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Priority Setting for Health: A Critique of Alternative Models

**Report to the Population Health Division
Department of Health and Aged Care**

**Leonie Segal
Ying Chen**

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**Report to the Population Health Division
Department of Health and Aged Care**

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Acknowledgment of previous work

Much of the work reported in this Paper was developed by Leonie Segal as part of the requirements for her Doctor of Philosophy, through the Faculty of Business and Economics at Monash University. The thesis titled, *Allocative efficiency in health: The development of a model for priority setting and the application to NIDDM*, February 2000 is lodged with the library at Monash University. Much of the text of this Paper draws heavily and in detail on that work. Specifically Chapters 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11 incorporate substantial sections of text from that work. Material has also been drawn from a recent priority setting project conducted for the Cancer Strategies Group of the National Health Priorities Committee, by a team led by Robert Carter from the Health Economics Unit, Monash University. Chapter 12 draws heavily on the report of this study, by Carter, R., Stone C., Vos T., et al *Trial of Program Budgeting and Marginal Analysis (PBMA) to assist cancer control planning in Australia*, June 2000.

Contribution

Comments on a draft of the report by Rob Carter of the Health Economics Unit, Monash University, (particularly about the PBMA model), by Andrew Mitchell, Director, Pharmaceutical Evaluation Section, Pharmaceutical Benefits Branch, Department of Health and Aged Care, (who provided comments on the PBAC model) and Brian Harrison, Peter Woodley and Jean Douglass of the Population Health Division, Department of Health and Aged Care, were all extremely valuable. The content of the final report is however, the sole responsibility of the authors.

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List of Abbreviations

| | |
|---------|--|
| ABS | Australian Bureau of Statistics |
| AHMAC | Australian Health Ministers' Advisory Committee |
| AIHW | Australian Institute of Health and Welfare |
| AN-DRG | Australian National Diagnosis-Related Groups |
| BOD | Burden of Disease |
| CSG | Australian Cancer Strategies Group |
| DALY | Disability-Adjusted Life Years |
| DHAC | Commonwealth Department of Health and Aged Care |
| DHS | Department of Human Services (Victoria) |
| EBMA | evidence based marginal analysis |
| GBD | Global Burden of Disease |
| GDM | gestational diabetes mellitus |
| HBG | Health Benefit Group |
| HRG | Healthcare Resource Group |
| HSW-DBM | Health-Sector-Wide Disease-Based Model |
| IAHS | Illawarra Area Health Service |
| IGT | impaired glucose tolerance |
| MBS | Medicare Benefits Schedule |
| NCCI | National Cancer Control Initiative |
| NHMRC | National Health and Medical Research Council |
| NHS | National Health Services (UK) |
| NIDDM | non-insulin dependent diabetes mellitus |
| NPHP | National Public Health Partnership |
| NTHS | Northern Territory Health Services |
| PBAC | Pharmaceutical Benefits Advisory committee |
| PBMA | Program Budgeting and Marginal Analysis |
| PBS | Pharmaceutical Benefit Scheme |
| PHEBAM | Public Health Evidenced Based Advisory Mechanism |
| PTO | Person-Trade-Off technique |
| QALY | Quality-Adjusted Life Years |
| WHO | World Health Organisation |
| YLD | years lived with a disability |
| YLL | years of life lost |

Purpose of Paper and Overview

This Paper represents the first output of a priority setting research program commissioned by the Division to assist in the identification of preferred models to guide resource allocation for public health and the health sector more broadly. It is also hoped that the models reviewed here may provide a structure to assist in decisions about support for projects to be funded under PHEBAM (Public Health Evidenced Based Advisory Mechanism).

The Paper commences, in Section I with an explanation of the reasons why a formal approach to priority setting is needed, and development of criteria against which to assess the performance of alternative models. This is followed by a description and analysis of several health planning approaches and the major economic based approaches to priority setting. (Reported in Section II). A critique of the applications is drawn together in Chapter 10, where the Health-Sector-Wide Disease-Based Model (HSW-DBM) and the refined version of PBMA (incorporating evidence-based marginal analysis) are identified as clearly superior, against the seven performance criteria. These two models are therefore considered in further depth in Section III of this Paper, through consideration of two comprehensive applications, to non-insulin diabetes for the HSW-DBM and for selected interventions for cancer in relation to the refined PBMA. These applications have also been drawn on in developing a recommendation for a preferred approach to priority setting, which is reported in Section IV.

An Options Paper is to be prepared next for the Division, to explore several possibilities and select a suitable new application of the priority setting model recommended in this Priority Setting Paper