks: if clinicians cannot see the sense in the priority setting approach, they may well balk at acting upon it.

Highly Desirable Criteria

- Explicitness and transparency: priority setting has to be driven in part by values. Confusion, uncertainty or obfuscation regarding these values will make for difficulties in gaining acceptance by those in the system and patients and citizens for a priority setting approach
- An evidence-based approach
- Local NSW evidence: priorities are local; where at all possible local evidence is to be preferred
- Local NSW values: again priorities are local; where at all possible local values are to be preferred
- Efficiency: value for money (according to the principles or values that are being sought)
- Equity: this is an objective of health care in NSW and needs to be reflected in any priority setting system
- Inclusion of non health service costs: while priority setting tends to be focussed on health service costs, care needs to be exercised so that costs falling on patients, their relatives and other agencies are not ignored
- Able to resolve:
 - Whose values to adopt with respect to for example setting principles, defining benefit, trading off between different benefits. How equity is to be defined and by whom
 - How important equity is compared to efficiency and who decides: there is often a 'trade off' or conflict between these; the relative importance of each needs to be addressed.

Capacity Criteria

- To consider the feasibility of implementation
- To allow priority setting within individual networks
- To allow priority setting across these networks
- To be used with little adjustment in other settings.

Main approaches to priority setting emerging from the literature

The main approaches reviewed in the literature were as follows:

PBMA¹

Program Budgeting and Marginal Analysis (PBMA) is built round the idea of providing an information framework (the program budget) to allow a picture of where resources are currently going and thereafter looking at whether a movement of resources from program A to program B might increase total benefits (marginal analysis). It can also provide a basis for judging where to allocate new money to get 'the best buy'. The approach is based on the economic notions of opportunity cost – the benefit foregone in the best alternative use of the resources – and the margin – which highlights that priority setting is about change.

QALY league tables²

This device assumes that health services are about health only and that such health can be measured by Quality Adjusted Life Years. These 'QALYs' are a measure of health that seeks to combine length of life and quality of life. QALY league tables then seek to establish what the extra cost is per QALY of extending various different programs or services and the ranking these 'marginal costs per QALY' in ascending order. Any additional money would then be allocated first to the program 'at the top of the league' since that is where the most QALYs can be bought with extra monies.

Needs assessment, cost of illness and burden of disease³

These three approaches are lumped together as the target they share is to aim resources at big problems – respectively health need, the overall economic cost of illness and the extent of the problem – the so called 'burden of disease' – that a disease creates. Priorities are determined or as a minimum influenced by the size of the problem – the bigger the problem, the higher the priority.

¹ See for example Mooney G. Economics, Medicine and Health Care. Chapter 9. 2003; Pearson: Harlow; Mitton C, Donaldson C. Tools of the trade: a comparative analysis of approaches to priority setting in health care. Health Serv Manage Res. 2003; 16(2): 96; and Ruta D, Mitton C, Bate A, Donaldson C. PBMA: bridging the divide between doctors and managers. BMJ. 2005 ; 330:1501–1503.

² See for example Gerard K, Mooney G. QALY league tables: handle with care. Health Econ. 1993; 2(1):59–64.

³ More background is provided at Hope T, Osterdal LP, Hasman A. An inquiry into the principles of needs-based allocation of health care. Bioethics 2010; 24(9):460–480; Tarricone R. Cost-of-illness analysis. What room in health economics? Health Policy 2006; 77:51–63; Lopez AD, Mathers CD, Ezatti M, Jamison D, Murray CJL. Lancet. 2006; 367(9524):1747–1757; and Australian Institute of Health and Welfare. Burden of disease. The burden of disease and injury in Australia 2003 Available from: <http://www.aihw.gov.au/burden-of-disease/>

Target setting⁴

This is largely self-explanatory. This approach sets targets for (usually) reducing disease or increasing coverage (say of immunisation) and then allocates resources in such a way as to try to reduce the disease or improve uptake. It is often linked to needs assessment to provide the levels of the targets.

Core services⁵

The idea of core services is that some health services are in some sense essential and thus must be provided, whereas there is more discretion over 'non-core' services. This can be a mechanism for example for trying to decide which services are available in the public sector ('core services') and which in the private sector ('non-core services').

Generalised cost effectiveness⁶

With this approach, the costs and health benefits of various interventions are assessed as compared with a situation in which those interventions did not take place. The results are then put in three categories: very cost-effective, cost-ineffective, and somewhere in between. This approach thus deals with interventions and not marginal or incremental change. It looks at the world with and without these interventions. It also adopts a more global or generalised approach rather than a more local approach.

Other approaches

Additionally there is a trio of priority setting 'aids' (which are in essence quite similar) which have been dealt with in this review not as priority setting approaches per se even if some might see them in these terms. That view might well be justified in other contexts but, in this review, in NSW their practical usefulness has been interpreted as being as adjuncts to PBMA and to provide added strengths to the application of that technique if used with caution. These are option appraisal, multi-criteria decision analysis and multiple attribute utility analysis. They represent ways of allowing often-difficult-to-measure attributes (such as patient reassurance) to be included and weighted. Caution is needed however to ensure that such attributes are legitimate within the scope of the set principles or objectives.

Assessment of approaches against key criteria

As indicated, the background criteria and capacity criteria apply more or less equally across the board. This however is much less the case for the essential and highly desirable criteria. These are brought together in Table 1 below.

A ✓ indicates that that criterion applies in that approach. A ✓? indicates that it might apply or can apply to that approach. Where there is no marking that means that that criterion does not apply to or is absent from that approach.

⁴ For more information see Bevan G. Setting targets for health care. *Journal of the National Institute for Economics and Social Research* 2006;197:67–79. The most famous example is WHO's Global Strategy for Health for All in the Year 2000. Available from: <http://whqlibdoc.who.int/publications/9241800038.pdf>

⁵ See for example Cumming J. Core services and priority-setting: the New Zealand experience. *Health Policy* 1994; 29:41–60; and Campbell AV. Defining core health services: the New Zealand experience. *Bioethics*. 1995; 9(3):252–258.

⁶ Discussions of this approach can be found at Murray CJL, Evans, DB, Acharya A, Baltussen RMPM. Economic evaluation development of WHO guidelines on generalized cost-effectiveness analysis. *Health Econ*. 2000;9: 235–251; and Hutubessy R, Chisholm D, Edejer TTT, WHO-CHOICE. Generalized cost-effectiveness analysis for national-level priority-setting in the health sector. *Cost Eff Resour Alloc*. 2003; 1:8 doi:10.1186/1478-7547-1-8.

It must be recognised that in reaching decisions about these categorisations there is substantial judgment involved and also the markings relate to the general situation. There may well be exceptions. Thus the tables should be used with caution.

Table 1: Essential and highly desirable criteria by approach

Criteria		Approach					Generalised cost effectiveness
		PBMA	QALY league tables	Needs assessment/ COI/BOD	Target setting	Core	
Essential	Opportunity cost	✓	✓?				✓
	The margin	✓	✓				✓
	Acceptable principles/objectives	✓	✓?	✓?	✓?	✓?	
	Understandable to clinicians	✓	✓	✓	✓	✓	
Highly desirable	Explicit/transparent	✓	✓	✓?	✓?	✓	
	Evidence based	✓	✓	✓		✓?	✓
	Local NSW evidence	✓					
	Local NSW values	✓					
	Efficiency	✓	✓?				✓
	Equity	✓	✓?	✓?		✓	
	Non-health service costs included	✓?		✓?			
	Whose values re principles, benefits, etc.	✓	✓?				✓
	How and by whom equity is defined	✓	✓?				
Relative weight of efficiency vs. Equity and who weights	✓						

Legend:

- ✓ The criterion applies
- ✓? The criterion might or can apply
- [Blank] The criterion does not apply

With respect to the *capacity criteria*, PBMA followed by QALY league tables comes out on top. What is encouraging with respect to PBMA is that with respect to these criteria again PBMA does well and especially with respect to implementation. PBMA has been used a lot (sometimes certainly in conjunction with option appraisal, multiple utility analysis or multi criteria decision making) and repeatedly used in some health authorities such as Calgary in Canada.

Recommended approach

In the light of a review of the main approaches used and recommended internationally and in Australia, and as reflected in the tables and comments above, one approach emerges as being superior to others: Program Budgeting and Marginal Analysis (PBMA). This approach is built on two key technical criteria which it is argued in the review must be present in any good priority setting approach namely 'opportunity cost' and 'the margin'. When these two economic concepts are applied in practice this allows judgments to be made around questions which are fundamental to priority setting such as if the health services or agencies are faced with a fixed budget, where best to spend an extra say \$500,000 and where best to cut to obtain that money? Or if the total spend is to be increased by \$1 million, where best to spend that?

When these criteria are missing as is the case for most priority setting approaches reviewed (QALY league tables is the only one which comes close), then they cannot address these sorts of

questions which are fundamental to the process of priority setting. PBMA is not perfect but it has been widely used and where used initially it has often been used again, sometimes several times which represents some sort of endorsement.

Survey with researchers

The literature reviewed provides all too little regarding the success of priority setting exercises. As a result a special survey was conducted of 18 researchers in this field with a 100% response rate. That survey shows that there have been a substantial number of recommendations from priority setting studies, especially PBMA studies, which have been implemented and that some health jurisdictions have used PBMA several times. The extent to which the impact on efficiency and equity is known however is very limited. The key reasons for success in implementation are the presence of good leadership, a health economist 'embedded' in the system and ownership of the approach by those, especially clinicians, who have to make the system work.

Other questions addressed in the review

The extent to which the public might be involved in priority setting in NSW needs to be debated. The literature reveals a concern that in too few studies is the public involved. If this is to happen in NSW, citizens' juries are proposed for such involvement. Of the various methods of 'deliberative democracy' available to involve the public, these citizens' juries are recommended because they (1) are based on a random selection of the relevant population; (2) emphasise the role of citizens qua citizens in a group setting; (3) seek to ensure that 'the jury' is well informed; and (4) place clear budget constraints on their choices.

1 Background, introduction and methods used in selecting sources

This review seeks to provide guidance for the ACI as part of NSW Health's new governance arrangements on priority setting methods that support the key design principle of 'Efficient and appropriate allocation of resources where they can do most good on the basis of models of best practice which deliver best health outcomes'.

On the basis of a review of the main approaches both internationally and Australian, it indicates the sort of priority-setting framework which is best suited for use in NSW. It does so on the basis of criteria developed for a sound 'best practice' framework with specific reference to NSW.

It also addresses questions of implementation and engagement with the public of NSW.

The purpose of this review is thus to inform the selection of a priority-setting framework suitable for:

1. individual networks within the ACI that are developing clinician-led, condition-specific best practice clinical models of care to improve health outcomes at the local level
2. the ACI organisational level, where projects relating to models of care, unwarranted clinical variation and clinical innovation need to be prioritised across all networks and may be put forward for funding as part of a Ministry of Health funding process.

The review will contribute to the translation of network-specific recommendations regarding high priority areas into a coherent ACI-wide Strategy that includes a program of priorities to improve models of care, rollout clinical innovations and reduce unwarranted clinical variations in care and health outcomes.

The review first sets out to identify the criteria that might apply to best practice to meet the terms of reference of the review. Thus to achieve best practice in providing the necessary guidelines for priority setting in NSW as required any approach should incorporate some general criteria that are important in having success, whatever priority setting approach is adopted. These are:

- Acceptance of the need to prioritise
- Consideration of the feasibility of implementation
- Incentives for change
- Leadership/ championing.

There are then some criteria that are deemed to be *essential* to any good priority setting approach, essential in that without these it is argued the approach cannot make progress in any rational way:

- Opportunity cost within health care
- The concept of the margin
- Some set of acceptable principles or objectives
- Having the capacity to be understood and acted upon by clinicians in the ACI Network.

There are thereafter some *highly desirable properties*:

- Explicitness and transparency
- An evidence-based approach
- Local NSW evidence
- Local NSW values
- Efficiency
- Equity
- Inclusion of non health service costs
- Able to resolve:
 - Whose values to adopt with respect to for example setting principles, defining benefit, trading off between different benefits
 - How equity is to be defined and by whom
 - How important equity is compared to efficiency and who decides.

Capacity Criteria

- To consider the feasibility of implementation
- To allow priority setting within individual networks
- To allow priority setting across these networks
- To be used with little adjustment in other settings.

One issue regarding the content of this review which might be a cause for concern for some readers is the question of evidence in an era where there is a constant and desirable call for decision making to be evidence based. The review is evidence based but in what is perhaps an unusual way. It is based primarily on judgements. First there are the judgements of the authors, in the light of reading a large number of studies, regarding what are appropriate criteria for assessing different priority setting approaches. Second there are the judgements of the authors regarding how well different approaches might perform in NSW. Third there are the judgements, largely from the 18 researchers on priority setting, on what they think the success of such studies has been and the reasons for success.

Certainly the content of any priority setting approach ought to be evidence based but that is a rather different matter. Even then, as the review brings out, evidence from elsewhere may need to be 'localised' and that will inevitably bring in more judgements.

The method used for search and selecting sources

To identify relevant studies for inclusion in the discussion surrounding the development of this report, the researchers searched Medline using appropriate MESH terms for each priority setting framework. Abstracts of returned studies were scanned for relevance to the paper. Once relevant studies were found, researchers searched Medline using the keywords and MESH terms associated with the identified papers to find further articles. Reference lists of identified papers were scrutinised for other relevant studies and citing articles were identified using Medline, and their abstracts also scanned for relevance to the paper. Grey literature was identified through Google searches as well as searches of relevant government websites.

2 Criteria for 'best practice' priority setting

There are many different ways of setting priorities, some good, some less so. Some are more apposite for particular health services or agencies than others. There are also many different set-ups or contexts or cultures in which such priority setting can take place. What is clear is that priorities in health care have to be set. This choosing can be explicit or implicit. It cannot be avoided and why? Because there will never ever be enough resources in any country, no matter how rich, to allow all the needs for health care to be met. It is crucial to any priority setting system that this is recognized so that any reasoned debate about priority setting focuses on how rather than whether.

Thus the reason why priority setting is necessary is because resources are scarce. There are not and never will be enough resources to do all that is desirable or technically feasible in health care. What this means most fundamentally is that any reasoned priority setting system must have at its core a recognition of such scarcity and some way of dealing with it. It cannot be assumed away; it has to be addressed. This involves the economic concept of opportunity cost – the idea that when a resource or set of resources is committed to the provision of one service, it cannot be used in the provision of another. Opportunity cost, strictly defined, is the benefit foregone in the best alternative use of resources.

Secondly a closely related but separate point, and needing separate acknowledgement, is that if the idea of scarcity and in turn of choice is not accepted by the key players in the relevant services, then attempting to get the recommendations from any priority setting system implemented is all too likely to fail.

A third point is that priority setting is about change and trying to determine whether some redeployment of resources can result in greater benefits. It is about altering the balance of resources within some fixed budget to squeeze more benefit out of them; or if more resources become available establishing where the extra resources will do most good; or if there is a fall in the monies available where cuts can be made to do least harm. This means that priorities are to be established in terms of opportunity cost and 'the margin', where the margin relates to change.

Strictly the marginal change is a change of one, for example a change of one in the level of output i.e. one extra unit of output. The 'rule' governing the efficient use of resources in a world of scarcity where efforts are being made to maximise benefit (equity is left to one side for the moment) is that resources are allocated across competing projects or services until the point is reached where the ratio of marginal benefits to marginal costs in every service is the same. Translating that idea into lay language it means that benefits are maximised when resources are allocated in such a way that to move some from one service to another would lead to a fall in total benefit.

Thus priority setting is about change and about balance. Priorities in health care are not 'lexicographic'. An example of a lexicographic ordering is to say that prevention is better than cure and mean by that that prevention is *always* better than cure and that therefore we should do everything possible in prevention before getting round to doing anything in cure. The relevant issue here is rather, if there is a fixed budget, is overall benefit higher by taking a marginal million out of cure and reallocating it to prevention? If the answer is yes, then there would be a need to look at another \$million; and so on. If total benefit is not greater with the first move of a million dollars from cure to prevention, then there is a need to look at moving resources in the opposite direction. This thinking is crucial to any good priority setting system.

A fourth point is that any reasoned priority setting system must be based on some set of principles (or values) or be seeking to support the attainment of some objective or set of objectives. This means that there needs to be acknowledgement that the organisation involved is (a) objectives focused; (b) based on some set of principles (or what has been called a constitution); or (c) some combination of these two. In turn these objectives and principles need to be made explicit. These are discussed further below.

While no discipline has a monopoly on systems of priority setting, it is priority setting (or choosing) when resources are scarce that economics is about. Indeed economics is the science or the art of choice. While this discipline has been called the dismal science that is unfair in that economics argues that limited resources are to be allocated in such a way as to maximise benefits – read happiness if you will. The issue here is the notion of efficiency which comes in two guises: operational efficiency which is about meeting objectives at least cost; and allocative efficiency which seeks to maximise benefits with the resources available. Economics also seeks to try to ensure that health service resources are allocated in a way that is seen as fair in the eyes of the society served.

Fifthly, the setting of objectives and principles involves the use of values. Again it is ideal if such values are made explicit and some agreement is reached regarding whose values are to count in which circumstances.

What this means in practice is that some rational informed system of priority setting matters because:

1. Some system of rationing is inevitable and it is better that it be rational and explicit than irrational and implicit
2. Without an acceptance of the need for priority setting, any recommendations from any priority setting approach may well be ignored
3. This is a way to try to use resources in health care to maximise the benefits sought, to pursue fairness and to acknowledge explicitly the trade off between these two
4. This raises important value issues regarding the relative weights to be attached to such principles as efficiency and equity – and the trade off between them.

Given these comments what is quite strange is just how little priority setting in health care takes place that could be described as rational, informed and explicit. This is especially true in Australia. It can be the case that using economic analysis in an ideal fashion can be difficult, given in particular the demands on measuring techniques, especially of the benefits of health care. These are still being developed. There are also data deficiencies in all health care systems in the sense that on both the costs and the benefits side the information does not exist in the form, detail and precision that is ideally wanted.

What needs to be recognised here is that until there is a real push for good priority setting and a recognition that it has to be done and as such is better done well, then the prospects for getting the data necessary for the sort of priority setting that is anywhere close to the ideal are not good. In that statement lies a major challenge. What happens in the meantime is that inferior methods are often used and for two reasons: first because they are less threatening to existing interests in health care; and second because they are able to use data that are more readily available. Adopting a priority setting system that is explicit can be threatening to the existing power structure. With the understandable desire for rigour in health policy, through for example evidence-based medicine, there is an accompanying push for quantification. That can lead to policy approaches being devised which start by asking 'what data do we have?' and adopting an approach that allows the data to drive both the approach and the philosophy underpinning priority setting. As is the case in so many fields it is argued here that getting the principles or the ideas right is what matters; data can be less precise and still be OK.

Thus it is better to have a good approach and poor data than a poor approach and good data.

Economics is first and foremost about a way of thinking about resource allocation. In priority setting this is especially true. The key message here is that unless the thinking underlying priority setting is 'right' – and there is scope for debate about precisely what that means – then there is no possibility except by luck of getting priorities set in such a way that they will further the objectives of health care. It may well be the case in the foreseeable future that economic analysis in priority setting will not be implemented in any ideal fashion. However, a set of inadequate data and poor measuring supporting the right thinking is more likely to get us to an approximation of where it is desirable to be than will better data and better measuring techniques where the thinking is wrong.

One issue that is important and can be overlooked in priority setting is that while an evidence-base is crucial, it needs ideally to be a *local* evidence base. Thus the question with respect to health benefits and losses is this: if in this speciality in this hospital, there is an increase of spending of \$500,000 (say) what benefits will that bring? The general literature because it is general almost certainly will not address this issue. It can indicate what the impact across a range of other sites is but probably not with respect to some change in resource allocation that is being contemplated in that speciality in that hospital in NSW. That makes getting the relevant evidence more difficult but stresses the need to make that evidence as local as possible. Here there is another rule of priority setting. Better somewhat rough local evidence rather than precise 'foreign' evidence. This rule applies not only to health benefits but all benefits; it also applies to costs.

Measurement and data problems are present *whatever* methods are used to address priorities. Rational priorities in health care cannot be set without having some estimate, even if imprecise, about the costs and benefits of different patterns of intervention and more particularly the costs and benefits of changes in these patterns. Thus while it has been argued that the approach of economics to priority setting creates problems because it is data intensive, that is a false charge. These problems exist whatever priority setting approach is used. In so far as other approaches sidestep these problems they cannot be genuinely useful methods for priority setting in getting any health care jurisdiction down the road to more efficient and equitable health services.

This issue is important. Most of the criticisms that are aimed at the economic approach to priority setting seem to centre on the practical problems of implementation. These concerns are very often with the data demands and the demands on measuring techniques that the economic approach makes.

Beyond the four points listed above, other major criteria are required for good priority setting. What is meant by benefit when efficiency is defined in terms of maximising benefits with the resources available? There are different ways of looking at this depending on the nature of the institution involved. The organisation may be based on an exchange paradigm, a goals paradigm or a principles (or constitutional) paradigm. An exchange paradigm stems from the market where benefit is either left undefined or called utility which might be equated with satisfaction and the social benefit is an aggregation of individuals' utilities. This requires that consumers are well informed and that the community value can be equated with the sum of the consumers' values. Neither is likely to be valid in health care.

The goals paradigm for an organisation indicates that the driving force of the organisation is to attain certain goals. This might be for example to maximise health. One of the key questions that then arises is who is to determine what the goals are. This is discussed more below particularly as this goals paradigm is the most common in health care systems.

The third paradigm is the constitutional paradigm. This argues that an organisation is or seeks to be based on a set of principles or explicit values, called in this context a 'constitution'. These might include such considerations as transparency in decision making, respect for patient autonomy and the ethics of treatment. Others might be efficiency and equity without necessarily requiring that these be measured. If measurement were to occur then that might well change principles to goals and the paradigm from constitutional to goals. Thus these two paradigms are closely linked but nonetheless are different. In the context of priority setting this distinction is especially important since so often, while the goals may be identified, there is a tendency to rush past or even ignore the issue of principles or values.

Yet another issue to be determined in any priority setting approach relates to the question of whose values are to count. A clearly closely related matter is that of how these are to be obtained. This can be a vexed issue with many different parties often vying to have their values count. Here it is important to distinguish between the questions of whose values and whose decision. These are not necessarily to be obtained from or made by the same people but nonetheless the two – the valuers and the decision makers – can be confused.

In part the resolution of the question of whose values can be achieved by looking at this at different levels. Too often it seems that the question is answered: everyone's. Much better to appreciate that there are 'horses for courses'. In other words there are decisions to be made at different levels and different values to be applied at these different levels. Thus for a clinician in a ward, she is the one who to a major extent uses her values to form judgments about prioritising her time across different patients. Questions however of the optimal split between prevention and cure, the priority between the care of children and the care of elderly people, between cancer patients and those with heart disease and the trade off between efficiency and equity (mentioned above) are all social priorities where it might be seen as better to bring the community voice to bear (on the basis of good evidence of course) but a well informed community and not 'the puff of public fancy'.

When efficiency in particular but also equity is being pursued, the question arises: the efficiency and equity of the allocation of *which* resources? Most often the resources included in priority setting exercises are limited to health service resources. While this is a legitimate focus, there are problems or risks associated with it as it omits consideration of for example other social services resources and the resources of patients, of their relatives and of their friends. There is then a risk that priority setting exercises result in giving greater priority than would otherwise be merited to certain activities which 'unload' in part or in full to other sectors (for example out of hospital to residential home care) or which recommend reducing community nurse visiting by relying more heavily on family carers.

This is a difficult issue and in an ideal world would mean that each and every action of the health service be subject to a cost benefit analysis. In full bloom this would involve determining the optimal size of the health service budget through cost benefit analysis. While this is clearly impractical, none the less in any good priority setting system there needs to be some mechanism for handling this issue such as – while less than pure – allowing for non health service costs as a form of negative benefit on the benefit side of the priority setting exercise. Non *health* benefits should be included anyway if the principles/objectives include these.

A further issue that any good priority setting system needs to address is that of getting action in the wake of any recommendations emerging from the priority setting exercise. This involves changing the behaviour of some of the key actors in the system, often clinicians, who need to be 'sold' the approach and somehow encouraged to own it. While it is an obvious point to make, any priority setting system is a waste of time if it changes nothing. Priority setting is undertaken because there is a belief that in some way or other there is scope for improvement in the way that resources are being used. But the resources have to be shifted if the process is to have any chance of success.

This means that a crucially important part of any priority setting system is implementation and the addressing of issues around how to get the changes necessary which will allow the recommendations to be put in place. There are in essence two barriers to implementation: inappropriate incentives and power structures. These are clearly related. There are incentives in any system and the question that needs to be addressed is how to get the right incentives in place to allow the relevant actors first to buy into or feel ownership of the process and second to be prepared to alter their behaviour to pursue the objectives or principles that the priority setting system seeks to pursue. Thus an important part of the priority setting system is fostering behavioural change.

Alongside this issue is that of the power structure within health care and the need often to seek to change that. Introducing a new explicit priority setting system can be threatening to certain parties within the system and there needs to be a recognition of this. The adage that information is power is true here and making priority setting explicit can threaten to usurp the power of existing decision makers. This is no easy matter to handle but it is here that first class leadership is needed to try to gain the necessary 'buy in' from those parties who otherwise might feel threatened. Part of this involves trying to get key figures, often clinicians, to grasp the need for looking beyond 'their own patch', be that their own specialty or their own hospital, and engage in what amounts to being advocates for the local health system. This can be difficult. Nonetheless these are issues that ideally any priority setting system has to try to embrace. It is wholly understandable that clinicians focus on their patients and their hospital but, for systems-wide priority setting to work successfully, a broader view must also be present.

One difficult area in priority setting is that of gaming or the minimising of gaming. An example of this is where, in identifying candidates within their own specialties for disinvestment or investment, clinicians may be wont to exaggerate the impact on their patients of any possible cuts or benefits from any interventions. This issue of loyalty to own patients versus loyalty to the hospital versus loyalty to the local health system needs to be addressed in any good priority setting system. Making the process explicit and transparent; persuading actors in the system through key leaders or champions to adopt a systems approach; and seeking to get them to take ownership of the priority setting system are crucial elements that need to be considered. Giving clinicians a good understanding of some of the basic economic concepts here is an essential ingredient but also building a management culture which is a mix of competitiveness – if A's patients have more, then B's must have less – and cooperation aimed at the common good.

There is also a case for bringing in outside clinicians to assess whether claims made for both the benefits of extra resources and the disbenefits of cuts in resources (both of which under gaming may be exaggerated) are justified and ideally evidence based. This 'reviewing' process need not be applied on any regular basis but only where there is a concern either that gaming is taking place or for some other reason to think that the basis of any claim regarding the size or nature of any benefit loss or gain is not justified.

Returning to the question of implementation, this has a number of features. It must be able to be understood by those who will have to use it or live by it and whose behaviour in responding to it can make or break it. It has to be able to be 'sold' rather than imposed. It must seek to the extent possible to ensure that the behaviour of clinicians and other key actors is such that the goals they seek and the incentives they respond to are ones that serve the system's goals of efficiency and equity. Few priority setting systems seem to recognise the importance of this issue.

Finally there needs to be leadership in implementing any priority setting system – champions for efficiency and equity. This is at three levels. One is within the clinician community itself. That body is much more likely to listen to one of its own. Second having a health economist 'embedded' in the system; or at least 'to hand' is important in implementation. The third is at

the head of the whole system be it the minister or the CEO or whoever. The buck for both efficiency and equity must stop with someone. Thus any good priority setting system must identify who is accountable within the system for the efficiency and equity of the system as a whole.

Remaining issues for a good priority setting approach include that it be capable of resolving certain issues. These include:

1. Whose values are to be used in which context. This can be resolved fairly easily in some contexts such as the prescribing of drugs. But in other contexts this is less clear. In the private business world, decision and value hierarchies are often formally laid out. In health care on the other hand this can be a source of tension, confusion and disagreement. Clarity and explicitness not only of values but of whose values are vital here
2. How equity is to be defined. There are many different definitions of equity and each has different implications for policy and for the potential trade-offs that often exist between equity and efficiency. It is necessary that a good priority setting approach not only recognises this but has in place a way to establish which definition is to be used; who is to define it; and what weight is to be attached to equity versus efficiency – and who is to decide that.

It must also have the capacity to:

1. Be understood by clinicians across the whole ACI network
2. Allow priority setting within individual networks such as aged health and urology
3. Allow priority setting across these networks
4. Be used with little adjustment in other settings.

3 Recommended approach: program budgeting and marginal analysis (PBMA)

The approach of Program Budgeting and Marginal Analysis (PBMA) is the one which best fits the criteria listed in the previous section and which seems best suited to the needs of the commissioning agencies. It is not perfect but is considered to be well ahead of any of the alternative approaches that have been reviewed. The closest alternative is 'QALY league tables'. These are reviewed later but they suffer from assuming inter alia that the only benefit that is to be considered is health. Given the discussion earlier, this is seen as being based on a rather restricted form of objective. It is of note in their review of the priority setting literature that Mitton and Donaldson (2003) indicate that *"there is a widely held belief that evidence from research should play some part in this decision making process"* which PBMA can do. They also suggest from their review that while it has 'challenges' PBMA *"does, at least from a health economic perspective, seem to 'get the thinking right'."*

While as indicated, in their experience, PBMA is not perfect, Mitton and Donaldson draw attention to the fact that what most commonly happens now in health service priority setting *"is simply to base funding decisions on what has been funded traditionally ... historical funding is favoured because it is safe and apolitical, and further, in the reactive culture of most health regions, it is the one mechanism that takes the least amount of time to implement."* There is no priority setting system for which it is possible in any setting to 'tick all the boxes' but, given what so often happens currently in priority setting, there is much scope for improvement.

One specific study of what currently happens in priority setting (Robinson et al. 2011) was carried out to determine what priority setting approaches were being used in Primary Care Trusts (PCTs) in England. Additionally the survey looked at the barriers to implementation, the strengths and weaknesses of different approaches and what lessons might be learned from these experiences.

While the majority of PCTs had some formal approach to priority setting 'these are geared primarily towards allocation of new monies and developments, rather than core PCT spend or disinvestment'. These approaches mainly involved senior NHS managers and doctors while 'the general population, carers and health care providers from the acute, mental health, private and voluntary sectors had much less input'.

It is noteworthy that the main approach used was needs assessment (see below) using population-level health data. Important strengths were seen as simplicity, transparency and the use of evidence. Weaknesses were insufficient evidence for decisions and 'the tendency for priority setting to take place at just one point in the financial year' and with a 'typically narrow focus of the activity'.

Lessons learned included that there was a 'lack of robust public and local political involvement' and that disinvestment was not being tackled to any significant extent.

Birch and Gafni (2006) echo much of the thinking underlying PBMA even if they restrict the benefit side to health. They state: *"If available resources are to be used in ways that collectively produce the greatest health gain, we must determine whether in choosing to use some of these resources for one particular intervention, the health gains produced by this intervention exceed the health gains that are forgone by not using the same resources for all other possible interventions. Although the data requirements for following this approach may be substantial, they reflect the complexity of the decision-makers' problem."* (p. 49).

They propose a less data hungry approach which is to adopt 'new interventions only where the adoption leads to an unambiguous increase in health gains from available resources' suggesting that this "requires information on:

- *The incremental costs and effects of the proposed intervention*
- *The incremental costs and effects of those interventions being considered for cancellation or reduction as possible sources of the additional resource requirements for the proposed intervention."*

While they do not call this PBMA, that is what it is.

PBMA also has the advantage of allowing, indeed requiring, doctors and resource managers to work together. Ruta et al. (2005) thus argue: "*Delivery of efficient ... health care requires doctors to take responsibility for resources and to consider the needs of populations while managers need to become more outcome and patient centred. One economic approach, called PBMA, has the potential to align the goals of doctors and managers and create common ground between them*" (p. 1501).

Clearly this aspect of PBMA can be essential to get the process to work. Ruta et al. (2005 p. 1503) conclude: "*A successful partnership between medicine and management is widely believed to require joint leadership and alignment of goals. To achieve this Ham (2003 p. 1980) suggests we need to '[h]arness the energies of clinicians and reformers in the quest for improvements in performance that benefit patients. The PBMA process has the potential to do this, providing a practical framework to facilitate joint working in several ways.'*"

The starting point for PBMA is to use the PB part to set out how resources are currently being used. Let us assume that the priority setting questions to be addressed involve either some changes in resource deployment within an existing budget or how best to spend some additional resources. This is the process normally referred to as 'marginal analysis' or MA. It is simple and involves considering whether a shift of resources of, say, \$Z from program, project or procedure A to program, project or procedure B will result in an increase in total benefits from the resources available. If it does, then the principle lying behind the approach suggests that the movement of resources should take place. The process is then repeated until no further shift of resources is worthwhile (in the sense of leading to a gain in total net benefit). Where there is some increase in resources then the issue becomes simply finding 'on the margin' where the best buys are in terms of increasing benefits. Thus the economic approach is a combination of program budgeting and marginal analysis (PBMA) with the key concepts being opportunity cost and the margin.

Program budgeting is a mechanism for providing an information framework to assist the process of allowing resource use and outputs generated to be set alongside health service objectives and for helping to identify and begin the examination of relevant margins through marginal analysis. Program budgeting is not evaluative in itself, but rather creates a framework in which evaluation is facilitated and encouraged.

In the current context it will be possible to identify a series of broad programs, for example, by disease group – cancer, respiratory disease, etc.; by client group – the elderly, mentally ill, etc.; or perhaps by geographical location. There is a range of possibilities. However the distinguishing feature of programs is that they are 'output' orientated rather than 'input' orientated, as is the case with standard budgetary procedures. This is desired because, while the total spending on nurses (an input), for example, is an important piece of information in managing health services, the role of program budgeting is to allow planning of health care and priority setting across different aspects of health care in ways that relate to the objectives of health care. It is this 'objectives' orientation that requires program budgeting to be output orientated. More simply, it might be said that the designation of programs ought to be such

that all programs can have health care objectives associated with them, which is clearly the case for say maternity care or cancer therapy. It is this output and objectives orientation that distinguishes program budgeting from other forms of budgeting.

It is also potentially important that these programs can be disaggregated into sub-programs such as, in the context of say maternity care, ante-natal care, the labour/birth period, and post-natal care. For each program and eventually each sub-program, the task is to set out what is being spent on each and also what is being achieved with each. For the latter, while the most accurate and appropriate indicators of output should be used as possible, in reality it will often be some readily available (and hence very often rather imprecise) measure that will be used, such as occupied bed days or discharges or consultations. It may also be useful to do this for more than the most recent year for which data are available, and go back to establish what trend there has been over the last few years. Here much will depend on data availability and the precise purpose of the planning and priority setting exercise.

While there are various ways in which these tasks might be accomplished, it would seem sensible to establish a program group or program management group for each of the programs. These might comprise professional staff working with the patients in the program group – doctors, nurses, etc., managers for the program, information and finance staff, and perhaps lay representatives. How such groups are set up will again depend on the local circumstances, but some grouping into ‘program management groups’ will certainly be needed to get the process working in practice.

Having set up programs and sub-programs and estimated the levels of expenditures on these and the outputs from these for at least one year and perhaps more, the scene is set – we have the ‘information framework’ – to begin to consider marginal shifts in resources. In practice, it might be that particular programs can be analysed on the margin without actually setting out the program budgets as suggested above. However, experience suggests that the health service managers involved do not necessarily have a clear idea about what is contained within particular programs nor any real idea of the size of different parts of the total expenditures within programs. As a result managers and clinicians may well welcome the push that program budgeting provides to specify the contents of programs and to ‘get a handle on’ the sizes of the expenditures involved in fairly broad terms in both programs and sub-programs.

It is also the case that the designation of programs, and just as much sub-programs, is a particularly important aspect of the process. This is because every division of the cake, be it between programs or within programs, constitutes a possible ‘boundary’ across which resources may be moved. It is likely to be in the same terms that the margins will be defined when marginal analysis is undertaken.

Two questions can be asked:

1. If there are no more resources available, can, say, \$1million be moved from program X to program Y and the overall total benefit be increased?
2. If more resources are made available, on which program or sub-program are these additional resources best spent in the sense of creating most extra benefit?

The theory underlying this approach is simple. On the margin of each program or sub-program, for some fixed size of budget allocated across the whole set of programs, the optimal allocation of the budget occurs where the ratio of marginal benefit to marginal cost is the same across all programs or sub-programs.

This is equivalent to saying that if it is possible to move \$Z from A to B and as a result increase the overall total benefit (i.e. the gain in B is greater than the loss of benefit in A), then this represents an improvement in efficiency and as such should be done. Such moves should continue until it is the case that no further movement of funds will result in still greater benefits being provided. When this stage is reached with respect to all programs, i.e. it is not possible to provide still greater benefits unless more resources *in toto* are provided, that is the optimal situation with respect to efficiency.

With respect to the measurement of benefits, this might move in the direction of trying to establish a QALY league table or some health gain or benefit gain league table. (See below.) Certainly, any step in this direction will be useful, but it is as well to recognise that in the current state of the art, any assessment of benefit will be less than precise. Of course, there is no way of removing totally the subjectivity involved in such choices – to trade off health gains for the elderly against health gains for children has to be subjective. There may not however be very good information available even on the technical issue of the likely impact on health and other benefits of various ways of using the extra monies. This has to be accepted and overcome to the extent that available analytical resources or the existing literature on effectiveness will allow.

The same problems exist, of course, when there is a need to think about reductions in various programs or sub-programs. Again, there may be at best poor information about the benefit losses likely to occur in these circumstances.

It is also unlikely that there will be a lot of information readily available about the marginal costs of the various changes that might be considered as possibles for shifting resources. There are likely to be data about average costs, and while there will be a great temptation to use these, the chances are very strong that the use of these average cost figures will lead to the costings being wrong. It is not that we can automatically assume that average costs will be different from marginal costs, but to assume that they will be different rather than assuming that they will be the same is a much better starting point!

Many costing studies would thus be needed and this in itself could be a very big exercise. To avoid this potentially long and time-consuming process, which could tie up the relatively few staff that health services or agencies might make available for conducting analyses for the priority-setting exercises as a whole, this stage of the procedure is split into three. First, the program management groups are asked to draw up 'wish lists' but without at that stage having good data available either on benefits or on costs. These will contain their best guesses about what the activities are that they would most like to see if more resources were made available to their program or their sub-programs (the 'incremental wish list') and similarly those activities they would be least reluctant to stop if they had a cut in their allocation of resources (the 'decremental wish list'). Second, these wish lists would be costed and assessed in more detail with respect to the impact each listed option would have on benefits. Third, the program management group would perform the marginal analysis proper where they would assess the impact of shifts of resources of certain amounts, such as \$100,000, as they would then have the necessary cost data to do this and as good information as could be made available on the benefit effects.

A number of issues must be noted here. First the question of what is meant by benefit needs to be considered. Benefit and health gain (or improvement) may be treated as synonymous and that may well be justified – but this is not necessarily the case. This issue relates back to the question of principles and goals as discussed under the section on criteria. These are likely to determine what are deemed to be relevant possible benefits from health care beyond health *per se*, such as patients being treated with dignity, respect for autonomy and issues around equity (of which more later). Somebody somewhere needs to consider what does constitute a benefit and reaching agreement about who that somebody is is likely to matter. PBMA has the

flexibility that whatever the nature of the benefits and whoever is charged with determining that and valuing the benefits it can cope.

The issue of non health service costs must not be ignored and yet these do not fit easily into any priority setting approach. It is of note that NICE, the key priority setting body in the UK, according to Brouwer et al. (2006) does not formally include non health service costs “*although room is left for a somewhat broader scope – which should be presented additionally – if the inclusion of a wider set of costs or outcomes is expected to influence the results significantly*”. They go on: “*the wider set of costs will, according to NICE, normally not entail productivity costs, but mainly relate to direct costs for patients and carers and those in other public sectors. Such guidance seems to indicate that not all costs are equally important in making health-care decisions. Some costs are more important than others, while yet others are deemed completely irrelevant*” (p. 341).

To ignore non health service costs would be indefensible in terms of both equity and efficiency. To do so would almost certainly result in a shift of burden to patients themselves and their relatives and carers and to other government agencies. The question then is how best to include them. To note them and list them as negative benefits is probably the best practical option.

Second PBMA ideally needs to be evidence based when trying to assess what the impact of any increase or decrease in spending might be. This can be difficult because again what is needed is to know what the impact of any change will be in the specific authority involved or in the set of issues within an authority, where the priority setting exercise is taking place. Thus let us say that a judgment is needed about the likely effect if an extra \$1m is spent on heart transplants. This can be informed from various trials conducted elsewhere but the more precise answer for NSW will also depend on the existing program there, the nature and extent of that program, what sorts of patients might be included if the program were extended and/or whether the extra money might be spent on improving rather than extending the existing program. The marginal or incremental benefit in the local health service or agency might be quite different from the benefit estimate that might be available from studies conducted elsewhere. The extent to which this is an issue will almost certainly vary from one specialty to another and even one type of case to another.

What this means in practice (again!) is that the local context is crucial: what will happen locally, what will be the effects locally, if more or less is spent on that local program? Certainly using available evidence in the literature is important as a guide but perhaps more important will be the ability to form judgments using local evidence where it is available of what the impact of any change will be locally. It is also the case that again, while evidence on the effectiveness in terms of health improvements of interventions elsewhere will be highly relevant, the extent to which an American or a British QALY can be translated to an Australian or NSW QALY may be limited. That issue must at least be investigated. A further issue is that what US citizens or UK citizens want beyond health improvement from their health care may well differ. It is clear for example that when the Scandinavians look at their health care systems they are more interested in equity than Australians. Health care systems are social and cultural institutions in the sense that what the population of one country or culture want from their health care system will vary.

As Hauck et al. (2004), in a major review of approaches to priority setting, conclude: “*Optimal solutions to the priority-setting process will depend heavily on local circumstances and constraints. Our findings nevertheless suggest that, at least theoretically, the traditional economic approach can be expanded to incorporate both equity concerns and a wealth of practical constraints that will influence decisions. Making these principles operational offers a rich and challenging agenda for researchers and policymakers*” (p. 61).

PBMA is a 'local' technique. It seeks to reflect local circumstances. It has to, since the priorities that are sought generally and more specifically in health services in a particular jurisdiction are local to those services in that jurisdiction.

While the discussion above has emphasised the need to 'localise' benefits and effectiveness information and judgments, the same is just as true on the cost side. This however, while equally important, seems to be a matter that is much more readily accepted. The transferability of cost functions from one country or even one state to another is filled with uncertainty and not to be recommended. The issue of establishing marginal costs is very clearly a local enterprise. Use of local accounting data is a better place to start but caution is again needed here. These are by definition from the past and relate to averages.

While the estimation of marginal costs locally can be difficult and time consuming, it need not be and again the principle of approximate measurement of precisely the right thing comes into play. In a situation where a maternity hospital or ward has to plan for an extra say 50 deliveries next year, using costing figures for some other country or state or even from the local accounts for last year are unlikely to be helpful. Here the questions to be addressed are what sorts of births are these likely to be, how many extra hours of doctor time, nurse time, food, etc. are likely to be needed and then to put financial costs on these. Not so hard and the best way to do it.

One way to handle the approach of PBMA in either the local health service or NSW more generally where the budget is not increased is to ask each program (or specialty) to indicate what they would do if faced with a cut of say X% and what the impact on benefits would be. Beyond that, centrally a competitive process would be put in place which would see the different programs competing for the X% of resources that could now be 'reinstated'. This competition would be based on providing evidence to show how much benefit each program would provide if it then got more resources. Some might get none and so take an X% cut; some might get X%; some more. Where there is an increase in the budget, the 'competition' would be around who or which program can create the greatest extra benefit if they were to get extra resources. In other words this is the simple issue of: 'Where are the best buys?'

All of the above has been concerned with efficiency and we now need to turn to see how PBMA does or can deal with equity. Often in practice the answer is badly, but it can be done well. Much depends on how equity is defined in any set of principles or constitution that is established.

The most likely definition will be in terms of equality of access and in turn this may be couched as horizontal equity (the equal treatment of equals) or vertical equity (the unequal but equitable treatment of unequals). What equity in this context entails is an acceptance that some distributions of resources are more equitable than others and hence are preferred to others, that any goal of maximising benefit may be compromised by aiming for equity (i.e. there is a trade off between the maximising goal of efficiency and the distributive goal of equity) and that establishing the relative weights to be attached to equity and efficiency is better done explicitly (which means that in turn the question of who is to do this needs to be resolved).

PBMA can handle equity in a number of ways. If it is the case that equity is defined along the lines of equality of access for equal need, what this does is place a higher priority on some people having access than others. Thus it might be argued that independently of any possible differential in effectiveness of care or treatment, poor people might be given greater access to care to try to ensure that they use health services more than they otherwise would.

This is potentially difficult territory to negotiate. To do so there is a need to be clear what equal access means. It has been defined in various ways (often guided too much by what data are

available) but the definition that is perhaps most useful is as follows. Equal access occurs when two or more groups perceive the barriers they face to use care as being the same height. This incorporates two important features. First it accepts that access is best seen from the point of view of the potential users. Second it allows different groups to define the barriers that they see and to perceive potentially different barriers or different heights of the same barriers differently from other groups. Thus depending on the group, it may see cultural barriers that others do not see; or the same distance may be a greater barrier (e.g. non car owners) than for others; or the same level of fee may be more of a barrier for the poor; or only being able to see a male doctor may be a barrier for some women.

There is some more recent and useful work on access by Thiede and colleagues (2007) which represents one of the few attempts to put some empirical flesh on the conceptual bones of access. They suggest that there are three components to access: availability, affordability and acceptability. Availability is about *"whether or not the appropriate health services are available in the right place and at the time that they are needed"* (Thiede et al. p. 108). Most commonly in the literature this is seen in terms of geographical availability. Affordability *"concerns the 'degree of fit' between the cost of utilising health care services and individuals' ability to pay"* (Thiede et al. p. 109), most often set in financial terms. Finally acceptability is defined by these authors as *"the nature of service provision and how this is perceived by individuals and communities"* (Thiede et al. p. 110). This reflects inter alia issues of the 'interaction between the expectations of providers and patients' (p. 110), with respect being central.

In addition to access, the other word that can create problems in examining equity is need, since the most common definition of equity is equal access for equal need. Need can be seen in many ways but two are identified here: what is often called sickness need and the other capacity to benefit. Sickness need has been around in priority setting and resource allocation debates for a long time and at least since the 'RAWP Formula' of the mid 1970s in the UK (DHSS 1976). This formula from the Resource Allocation Working Party (hence RAWP) assumed inter alia that, in allocating health care resources across different geographical areas, if two regions were equal in all regards except the extent of sickness then resources would be allocated pro rata with the amount of sickness. Thus if North Region had the same population and other relevant features were the same as South Region but the former had 10% more sickness, in allocating resources North Region would be given higher priority and get 10% more resources. Here resource allocation is determined by the size of the health problem.

The other main way to see need in this context is as capacity to benefit (Mooney and Houston 2004). Here the idea is to assess how much different regions might be able to benefit – establish their capacity to benefit—and allocate resources pro rata with that. This is closer to an efficiency criterion if left at that. Hence it has been proposed that it be shifted to embrace equity by weighting that capacity to benefit to reflect the disadvantage that a region suffers. This weighted capacity to benefit would now be a version of vertical equity, acknowledging that if a particular area or group of people is in some sense disadvantaged, policy makers might decide to encapsulate some desire to discriminate positively in the allocation of resources for those disadvantaged. Thus for example for those further down the health 'ladder' to move them up one rung might be more socially valued than to move those already high on the ladder up one rung.

This construct of vertical equity is currently incorporated in the NSW Health resource allocation formula (NSW Health 2005) by weighting Aboriginal people above one to allow greater resources to be allocated for Aboriginal people. The weights here are not objective or scientific but rather are a measure of the compassion in a society, the more compassionate the higher the weight.

This construct of need can be accompanied by what is called 'MESH' infrastructure where MESH stands for Management, Economic, Social and Human. It is argued that simply addressing inequities in health or need or capacity to benefit may miss out on inequities of governance. Some health authorities as organisations are more efficient than others and such variations in efficiency may be a function of any of the four factors of management, economic, social and human or indeed any combination of these. It is then argued that addressing such governance inefficiencies matters to both efficiency and equity. Thus any funding formula aimed at improving equity needs to try to sort out these governance inefficiencies, for example by providing monies to allow these inefficiencies to be addressed. This was suggested in the Indigenous Funding Inquiry of the Commonwealth Grants Commission in 2001 (CGC 2001).

There are other constructs of equity, most commonly equal use for equal need and equal health. Access and use differ in that access implies some opportunity to use which may or may not translate into actual use. Adopting a definition of equal use (which in the literature and in policy is quite often done in practice as a proxy for equal access) would seem to be problematical. It takes away any opportunity of the individual to choose. That may be acceptable in some circumstances such as where there are major externalities, such as with immunisation, which might then be deemed compulsory. In most instances however to remove individual choice is like to be deemed unethical.

Equal health suffers from a number of potential problems. First one can query why a society might want to have equal health for everyone including at one end those who willingly take risks such as sky divers to at the other those who are very risk averse. Second it would seem impractical given people's different, e.g. genetic make up. Third it again seems to deny individuals' freedom to choose. And fourth to ask a health service to deliver equal health when there are so many other factors in society – the social determinants of health – which influence health levels seems to place too great and unfair a burden on the health service.

There is a sense in which *faute de mieux* societies and health services are pushed back on to equal access for equal need as an equity goal. But there is also some evidence that critically informed Australian citizens in Citizens' Juries choose equal access for equal need as their preferred definition of equity (of which more later).

The other issue, and it is an important one, that has to be resolved in any approach to priority setting including PBMA is the trade off that can often (but not always) occur between equity and efficiency. This in principle is easily resolved by giving different weights to the two to reflect the relative importance that is to be placed on them. In practice this means also establishing who is to determine these weights. This is an ethical call but as equity in health care certainly and efficiency probably are social concerns, the answer may well be the critically informed public.

With respect to progressing equity, it is important that the government or some senior policy group (or critically informed citizens) makes a clear statement about what their operational goal for equity is in terms of health, access or use. Thereafter, they might try (but it is difficult) to give guidance as to the relative weight to be attached to equity and in what dimensions: gender, social class and geographical location are the three fairly obvious ones. These equity guidelines would then be presented to the program management groups to assist them in their deliberations, the idea being that they concentrate initially on efficiency concerns but then indicate what the equity impact would be of the various possible strategies.

When the choices overall come back to the agency from the program management groups, the final trade-offs between equity and efficiency would be made. Given the inevitably political nature of these choices, it would seem appropriate that these choices with respect to equity are made at this high level.

It is worth noting too that no matter at what level priority setting occurs, it will be influenced by what is happening at other levels. Thus Kafiriri et al. (2007) bring out that priority setting at any level is affected by the level above, thus "*macro-level [systems] decision-makers set the context for priority setting at the meso- [hospital] and micro [clinical] -levels. Macro level planners provide guidelines for the lower levels to follow and inhibit their absolute autonomy to set priorities ... which has both legal and economic implications if violated*" (p. 90). That is not a problem as long as there is a recognition that these interactions between levels will occur and that it is legitimate that they do.

A somewhat negative view of priority setting, and perhaps more specifically PBMA, is that of Holm (1998) who states: "*The goal of a public healthcare system is a complex composite of many goals, including fuzzy goals such as maintaining a sense of security in the population. There is no natural way to balance these goals against each other. We can state that one goal is more important than another in specific situations, but an attempt to raise one goal as the most important in all situations is implausible. This means that it becomes impossible to use a simple maximising algorithm as a basis for priority setting*" (p. 1001).

While agreeing that there can be many goals, some of which may be fuzzy at least initially, Holm is wrong then to argue that 'there is no natural way to balance these goals against each other'. This is done by economists regularly. For example QALYs combine two goals – length of life and quality of life. Again to state that to 'attempt to raise one goal as the most important in all situations is implausible' is correct but that is not what is being proposed. That would mean lexicographic ordering of priorities which, earlier in this report, was very firmly rejected.

Segal and Mortimer (2006) are also critical of PBMA when putting forward what they claim to be a different model for priority setting which they call their 'Health-sector Wide (HsW) priority setting model'. This however seems to be based on a misunderstanding of PBMA. Thus they write: "*the key limitation of PBMA relates to the subjectivity of the process and consequent lack of confidence in the rankings specifically in the expansion and contraction set identified.*" They refer to a study by Peacock et al. (1999) which reports "*only a weak relationship between recommended panel rankings and cost-effectiveness estimates prepared by the research team*" and argue that "*rankings that rely heavily on subjective assessments will ... reflect decision makers' values.*" That is true but applying any methodology badly is never defensible and that is true of PBMA as well. That is no reason to abandon the methodology. These authors suggest that an advantage of their model is that it can cover the entire health sector but that is no different from PBMA. Their desire to use 'objective evidence' is also endorsed by PBMA but what they risk in their approach is being overly concerned with objective evidence – essentially the results of cost-effectiveness studies from elsewhere and which may not be directly relevant to the local circumstances.

Appendix to PBMA: Option appraisal, multi-attribute utility theory and multi criteria decision analysis

While these are sometimes seen as priority setting approaches in their own rights, in the specific context of this review, they are best seen as ways of organising, defining and weighting different benefits. As such they can be useful adjuncts to PBMA.

Option appraisal (Henderson 1984) permits often seemingly complex issues to be set out in a structured common sense way which allows participants to weigh up the costs and benefits of various options for addressing some issue or problem. This approach is often seen under the heading of the Portsmouth Score Card (Watson et al. nd). The process allows debate and clarification of the objectives of any policy, of the relative importance of different objectives, the identification of the relevant effects both positive and negative of different options, the weights to be attached to these effects and a way of bringing all of this together to be able to form an overall assessment of the relative worth of different options for addressing the issue or problem to hand. It is to be emphasised that a major part of the process involves debate about the objectives and about the values to be attached to the meeting of different objectives. More importantly still it is about forcing participants to be explicit about these objectives and values.

The starting point is to identify clearly what the nature of the problem is that is to be addressed. One point to be stressed is that there are many situations in addressing health service issues where the problem has been wrongly specified. It is also suggested that where a problem is wrongly specified the prospects of identifying solutions are somewhat diminished. If the wrong question gets asked, the right answer becomes still more elusive.

Peacock et al. (2007) use what they describe as a 'novel multi-attribute utility (MAU) approach of setting health service priorities using PBMA.' They argue: "*This approach includes identifying attributes of the MAU function; describing and scaling attributes; quantifying trade-offs between attributes; and combining single condition utility functions into the MAU function*" (p. 897).

They further claim: "*The multiplicative weights for the MAU functional form avoids a major weakness of the simple additive MAU function: that programmes which do not offer improvements in health for individuals can score highly if they perform well in terms of other attributes. This problem appears to have gone unnoticed in the PBMA literature*" (p. 908).

This approach is useful. However most of what is claimed can be claimed for option appraisal and, as that is simpler, to adopt the simpler approach may be the preferred option.

Indeed Peacock et al. (2007) go some way to recognising this when they write: "*The MAU approach to marginal analysis ... has extended the options appraisal methodology of earlier PBMA studies. Our MAU approach is based on the notion that benefits from health programmes are multifaceted, and extend beyond health gains for individuals*" (p. 907). This is a slightly odd comment since option appraisal and PBMA more generally already go beyond health gains and accept that 'benefits from health programmes are multi-faceted'.

Multi criteria decision analysis also comes out of the same stable of trying to provide some process to allow decision makers to be explicit about weights to be attached to different objectives or principles. Such MCDA comes in various guises such as the Portsmouth Scorecard. It is described (HM Treasury nd) as "*a way of assessing a mix of both monetary and non-monetary benefits. The extent to which each option meets the identified criteria is measured,*

and explicit weights are given to each of the criteria to reflect their relative importance. Using this technique, options can be ranked and a preferred option identified."

Baltussen et al. (2010) describe MCDA as a "second application of priority setting studies in a country, which goes beyond the scope of PBMA, [and which] is to guide decisions on a wide range of interventions, to provide general information on their relative rank ordering to arrive at a more informed debate on resource allocation priorities" (p. 262). This is still not intended to address priorities in specific contexts but rather is restricted to 'general perceptions on priorities' and to "defining the set of options that are debated without defining the allocation of resources in a precise fashion" (p. 263). Again the task here is specific.

Baltussen and Niessen (2006) suggest that when policy makers are faced with complex priority setting problem problems, they 'tend to use intuitive or heuristic approaches ... and priority setting is ad-hoc'. They believe that 'policy makers may not always [be] well placed to make informed well-thought choices involving trade-offs of societal values'.

That is undoubtedly true and they then argue that MCDA "establishes preferences between options by reference to an explicit set of objectives that the decision making body has identified, and for which it has established measurable criteria to assess the extent to which the objectives have been achieved". To that extent it can certainly be useful but again as an adjunct to PBMA. This MCDA also uses "an advisory panel .. [which] ... comprises key stakeholders such as health personnel, policy makers, finance and information staff, and community representatives. The panel has an important role in the definition of the relevant criteria and their relative importance for priority setting, and making recommendations for reallocating resources". The PBMA 'program management groups' can play the role of these panels.

4 Other main approaches

In this section of the paper other priority setting approaches are reviewed and critiqued. This is done in less detail than the section above on PBMA because, given the criteria set out earlier, these other methods are very clearly inferior. Why that is the judgment of them however is the main content of this section.

The approaches discussed here, which are the main ones in the literature, are:

- QALY league tables
- Needs assessment, cost of illness and burden of disease
- Target setting
- Core and necessary health services
- Generalised cost-effectiveness.

Additionally two others are included:

- Accounting for reasonableness
- Swedish priority setting.

'Accounting for reasonableness' represents not strictly a priority setting approach but rather a way of judging priority setting approaches. The example of Swedish priority setting is included to allow the reader to see how Sweden, which is one of the leaders in the field, addresses both priority setting and the setting of principles lying behind priority setting.

QALY league tables

As part of the push for better priority setting, the idea of QALY league tables was developed. These sparked much interest among policy makers particularly in the 1990s. Some certainly have argued that the use of such tables represents the best way to go in setting priorities.

In this review however the emphasis is one of caution (Gerard and Mooney 1993; Mason et al. 1993). Priority setting is hard, and fraught with various difficulties and pitfalls. QALY league tables avoid some pitfalls, they do meet some of the key criteria for this study, but they do not match up to the ability of PBMA to meet the listed criteria.

A QALY league table is an approach aimed at allowing priority setting of possible changes in health care programs when these are competing for limited resources, and choices have to be made about where to make changes. The 'league table' ranks different procedures according to the 'cost per QALY' of implementing these procedures. The resource allocation decision rule underlying the use of these tables is that changes in programs should be implemented on the rank order basis of ascending cost per QALY.

Strictly, QALY league tables ought to be labelled as and thought of as 'marginal health service cost per QALY gained league tables (given various assumptions about existing resource allocation and about the objectives that health services are trying to meet in their priority setting)'. This clarification is important.

First, the fact that QALY league tables are about marginal costs per extra QALY is important and meets one of the key criteria. The issue arises: margin with respect to what? In other words,

from where are we starting? The answer to this question is that we are starting from where we are. QALY league tables are based on answers to the question: given the current allocation of resources in a particular area, what are the costs involved in purchasing additional QALYs through the implementation of more of the various procedures that are currently available or through implementing some new procedures altogether? If, say, there is an extra \$100,000 to spend on health care, what is the maximum number of extra QALYs that that can buy? In which procedures is it best to invest more?

Thus QALY league tables embrace two key criteria namely the notions of opportunity costs and the margin. The cost of buying extra QALYs in a program will be a function of a number of factors. Almost certainly one of these will be how much of that program is already being performed. As more and more is invested in a program, it is likely that the cost per QALY on the margin will rise. This is because it is logical and rational (and efficient) to treat those patients first where the return in terms of QALYs per dollar spent is highest and gradually work down to patients where the cost per QALY is getting higher and higher.

It follows that, as with PBMA, the contents of a QALY league table are a function of what is currently going on within the geographical area for which the priority setting is being done. If, say, a particular health authority has already implemented a sizeable program of heart transplants, then *ceteris paribus* the marginal cost per QALY of more heart transplants is likely to be higher than in an area which is lagging behind in its heart transplant program. This is because the first authority will already have given transplants to those patients who are 'good buys' for such a procedure.

Further like PBMA, QALY league tables are about marginal costs, in this case per QALY. Thus there is a recognition (again as with PBMA) that priority setting is not about the choice between programs *per se*. It is about choices between changes in the scale of different programs. The way in which they consider this however is such that they are comparing the situation with and without the extension of that program rather than the question of the extension of that program versus the extension of another program which is what PBMA does.

Another important aspect of QALY league tables is that they are about QALYs. Now while that is a rather obvious statement there is the question of the extent to which QALYs are an accurate and acceptable measure of what is to be measured here. The question becomes: are QALYs an adequate measure of health; or more accurately, given the marginal nature of such matters, are QALYs gained an adequate measure of health gains? In the context of QALY league tables it is likely to be the case that for policy making, the QALY is as good a measure of health as is available, and for most purposes in priority setting an adequate measure.

What is worth stressing is that QALY league tables are seen as particularly useful in making comparisons across programs, essentially because the QALY is not program-specific. It is this broad nature of QALYs that allows the QALY league table to be used in priority setting across surgical, psychiatric, dermatological, etc., programs. If this generality were to be cast in doubt then much of the value of the QALY league table would disappear.

QALY league tables also assume that all that is relevant in the pursuit of priority setting in health care is that health is to be maximised. In so far as other considerations come into play in deciding how best to allocate resources to health and within health care, then QALY league tables will inevitably be deficient. Thus, if there are other forms of benefit that are relevant in allocating resources – such as information, the protection of autonomy, or whatever – then the use of QALY league tables will lead to some distortions of the 'true' priorities.

Further, QALY league tables are about efficiency – essentially allocative efficiency, i.e. maximising the additional benefit from the additional resources available. They say nothing about equity, except in so far as equity is assumed away by arguing that a QALY is a QALY is a

QALY, no matter who receives it and assuming that equity is to be seen in terms of health and not in terms of access or of use. They can be adjusted however to accommodate different weightings for QALY gains such that say such gains for disadvantaged groups might be weighted above one.

The objectives of health care as assumed by QALY league tables are also somewhat problematical on the cost or resource side. On the benefit side the only benefit allowed is health. This means that, in terms of allocative efficiency, the only form that cost can take legitimately is in terms of opportunity costs where the benefit forgone is in terms of health.

This seems a reasonable assumption, if it is accepted that health care is only about health, for those resources which are within the health care budget. But there are other resources which would normally be embraced in any economic evaluation of health care. These would include, for example, the resources of patients and their relatives; those of other social services such as housing and education services; and so on. But these provide potentially not just health benefits but also other forms of benefit: for the patient, the family and friends, the time input to care might have been used in a very wide range of other activities from watching TV to climbing mountains; the education services could have been producing more or different forms of education; and so on. The point is simply that these resources from outside the formal health care budget are not restricted in their use and hence in their opportunity costs to health-inducing activities. It is then difficult, indeed impossible, within the constraints imposed by a cost-utility framework to consider non-health service resource use within a QALY league table. It is simply not possible to say that patient time is best spent on this or that treatment, since that judgement can only be made across a much wider range of activities to which that patient time might have been an input.

That means that QALY league tables have to be restricted on the input or resource side in a similar way to that in which they are restricted on the output side, i.e. to health and, with respect to resources, to health service resources which have no alternative use than the production of health.

These caveats do not mean that we should then abandon QALY league tables in priority setting. They are not perfect. They do have problems. But then so do all the existing approaches to priority setting. At least with QALY league tables some of the key criteria of priority setting (as listed earlier) are adhered to. What does emerge from this discussion is that we need to understand fully what QALY league tables can and cannot do, and that when they are constructed and used they should be treated with caution. Interpretation is crucial. It is the case however that PBMA remains the preferred approach.

It can be argued however that transfer of effectiveness data, cost data and hence the results of cost utility studies from one geographical location to another is not appropriate and that it is the results of *local* cost-utility analysis (CUA) studies that should be used in the construction of any QALY league table. In other words, ideally each country, or region, or area, should construct its own QALY league table to reflect the conditions which that country, or region, or area, faces locally. Certainly, there is a sense in which that would be good, especially if one accepts that the valuation of QALYs may well and legitimately vary from one area to another. There is no reason to believe, for example, that the relative weights attached to length of life and all sorts of different forms of quality of life will be constant across different areas of a country, never mind across different countries.

Perhaps this issue is best understood if it is put round the other way. If we were to accept that QALY league tables – the same QALY league table – could be used in Humberside, Hobart, Hamilton and Harare, then this would mean that all these places would have the same priorities for health care, irrespective of how they were currently delivering services and independently of what they were already doing in allocating resources and of what the

diseases were and their prevalence in these locations, and how illness and disease were valued in these areas and what the costs structures were in different treatment and prevention regimens. That seems a most unlikely scenario!

Should QALY league tables be constructed? Should they be used? And if so, how and in what circumstances?

What NICE in England (NICE 2008) does with respect to priority setting is a form of QALY league table. That operates according to two sets of principles, moral and procedural. The former comprise:

- Respect for autonomy
- Non-maleficence
- Beneficence
- Distributive justice.

The procedural principles are:

- Scientific rigour
- Inclusiveness
- Transparency
- Independence
- Challenge
- Review
- Support for implementation
- Timeliness.

These are then translated to more detail under eight headings which include being evidence based and assessing the merits of interventions on the basis of costs and benefits and other factors. In the context of this review perhaps one principle is most relevant and this is set out in full:

"NICE usually expresses the cost effectiveness of an intervention as the 'cost (in £) per quality-adjusted life year (QALY) gained.' This is based on an assessment of how much the intervention costs and how much health benefit it produces compared to an alternative. NICE should explain its reasons when it decides that an intervention with an ICER [Incremental Cost Effectiveness Ratio] below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective."

Thus NICE is operating a cost per QALY regime but not just that: it is a cost per QALY regime with the controversial idea of a cut-off point in terms of spending per QALY gained. There is considerable debate about the merits of this but with respect again to this review, the idea of a cut-off point is not relevant so there is no need to debate or resolve that controversy here. The sources of the controversy are (1) the fact that on the benefit side there is only health, and PBMA overcomes that problem; and (2) what in NICE is being compared i.e. what the margin constitutes. In PBMA that issue is taken care of not by looking at the costs per unit of marginal benefit but by asking (a) if giving up benefit on the margin of program A is worth it to gain benefit on the margin of program B or (b) where the best buys are. As the review is recommending PBMA and not QALY league tables there is no need to 'resolve' this

controversy. This is not to deny the potential benefits of grappling with QALYs as a measure of health. It is the way in which marginal cost per QALY is used which can be suspect.

The most famous example of the use of QALY league tables arose in Oregon in the United States. The aim there was to produce a QALY league table for services provided under the state of Oregon's Medicaid program. The story of Oregon is well documented. (See for example Hadhorn 1991.) It remains the case that to have tried this experiment in the United States was a major innovation. Much of the criticism of the Oregon experiment, however, is specific to Oregon rather than to QALY league tables as such.

Certainly they created list of priorities for their health services but these were services per se rather than changes in the amounts of different services. Further as Hadhorn (1991) reports in the end their priority lists were not based on costs at all! As such Oregon cannot be seen as a genuine effort to use QALY league tables for priority setting.

The key message with respect to the use of QALY league tables in health care policy making is that there are advantages in using them but that these will be lost if they are not used with care. To date the extent to which there have been 'warnings on the packaging' about the problems of misuse and overuse has been too little. As a result there is a danger of policy makers getting things wrong using QALY league tables and for the future perhaps becoming disenchanted with the whole idea of priority setting.

PBMA despite its appearance of being less scientific remains for the present the preferred approach. These criticisms of QALY league tables are not a counsel of despair but rather a plea – yet again – for keeping to key criteria and using initiative and ingenuity in manipulating data to allow the criteria to be adhered to. That sort of thinking – good criteria and pragmatism with data – is a key feature of this report.

Needs assessment, cost of illness and burden of disease

A number of other approaches are used in priority setting in health care. These vary from country to country. However, most seem to come under the rather broad heading of 'needs assessment', or variants on this. Here this section looks at the approach of needs assessment, together with its 'sister' approaches of burden of disease and cost of illness studies. These approaches are reviewed here not with the intent of being comprehensive, but simply to outline them and their problems. They are lumped together because the prime principle on which they are built is what might be called 'addressing the size of the problem'.

The most common approach to priority setting found in policy even if not necessarily in the academic literature would appear to be what is normally referred to as 'needs assessment'. This comes in various guises but in essence involves an attempt to assess the 'total needs' for health care for a population as a whole, or for a particular disease group, or a particular client or age group. This leads into priority-setting exercises which are initially concerned with assessing the needs for child health services, or for cancer patients, or for elderly people, and perhaps in aggregation of the people as a whole living in a particular location.

The principle lying behind this approach is that the total needs for health care can be established and that this will provide a basis for setting priorities. What is less clear, however, is how to use this information on needs assessment. If one can establish the total needs for child health care, how do we move forward from that to establish priorities? If the needs for children aged 0 to 1 are greater than for those aged 1 to 2, what does this mean for the allocation of resources between these two groups? If the needs are twice as great, does this mean that resources should be allocated *pro rata* with the size of the relative needs? Are all needs in this

sense equally weighted? In fact, before these sorts of questions can be addressed, there is a need to establish what is meant by need.

Need in this context is directly related to illness or sickness. The approach to needs assessment is usually that the more sickness there is in a population, the greater is the need (presumably for health care). Such a view of need would suggest that needs assessment would involve establishing a sickness profile, covering *inter alia* the incidence and prevalence of diseases in the relevant population. It would also be independent, at any moment, of the technological ability to deal with sickness.

If there is a desire to establish the total need for, say, cancer services, then the needs for care for different cancers have to be established and in some way aggregated. But how is this aggregation to be done? One possibility is to establish some sort of indicator, which would reflect the amount of health gain in the community if diseases were *eradicated*. This might be in terms of something rather crude like years of life lost prematurely from a disease. Or it might involve an estimate of the 'burden of disease' in terms of, say, 'total QALYs lost from breast cancer' or 'total QALYs lost from breast cancer among women aged 40 to 50'. It might adopt some sort of 'cost of illness' calculation (see below) where the burden of the disease in terms of sickness might be added to the cost of treatment and the costs of lost output in the economy as a result of the disease's existence. But while the literature is not always clear on this point, some measure of need is required and it is presumed here that that measure has to be related in some way to the burden of disease (again, more below).

There seem to be various possibilities for what to do with this information. One is to argue that resources should be allocated *pro rata* with needs. But efficient resource use has to reflect the costs of treatment. What about the costs of meeting the needs? It would only be if the cost per unit of need met (perhaps health gain) were constant across all diseases and conditions, and that for all these diseases and conditions average and marginal cost were equal, that this estimate of needs assessed would be valid. That is most unlikely to hold good. Put another way, it would mean that all diseases would be treated in an equally operationally efficient way, i.e. that all diseases were equally cost effective in their treatment. It would require further that technological developments in medicine and in the delivery of health care were such that they did not affect the cost-effectiveness of such treatments at all. It would additionally mean that there were no economies (or diseconomies) of scale for any disease or condition.

A second possibility would be to argue more basically that the needs assessments should be used simply as an ordinal ranking, i.e. that the disease with the greatest needs should get more resources than that with the next greatest need, and so on. In some ways this is more appealing. However, if the cost effectiveness of interventions varies, then again there is no reason to think that the greatest need should be given priority. Further, if we adopted this ordinal ranking, how would it be used? At what point could it be said: that is enough spending on the 'top' need, now move to the next. In other words, the lack of cardinality leaves in its wake an inability to use the margin in resource allocation decision making.

A third possibility is to use the needs assessment information in some form of weighting process, which might reflect priorities. Thus if it were felt that those diseases or conditions that created the most need in society should be given priority over and above any considerations of some simple cost-effectiveness criterion of allocating resources in such a way as to maximise health gains, then the ranking of needs assessment could be used to arrive at weights. Thus if, say, cardiovascular disease were the disease for which there was the greatest need, then the health gains from any interventions which had an impact on reducing the needs there might be weighted more highly than those for interventions on other diseases which came further down the needs league table.

This 'size of the problem' imperative is perhaps understandable in that policy makers might be attracted by the approach at a superficial level. It is difficult to see however how the approach survives any detailed scrutiny. It certainly performs poorly when looked at in terms of the criteria set out early in this report. Especially it is deficient with respect to the essential criteria of opportunity cost, the margin and principles or goals setting. It does not consider opportunity cost or the margin at all and, with respect to principles or objectives, these are set in terms of the size of the problem governing the level of priority.

Some of the issues here are summed up by Hope et al. (2010): *"we consider three features typical of healthcare interventions that challenge the applicability of need satisfaction as a guide to resource allocation. These three features are: that many interventions have only a probability of achieving a desired effect; that health benefits of different interventions occur at varying times after the interventions; and that the best outcomes for patients are often obtained through a combination of interventions. Whereas welfarist approaches, such as cost-effectiveness analysis, are able to take each of the three features of health care interventions systematically into account, it is by no means clear how they can be accommodated by needs theories"* (p. 471).

If in priority setting there is no allowance for the costs of intervening, then this would mean that if some new technology allowed heart transplants to be carried out at one tenth of their current cost, then such a change would have no effect on priorities in health care. Again, if the costs of hip replacements rose sixfold, would this not have an effect - should this not have an effect - on the level of supply of hip replacements?

The approach of needs assessment is seriously flawed when set against the criteria that have been established earlier in this review. It is possible that a better case can be made for adopting a needs assessing approach in the context of equity but even then with considerable caution. There does not appear to be a case for total needs assessment exercises for promoting allocative efficiency.

There is a substantial literature on cost of illness studies where at least a part – and normally a major part – of the defence for doing these studies is that they can be used as a basis for setting priorities. Cost of illness normally covers the costs of treating the illness together with the costs (for example, from absence from work) arising as a result of the illness. The logic appears to be that if the costs of a particular illness are high as compared with another illness, then the higher-cost illness should get higher priority. To this extent they are an extension of the needs assessment type of approach.

What can explain their popularity? That is difficult to answer. There is a superficial attraction, somewhat similar to that in the needs assessment approach, in allocating resources to 'big problems', but that is so superficial that it is difficult to see that that is the real explanation. Partly too it may be that big numbers look impressive, and it may be for this reason that the pharmaceutical industry seems so keen to fund cost of illness studies. If they can show that a disease for which they have a product which will reduce or ameliorate the disease costs a large sum, then this may be a useful advertising weapon. It is difficult to believe that policy makers or politicians would succumb to such an argument, yet it seems that many burden of disease and cost of illness studies are funded by the industry, so perhaps there is something in that argument.

The use of cost of illness and burden of disease studies as a basis for priority setting in health care will not lead to an efficient allocation of resources. These approaches do not represent a way of getting to something approximating to efficiency. As two Australian observers (Davey and Leeder 1993) note in a neat, dismissive and accurate phrase: *"To know the cost of illness is to know nothing of real importance in deciding what we should do about the illness."*

Others however have sought to defend the use of cost-of-illness (COI) studies in priority setting. For example Tarricone (2006) states: *"COI can be a good economic tool to inform decision makers if it is considered [as] a descriptive study that can provide information to support the political process as well as the management functions at different levels of the health care organisations. To do that the design of the study must be innovative, capable of measuring the true cost to society, to identify the different subjects who bear the costs and to explain cost variability"* (p. 62).

Finkelstein and Corso (2003) suggest that: *"The merits of COI studies may seem obvious: if nothing else they are a valuable tool for promoting attention towards a particular illness or condition and stimulating the public policy debate"* (p. 367).

Somewhat similarly Larg and Moss (2011) suggest that *"these studies can aid our understanding of the importance of health problems by describing their impact on healthcare resources and labour productivity. COI studies have been used to draw the public's attention to particular health problems and encourage policy debate, and also to inform planning of health care services, the prioritization of prevention research and the evaluation of policy options"* (p. 654).

These sorts of defence are open to criticism as they imply that knowing about the size of a disease problem in some terms or other is in itself useful. More important in the context of this review however is that even if COI studies can produce results that are useful in a descriptive sense that is not what this review seeks. The task is to find an approach or approaches that can be useful to priority setting. Fundamentally, the problem with COI is that it provides information on the size of a problem but not on marginal costs or benefits. Determining priorities, deciding where to allocate scarce resources without knowing what interventions cost or what benefits they provide does not make good sense. Priority setting is about change; it is about altering the balance of resources in such a way as to do more good, to produce more benefit at the lowest opportunity cost. COI studies do not provide that information.

Thus the statements from the researchers above may well be true but with respect to priority setting is the size of the problem a relevant consideration 'in promoting attention towards a particular disease or condition' or in aiding 'our understanding of the importance of health problems'? Larg and Moss (2011) may have a point with respect to prioritising prevention research where neither the costs of such research interventions are known nor the impact of such research. 'Big problems' might then be a justified basis for determining where to put research dollars. When we do know costs and have some idea about impact as is more normally the case with health services or treatment interventions, the usefulness of COI estimates become flimsy or non-existent.

Finkelstein and Corso (2003) seek to sum up the arguments of critics of the COI approach as being (p. 368) *"that what should be important is not how much of a burden is associated with a particular illness but how much of a burden could be eliminated should the illness be cured."* That is not the point. The criticisms are primarily that the concepts of opportunity cost and the margin are missing. Knowing the burden that could be eliminated if the illness were cured is not what matters. It is that what knowledge is needed is what an intervention costs and what impact it would have if implemented. They are thus wrong to argue that (p. 369) *"a carefully conducted COI study that clearly documents all assumptions and limitations can minimize many of the concerns ... and provide valuable information."* Larg and Moss (2011) may however be nearer the mark in explaining the popularity of COI studies, especially in research funded by the pharmaceutical industry when they state: *"large 'cost' estimates may simply be one-upmanship by disease advocates vying for greater funding"* (p. 654).

A key point is made by Byford et al. (2000): *"The 'cost savings' of either fully or partially preventing a given disease are, to a large extent illusory... a high cost condition is not necessarily amenable to treatment by current medical technology... in contrast a condition*

which presents a low cost to society may be fully amenable to low cost prevention, leading to high individual health gains."

In summary on COI studies, Koopmanschap (1998) suggests: *"Some authors argue that this type of study does not deliver relevant information for health care policy, while other are more optimistic"* (p. 143). This review has tried to show that while Koopmanschap is right in his assessment of the literature, that is not the issue that is most germane. Rather it is: do COI studies meet the key criteria for priority setting for this review? The answer is 'no'.

In a major review of priority setting studies, Hauck et al. (2004) describe Global Burden of Disease (GBD) (or Burden of Disease) studies thus. *"Resources should be devoted not just to the most cost-effective interventions but also to the cost-effective interventions that have the potential to substantially improve population health status. GBD calculations base priorities on the size of the problem."* They continue: *"This is the main reason the value of GBD studies has been questioned ... Mooney and Wiseman (2000) argue that priority setting should be based on information about the value of interventions. Otherwise, vast amounts of resources may be wasted trying to combat disease for which there is no cure. Thus the GBD approach might be best seen as a means of supporting the political process by offering some (if incomplete) objective evidence on the claims of competing interest groups among the sick"* (p. 44).

These authors conclude their review as follows: *"Priority setting in health care is a complex task. Our review illustrates the many theoretical, political, and practical obstacles facing the decision maker. As a consequence, it would perhaps be easy to conclude that the task is insurmountable instead of merely difficult. We believe this would be unduly pessimistic. We have shown that adopting an economic approach to priority setting has many advantages, not least that it forces the decision maker to define explicitly the objectives of the priority-setting process, even if they cannot be easily measured. It also allows the many conflicts that arise in priority setting to be explored explicitly rather than merely avoided and as a consequence the nature of the trade-offs involved in setting priorities is made clear."*

That view is endorsed in this review as well.

Target setting

There is in itself little wrong with the idea of setting targets in priority setting. Indeed, targets can provide incentives for action and the issue of incentives more generally is one that is somewhat neglected in priority setting. However, very much depends on how the targets are set, and it is here that reservations have to be expressed. The experience to date is not encouraging.

The most famous, or notorious, targets in health and health care were those set by the World Health Organisation (WHO) in their pursuit of the goal of Health For All in the Year 2000 (WHO 1981). These were in essence largely challenges rather than anything more substantial. They were a mixture of concerns for better health; greater equity especially across countries; a desire to involve all sectors of the economy in the provision and promotion of health and not just the formal health care sector; and a large effort at exhortation. They largely failed, although as a source of propaganda for health they may have been effective.

The targets in themselves were fairly harmless. However, the long-term impact might well have been deleterious on three fronts. First, for those countries well below the targets when they were set – Hungary as compared to Sweden, say – there might well have been a concern that there was a lack of understanding in WHO about the differences in all sorts of cultural and economic phenomena which these two countries faced. This could well have had the effect of depressing morale among Hungarian policy makers – the exact opposite of what the target setters intended. Second, others have followed in the steps of WHO and gone for target setting

as a vehicle for health policy. However, at a national level the sorts of target setting that might have been appropriate for WHO are less likely to be so for a national government which has at least some executive power to influence what actually happens on the ground.

Third, and in a sense related to the last point, the WHO targets were in essence part of their propaganda and 'sloganising' for health. WHO does not have to take responsibility for their implementation. Among national governments adopting the 'sloganising' approach may well prove counter-productive. There is a responsibility at that level to go beyond slogans and consider operational planning of health care. As a result of the WHO target setting bandwagon, increasingly it seems governments may be stepping back from health care policy-making. They set targets and then leave those at the lower echelons of policy making to determine how the targets are to be reached.

This is heady but dangerous stuff, because it means that objectives are set without due consideration of means. Goals may be too expensive to achieve. Resource considerations are too infrequently included in the process of target setting. It is words without due consideration of the actions necessary to make the words fulfilling.

Targets are, or ought to be, about allocative efficiency and equity. But at the level of allocative efficiency, objectives have to be pursued taking due account of costs and benefits on the margin. If this is not done, it is difficult to see how allocative efficiency can be advanced. If this process is not adopted in target setting, then there is a very real danger that the targets will not only fail to further efficiency but may actually promote inefficiency. In other words, it is not just that they are not 'perfect', they will not be even an approximation to perfection. They are not an approximation in principle, so it is difficult to see how – but for chance – they can result in an approximation in practice in what they can actually achieve.

It is worth re-emphasising that there is no desire to criticise target setting *per se*. If targets were set on the basis of weighing up costs and benefits on the margins – as they could be – then there could be considerable merit in them. Certainly, one would want to allow for variations at the local level, and advice and guidance would be needed at the local level about how to use the targets sensibly and flexibly. That is the key merit to target setting, i.e. this visibility in where we want to go, with the visibility allowing goals to be shared, striven for, and so on. But the targets that are most frequently used in health care do not embrace the marginal cost versus marginal benefit principle, so they fail to promote allocative efficiency. It is possible to get the advantages of target setting tied to the advantages of the pursuit of allocative efficiency. Indeed that is the challenge.

Core and necessary health care

There is a body of thought which is exemplified by the Core Services in New Zealand (Cumming 1994) but also various academic (often philosophical) writings (for example Hoedemaekers and Dekkers 2003) that argues that priority setting is best approached through identifying core or necessary care. The idea is simple. Certain health services are essential, others less so. The essential, it is sometimes argued, are to be available to all, often made so by the state and the discretionary ones paid for by those individuals who wish to have them and can afford to have them.

Hoedemaekers and Dekkers (2003) for example argue that: "*Health package decisions at macro level can be based on medical need (the severity of the condition), or the appropriateness of medical interventions (their effectiveness and cost-effectiveness) – or both.*" They propose that in reaching decisions about need: "*ideally all types of value-judgements should be represented ... including society at large*" (p. 320). With respect to

appropriateness they suggest medical professionals and health economists are 'the obvious choice' to make these judgments' but add that this is not ideal 'because determination of effectiveness and cost-effectiveness ... also involve moral judgements and value-judgments" and hence argue for the inclusion "of other evaluators as well'.

There is some confusion here which makes what is said not helpful in trying to address questions of priority setting. First in so far as it is possible, we need to distinguish between technical judgments and value judgement. The former are more objective, the latter more subjective but just where the dividing line falls can sometimes be difficult. Medical and epidemiological evidence is or should be more at the objective end of the spectrum involving what we can call technical judgments. Priority setting regarding efficiency and equity involve more value judgments and these in turn raise the question of whose values are to be used for which judgments.

This can be sorted out in a number of ways and perhaps best is to think through who has property rights over which decisions. What is best avoided is to seek to involve all parties or even several parties in valuing and/or making the same decisions. That might seem in some senses 'democratic' but there are 'horses for courses' and it seems best to try to sort out which horses for which courses. It is also the case that too often in pluralist decision making the powerful voices may drown out the meek ones (as happens often in current decision making where there is 'consumer engagement').

If we were to look at target setting and judge this approach against the criteria established earlier in this review it does not perform well at all as a priority setting approach *in its own right* especially on the essential criteria of opportunity cost and the margin. That does not mean however that target setting that did embrace more of the listed criteria would not be useful as an adjunct to other approaches.

Generalised cost-effectiveness analysis

Hutubessy et al. (2003) in outlining this approach to priority setting state:

1. *"The costs and health benefits of a set of related interventions are evaluated, singly and in combination, with respect to the counterfactual case that those interventions are not in place*
2. *CEA results are used to classify interventions into those that are very cost-effective, cost-ineffective, and somewhere in between rather than using a traditional league table approach."*

They go on to suggest that this use of the counterfactual is an advantage as it allows identification of *"current allocative inefficiencies as well as the efficiency of opportunities presented by the new interventions."* The claimed advantage of this 'generalised' approach is that *"the costs and effects on population health of adding interventions singly (and in combination) can be estimated, to give the complete set of information required to evaluate the health maximizing combination of interventions from any given level of resource constraints."*

A major problem with this approach is that it deals with interventions and not marginal or incremental change. It looks at the world with and without these interventions. The reason put forward for adopting this stance is interesting (Hutubessy et al. 2003). *"Because the current mix of interventions varies substantially across countries, the costs and effects of small changes in resource use also vary substantially, which is one factor limiting the transferability of results across settings. Removal of this constraint by using the counterfactual of what would happen in*

the absence of the intervention means that the results not only allow assessment of the efficiency of current resource use, but are also more generalisable across populations sharing similar demographic and epidemiological characteristics."

This stance runs counter to the emphasis placed in our criteria on local data and local judgments. The idea that this more global or generalised approach can be useful is exposed by these same authors when they write that across countries in implementing interventions 'the costs and effects of small changes in resource use [can] vary substantially' and that this 'is one factor limiting the transferability of results across settings'. Thus the value of this 'generalised' approach becomes severely limited when it is moved to a local situation. The question then that proponents of this approach need to answer is why do this at the general level at all and why not go straight to the local level?

The problems of this generalisation issue are further heightened by the following comments from Hutubessy et al. (2003): *"in most settings it is assumed that health care facilities deliver services at 80% capacity utilization ... or that regions have access to the lowest priced generic drugs internationally available"*. Again the question arises why not use the local data on capacity? They say the reason for this is *"that there is limited value in providing information to decision-makers on the costs and effectiveness of interventions that are undertaken poorly"* but if the interventions are undertaken poorly then that is precisely the data that should be used!

Finally Hutubessy et al. state: *"In order to facilitate more meaningful comparisons across regions, costs are expressed in international dollars (an international dollar has the same purchasing power as one US dollar has in the USA)." Thus it becomes clear that the key objective of this approach (which has been developed under the auspices of the WHO) is to look at this issue of 'meaningful comparisons across regions'. There have to be considerable reservations as to whether this generalised CEA approach can allow such 'meaningful comparisons'. More fundamentally however with respect to this review for NSW the issue of comparisons, meaningful or otherwise, is not relevant.*

Accountability for reasonableness

Accountability for reasonableness is an approach developed by Norman Daniels, the US philosopher. Daniels (2000) sums it up as follows.

"In pluralist societies we are likely to find reasonable disagreement about principles that should govern priority setting. For example, some will want to give more priority to the worst off, some less; some will be willing to aggregate benefits in ways that others will not. In the absence of consensus on principles, a fair process allows us to agree on what is legitimate and fair. Key elements of fair process will involve transparency about the grounds for decisions; appeals to rationales that all can accept as relevant to meeting health needs fairly; and procedures for revising decisions in the light of challenges to them. Together these elements assure 'accountability for reasonableness'" (Daniels 2000 p. 1300).

It is worth examining this statement in some detail. The premise on which the approach is based is that 'in pluralist societies we are likely to find reasonable disagreement about principles that should govern priority setting'. That may be true but no evidence is presented in support of this premise. In Australia across a number of Citizens' Juries, the evidence is that agreement is more the rule (Mooney 2010) and that Daniels' premise, at least in an Australian context, is false. It might well be that if individuals qua individuals were to be asked, Daniels might be right but asked as a group of citizens representing their community, in all of twelve such Australian juries by Mooney (2010) it has been possible to reach a consensus. Even if

Daniels were right, the challenge would then be to try to reach agreement on principles rather than to give up.

Beyond that, what Daniels then seems to do is assume that there will be agreement on what is fair. Thus he writes: "*In the absence of consensus on principles [note the assumed likelihood of this is now moved to being assumed to be certain] a fair process allows us to agree on what is legitimate and fair*" (p1300). Now it is not clear how legitimacy has been endorsed and otherwise this says that a fair process leads to fairness but still without fairness being defined. He then writes that the 'key elements of fair process' include transparency, fairness (still not defined) in meeting needs (also undefined) and procedures (also undefined) for 'revising decisions' by a committee at least if they are shown to be unfair. There is something strangely circular about his reasoning and some jumps in logic.

Daniels (2000 p. 1301) argues further that with respect to his 'accountability for reasonableness' approach "*the social learning that this approach facilitates provides our best prospect of achieving agreement over sharing medical resources fairly*". There are many ways of reaching agreement over sharing medical resources fairly and, particularly without agreement on a definition of fairness, it is difficult to see how he can sustain his claim that 'accountability for reasonableness' provides 'our best prospect of achieving agreement over sharing medical resources fairly'. And then, what about sharing them efficiently?

Daniels' 'accountability for reasonableness' seems to be based on what may well be a false premise. Also it is about fairness not efficiency but it is about the fairness primarily of the process of priority setting rather than of any allocation of health care resources. It does not take us forward with respect to how to define fairness, who should define it nor what weights to attach to fairness versus efficiency.

What it does do, even if this is not its intent, is to signal that the emphasis placed on our criteria in obtaining agreement on principles early in the priority setting process is wholly justified.

Swedish priority setting

This is a useful example of the setting out of certain principles on which priority setting is to be based. It is seen as being useful to this review, even if it is quite heavily criticised here, perhaps as how not to set principles.

The Swedish principles are as follows:

- The human dignity principle
- The needs and solidarity principle
- The cost-effectiveness principle.

Also in his survey of priority setting, Carlsson (2010) argues that there is a need to add 'the responsibility principle' suggesting that "*people have a responsibility for their health and self-care within the context of their own individual situations*".

That paper also suggests that "*there are reasons to discuss the rank order of different prioritisation principles*" and that "*the human dignity principle appears to convincingly override the other principles*". Beyond that it seems that the ranking should be done on a case by case basis. It is stated that: "*Decision makers are expected to present their positions in a transparent way so it can be reviewed and possibly accepted by others.*"

There is a strong argument, endorsed in this review, to set out principles before setting priorities. There is however the possibility of disagreement about just what is meant by the word principle in this context. Related to this issue is the question of what is or what should be *the good* of health care, such as for example maximising QALYs. But added to that might be the idea of considering that some distributions of health are better than others – for example distributions which involve less inequality. Such inequality might however not be set in terms of health per se; it might be something like unequal access or unequal use. And there might be equity concerns set in terms of equal access for equal need or equal use for equal need.

It is possible to settle for the good of horizontal equity i.e. the equal treatment of equals or go further and argue that there is more good in pursuing vertical equity i.e. the unequal but equitable treatment of unequals.

The point is that the nature of the good that is sought needs to be established as it is not possible to get far without it. The sort of question that any Swedish priority setting exercise has to address is then: 'if an extra 10 million Kroner were made available to Swedish health care, where or on what or on whom should it be spent?' The answer to this question is where it will do most good which means in turn there is a need to know what is meant by good. (In passing it might be noted that the Swedish good and the Australian good might be different and indeed that the NSW good might be different from the Australian good.)

Secondly there have to be doubts if the rank ordering of principles as is discussed in Sweden is a useful road to go down. Any move on resource allocation is likely to have an effect on more than one principle and a bit more of A and a bit less of B may do more 'good' than trying to argue that A is to be ranked above B. And to argue that it will *always* be ranked above B (as appears to be the case with this sort of rank ordering) is also unhelpful.

With respect to human dignity, which is deemed to be ranked highest, such a principle might be seen as coming in degrees; also affronts to or offences to human dignity can vary in the amount of harm or loss of dignity that they do. Some might be prepared to give up a bit of dignity to live a bit longer; or again to have greater fairness or solidarity in the system. So such rank ordering is better avoided. Weighting will be useful but this has to be 'on the margin' in the sense that for example if someone has a lot of human dignity and is faced with a very unfair health care system, sacrificing a bit of human dignity for greater fairness may well be acceptable.

There is also an assumption that the Swedish principles are independent of each other but that is challengeable. In Australia for example a poor Aboriginal person faced with a lack of solidarity as manifested in inequalities in access to health care might well have her human dignity diminished by being disadvantaged in this way.

Thirdly, the Swedish debate about priority setting and principles is being conducted among experts, *only* experts! One might ask: Where are the citizens?

5 Embracing the NSW public?

There is a major question around the issue of whose values to use in priority setting. The answer may well depend on the circumstances and context of priority setting but what is clear is that the literature often bemoans the fact that the public is not more often engaged in health service priority setting, not necessarily in making decisions but at least in supplying the values on which priorities are to be determined.

For example in their review of priority setting literature Mitton and Donaldson (2003) indicate the need for the process of priority setting to be open and that it 'should involve the public in some manner'.

Bruni et al. (2008) put forward four reasons for involving the public in some way in setting priorities in health care. *"First, because the public funds and uses the health care system, citizens are the most important stakeholders of the health care system ... Second, greater involvement of the public in policy making is in keeping with the principles of democracy. Third, empowering people to provide input in decisions that affect their lives encourages support for those decisions, which in turn improves the public's trust and confidence in the health care system. Fourth, public involvement provides a crucial perspective about the values and priorities of the community, which should lead to higher quality, or at least greater acceptance of, priority setting decisions"* (p. 15).

They also point to the need to avoid having public participation being taken over by advocacy groups. One such group which can dominate if the selection process of those involved is not handled carefully is the vociferous and articulate middle class. As Bruni et al. (2008) stress: *"Poorer members of our society already have worse health and access to health care than wealthier members. It is important that public engagement not involve only people of higher socioeconomic status, as this would exacerbate the disparities"* (p. 17). Careful selection is important on a number of fronts but Bruni et al.'s implication of selfishness on the part of individuals may not be justified. For example several Australian 'citizens' juries' (see below) have given priority to Aboriginal health and a jury drawn from only Perth citizens concerned with health care across the whole of WA gave priority to those in rural and remote areas and not those in Perth (Mooney 2010).

Mitton and colleagues (2009) further argue: *"Governments appear to recognize benefits in consulting multiple publics using a range of methods, though more traditional approaches to engagement continue to predominate. There appears to be growing interest in deliberative approaches to public engagement"* (p. 219).

To propose that the community get more involved in health service decision making is not new. WHO (1954), more than half a century ago, proposed a move to have citizens' values drive health service decision making. That idea has been around since, see for example the World Federation of Public Health Associations in 1984 (Vuori 1984) and more recently the Romanow Commission in Canada (Romanow 2002).

How to engage the public is probably best done through some deliberative process as Mitton and colleagues suggest even if Contandriopoulos (2004) argue that with respect to policy levels '[existing] literature does not help in the elaboration of productive and realistic [public] participation policies' (p. 322). That comment however was written eight years ago and in the meantime both internationally and in Australia much has been done and learnt with respect to deliberative processes involving a critically informed public.

Mitton et al. (2009) are more optimistic although this was five years after Contandriopoulos' assessment. *"There are some practices for public engagement in priority setting which appear promising ... for instance the use of multiple methods and the balancing of broad consultations with in-depth engagement using new deliberative techniques."* They do however add that *"a lack of evaluation studies constrains our ability to say that the evidence backs any particular approach to public engagement in priority setting. Judgements of success in the literature do not appear related to the presence or absence of evaluation. ... Careful consideration of the context must occur before any particular approach to engagement is adopted"* (p. 227).

How the involvement of citizens is conducted matters and in particular how any results of such engagements are used or not used. Abelson et al. (2004) suggest that *"Citizens have clearly experienced feelings of apathy toward democratic participation based on the 'way they have been treated in the past', but they also want to make a difference to their lives and to the lives of their communities, partly in response to the weaknesses of their existing democratic institutions"* (p. 211).

They emphasise that *"simply establishing another mechanism for 'giving citizens a say' without paying attention to issues of purpose and process has a good chance of failing to establish or re-establish trust between citizens and their governors"* (p. 212).

There are a number of different forms of 'deliberative democracy' of which citizens' juries is the basic and most widely practiced (Atlee 2003). There are also consensus conferences which are similar except that the jury members are involved in selecting the experts to testify before them, they usually take place in a public forum and the final recommendations are presented as a 'consensus statement'. There are also 'planning cells' which involve a number of citizens juries (cells) all operating simultaneously and all looking at the same topic. Another variation is 'citizen assemblies' which were used in Canada with 160 citizens (one man and one woman randomly selected from each legislative district) making recommendations on electoral reform. More basically there are focus groups, population polling and opinion polls.

Probably the three best known priority setting exercises involving the public were in Oregon, Canada and England. The most famous – Oregon – is also the poorest (Hadhorn 1991) as it was far removed from the criteria set out earlier for a good priority setting approach. It failed to use margins in its analysis and eventually even dropped costs totally. From the perspective of citizen engagement moreover, it failed to seek a random selection of the community or to strive for a representative cross mix of the community.

In Canada the Romanow Commission (2002) involved a review of the whole of the Canadian health service. It placed particular attention on obtaining citizens' values. The idea behind the 'citizens' dialogue' they used is summed up in the words that Commissioner Romanow used to the dialogue participants: *"There are no right or wrong answers here. What I want... is a better sense of what you collectively value as important and believe to be the right path to take and why. I want to understand what aspects of the solutions you prefer – and do not prefer – in order to better focus my Commission's final recommendations"* (Maxwell et al. 2002).

The process involved 12 sessions across Canada with a membership of about 40 citizens in each (Romanow 2002). *"Participants were randomly selected in a manner designed to provide a representative cross-section of the Canadian population ... They were informed and thoughtful when they arrived and it was remarkable how quickly they absorbed even more information, learning from each other and the dialogue materials."*

The focus was reform so participants were presented with four scenarios for reforming the health care system. They were asked to create their own vision of the health care system they would like to see in 10 years and thereafter got into more detailed discussion of various reform possibilities.

While the detailed findings per se do not matter here, the types of ideas are. They wanted to keep the basic principles of the Medicare model as they believed in the values of universality, equal access, solidarity, and fairness. The authors of the report (Romanow 2002) also noted that: "When given a chance to work through the issues, citizens are far more open to change in the delivery of health care services than most politicians imagine."

They conclude: "*Citizens across the country were clear and remarkably consistent in the improvements they wanted to see in the management of the system:*

- *Greater transparency*
- *Earmark taxes for health care*
- *Create an auditor general for health*
- *Greater efficiency and co-operation within and among governments, and responsibilities and accountabilities spelled out more clearly*
- *Establish a national ombudsman.*

The values they wanted adopted included:

- *Universality... everyone is included*
- *Equity... individual access is based on need*
- *Solidarity... we are in this together*
- *Fairness... we contribute based on means*
- *Quality... care is timely and responsive*
- *Wellness... prevention is key*
- *Efficiency... sound management and value for money*
- *Accountability...everyone is accountable for how they use or affect the system; decision making and spending are transparent."*

In England NICE has been to the fore in helping to set priorities nationally based as indicated earlier on what amounts to QALY league tables. But this NICE process is accompanied by an attempt to bring the public's voice to bear on the process which is the relevant issue in this section. They have established a 'Citizens Council' which 'brings the views of the public to NICE decision-making about guidance on the promotion of good health and the prevention and treatment of ill health. A group of 30 people drawn from all walks of life, the Citizens Council tackles challenging questions about values – such as fairness and need.

This Council is thus concerned with developing the social values that are to underpin the work of NICE at the more technical level. The Council members are not health professionals and represent a cross section of the population in terms of age, gender, socioeconomic status and ethnicity. They meet in a deliberative process to provide NICE with the social principles on which NICE builds its technical work. For example they wrestle with issues such as the balance between regulation and individual freedom.

In Australia the process most frequently used for deliberative democracy in health care in recent years is what is known as 'citizens' juries". These involve bringing together randomly selected citizens, usually about 15, giving them good relevant information and allow them time to reflect together as citizens before asking them to make recommendations regarding the sorts of principles and priorities they want from their health care services. They do this against a

background of being told that if they ask for more of something then they have to nominate what they will give up to pay for it (Mooney 2010).

Citizens – critically informed citizens – have few problems in accepting the idea that resources are scarce and thus that priority setting is necessary. They also have few problems in reaching a consensus. It is important beyond that however that action is taken on the basis of what the citizens have recommended otherwise the approach will fall into disrepute.

Again and echoing what the Canadians found in the Romanow review, citizens in Australia come to the task of being asked about their views on the health care system with great enthusiasm. They care about health care and not just for themselves but for their fellow citizens. And they enjoy being asked to be citizens.

Of the various methods of 'deliberative democracy' available to involve the public, these citizens' juries are recommended because they (1) are based on a random selection of the relevant population; (2) emphasise the role of citizens qua citizens in a group setting; (3) seek to ensure that 'the jury' is well informed; and (4) place clear budget constraints on their choices.

6 Implementation

There is comparatively little in the literature on implementation. This section reports on two studies that do touch on this but concentrates mainly on reporting on a survey conducted specially for this report.

Peacock et al. (2009) *"suggest that health researchers need to work with decision makers by 'embedding' researchers within the organization if the economic principles of opportunity cost and marginal analysis are to be adopted as part of the management process. In this capacity, the researcher acts both as a participant – providing specific expertise in priority setting methods – and as an observer – researching the priority setting process. In our experience both approaches can work well in practice. Whilst such approaches can be time intensive, they represent a practical and rigorous way forward for researchers seeking to translate knowledge into practice"* (p. 131).

An attempt to review the success of PBMA was made by Tsourapas and Frew (2011). They looked at all published PBMA studies and judged success in terms of 'whether participants gained a better understanding of the area under interest and therefore a change in the decision-making culture was achieved' (p. 178).

In the wake of their review they also list the ways that they encountered to evaluate PBMA.

1. To establish if a disinvestment list has been created
2. To assess if resources have been successfully moved from the disinvestment list to the investment list
3. To evaluate if the PBMA exercise has led to the improvement of participants' knowledge regarding the area under consideration
4. To assess if PBMA has improved patient outcomes
5. To observe if PBMA has influenced the organizational culture or way of thinking
6. To assess if PBMA has been adopted for future use by the organization' (p. 179).

It is noteworthy here that improved efficiency and/or improved equity is not listed. What is particularly important from their review is the comment that *"PBMA's success largely depends on whether participants consider the existing structures and processes of the area. It is important to understand how priority setting is currently undertaken, identify the goals and needs of the region and assess whether and how PBMA should be implemented"* (p. 180).

In a survey conducted specially for this review, 18 authors of key studies on priority setting or of papers addressing issues around priority setting were emailed and asked (to respond within a two week period) if they would address the following questions related to their own experiences as researchers:

1. To what extent recommendations from priority setting exercises have been implemented
2. Where implemented, what difference doing so made to efficiency and/or equity
3. Where implemented, what the key reasons were that this happened and, by implication, where they were not implemented, why not.

They were asked 'to address any or all of the three issues above with respect to their own work' or if they had not done actual studies themselves, any opinions they might have on these three issues. All responded. Those approached and who also responded are listed in Appendix 1. Our

thanks to them. Some respondents did not wish to be identified with their comments and this has been respected in what follows.

The three questions in this survey are little addressed in the academic literature and that was why the opportunity was taken to conduct the little survey. Perhaps the key points to make are that (a) respondents were keen to respond – there was a 100% response rate; (b) they felt such a survey was needed; and (c) for questions (2) and (3) there was considerable agreement in the responses.

With respect to question (1) there was an interesting three way split with about a third saying recommendations were implemented; a third saying they were not; and a third saying they did not know.

On (2) almost none could make claims for improved efficiency and or equity.

Two important common features with respect to success in implementation (question (3)) were good leadership (or 'a champion') and having a health economist around to guide the process. A suggested measure of success was if the process was repeated.

Two of the respondents related their comments to their own countries' efforts at a national level. For Denmark, Holm indicates that the recommendations of the Danish Council of Ethics in the late 1990s were implemented but in only one of the Danish counties, although others did consider doing so. He could find no evidence that it made any difference 'primarily because it only lasted a short time'. The main reason why it was unsuccessful was 'health care is one of the main functions of the counties' and 'this made it very difficult for politicians to be explicit and transparent' at a local level, especially about 'de-prioritising'.

In Sweden, at a national level, Carlsson reports that 'systematic and transparent priority setting' is 'ongoing' at two levels – for health services in general and more specifically for pharmaceuticals (somewhat akin to the PBAC in Australia). Carlsson adds however that it is difficult to say to what extent recommendations on priorities are implemented as 'explanations behind changes in practice are more complex' but there are 'lots of examples' where decisions and recommendations have been accepted and implemented. He knows of no evidence that would show whether efficiency and or equity has been affected. However he adds that "*there is less opposition nowadays when county councils present lists of disinvestments as compared with 2003 when it happened for the first time*".

A theme that several respondents raised is that where priority setting has sought to take resources away from an area and to do so explicitly and transparently this 'disinvestment' process has often floundered. These decisions as one observer put it 'are much easier when they are obscured and shrouded rather than open and transparent'.

Daniels, commenting on his approach of 'accountability for reasonableness', reports that there is a body of literature which examines whether decision procedures in various settings (mainly in Canada) conform to the conditions specified in accountability for reasonableness. Beyond that Daniels points to the measurement issue of trying to judge if for example equity is improved. He states: 'I know of no research that examines the outcome of the process to see if it makes decisions better in some relevant way.'

Jan suggests from his experience that the two areas where differences have occurred are the NSW vertical equity weighting for Aboriginality and the PBAC, the former primarily on equity and the latter on efficiency. The former success Jan puts down to there having been a recognised gap on the part of policy makers, strong advocacy from the researchers and an alignment of recommendations with the strategic thinking of the policy makers. On the latter the legislative mandate he sees as critical.

The most promising responses came from research in Canada (Donaldson, Mitton and Peacock). As Mitton reports: *"Of the thirty odd PBMA applications I have been involved in primarily in Canada, I've seen recommendations implemented in about 90% of these."* He adds however that 'I've yet to see a study measure efficiency or equity in a robust way'. Interestingly because of the problems of measuring and attributing changes in efficiency and or equity, he concludes: 'I'd be sceptical if anyone claimed that their process did improve equity/efficiency"! In general proving that changes are a result of any priority setting exercise is difficult; measuring such changes even more difficult. Yet the responders generally were keen to see this done in future if at all possible.

On leadership, along with clinical engagement which Mitton sees as crucial to success, he writes: *"I used to think incentives were critical but less so now ... In one case, one CEO backed away from implementation because despite there being support from senior managers he wanted a less transparent process ... because he didn't want anything pinned on him"*.

Mooney reports on a similar situation which arose in an Area health service in NSW where the CEO, having had the Area health service staff complete the PBMA exercise and with solid recommendations, called in NSW Health who then ignored the study recommendations and cut X% across the board. The CEO did not want to be seen in the local community to be responsible for the cuts. Mooney adds that there may be an optimal distance between cuts and making decisions about cuts – and it is 'not up close'.

Mitton also emphasises that *"implementation is tied to political backing, which speaks to the need for up front work on buy-in, acceptance of criteria and lots of engagement activity"* a point that Mooney echoes. He also stresses the need to get clinicians' support. Mooney reports on one study which went very well until an attempt to implement it in oncology was blocked by the head oncologist and seemingly no one could get him to become involved. That, combined with the loss of the clinical champion to another city, resulted in the attempts to implement it coming unstuck.

Much of the work of Donaldson was in conjunction with Mitton. He reports that with Mitton they came up with *"109 published papers on PBMA with it having been sued almost 90 times in over 70 organisations across 7 countries. Over half the organisations reported using the process again (i.e. after their initial attempt) but 60% reported a positive short or long term impact in that resources were realigned due to the use of PBMA."*

The Calgary health service in Canada used PBMA repeatedly over several years. As Donaldson states: *"They agreed with the principles, and so, despite imperfections in the process first time around, they continued to work with it to refine it rather than abandon it after a one-off exercise."*

The keys to success according to Donaldson are *"leadership, organisational readiness and simply having good project management skills and support in place"*. Failures arise because of rapid changes in health organisation personnel and agendas; lack of a champion; the absence of a health economist or other key personnel; and not having earmarked personnel, time or money for the PBMA study.

Specifically with respect to the burden of disease approach to priority setting, Lopez reveals that while he has not been involved greatly in implementation, he reported that *"there have been close to 50 national applications of [the] methodology since we first published it 20 years ago"*. Unfortunately that still leaves open the issue of implementation of the BOD approach. Vos however, particularly in an Australian context, does claim some success in some of his applications.

Ratcliffe reports on two studies, one on liver transplantation with the Department of Health in London as being successful, but this was at a micro level. More relevant to this study was her work for Grampian Health Board in Scotland on maternity services generally where leadership was a key factor in the successful implementation of this work.

Ruta emphasises that PBMA gets implemented more readily when there is extra money and no need for disinvestment. One can understand that but also recognise why, when disinvestment is necessary the environment including leadership and project management, becomes so important. He suggests that "*there is so much inefficiency in our health care systems and services that there is a lot of scope for a kind of technical efficiency application.*" That is encouraging especially as it is less threatening than a full 'allocative efficiency' approach to PBMA.

Peacock argues that "*there has been some variability in the extent to which recommendations have been implemented*". He believes that the studies he has been involved in have "*reflected efficiency and vertical equity considerations*". Yet again he emphasises strong leadership as a key issue in getting recommendations implemented – together with a culture open to change and buy-in from the bottom up. Problems in implementation have for Peacock arisen because of there being a change in leadership during the process.

In one district health authority in England, a PBMA exercise seemingly did lead to investing differently but this was halted when a waiting list initiative came in and altered the priorities for resource allocation. Again a PBMA study on mental health services did seemingly help to move resources geographically to areas that were identified in the PBMA exercise to have been underfunded.

Perhaps it is wrong to expect that academic studies will provide much information on implementation. Thus Baltussen suggests that there is a gap "*between what happens in reality in priority setting and what academic studies report on*". He argues that there has been little impact of priority setting studies on resource allocation in general but points to two examples in Thailand and Tanzania. The explanation for success there he suggests was "*a strong embedding of the research in the policy making context*".

To summarise on implementation, perhaps the most significant finding is that the literature on priority setting too seldom reports on whether and to what extent or why recommendations from priority setting exercises have or have not been implemented. It is also noteworthy that when authors of studies were approached directly (as in the survey reported above) much more information on these issues was then forthcoming. The 100% response to this survey and some of the comments from respondents suggest that the researchers themselves not only are aware of this lack but want to see it rectified.

Beyond that the findings on implementation are that having a climate that accepts that priority setting is needed is vital; the recommendations from PBMA studies do seem to have been those most frequently implemented; having good leadership, especially clinical leadership, is crucial; for there to be a health economist 'on the spot' increases the prospects of implementation; and a good measure of success is if, after an initial exercise in a health authority, other exercises follow.

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Appendix 1: List of researchers interviewed

Rob Baltussen (The Netherlands)

Per Carlsson (Sweden)

Norman Daniels (United States)

Cam Donaldson (Scotland)

Maria Goddard (England)

Marion Haas (Australia)

Soren Holm (Denmark)

Ruth Hussey (Wales)

Stephen Jan (Australia)

Alan Lopez (Australia)

Lynne Madden (Australia)

Craig Mitton (Canada)

Gavin Mooney (Australia)

Stuart Peacock (Canada)

Julie Ratcliffe (Scotland)

Danny Ruta (England)

Leonie Segal (Australia)

Theo Vos (Australia)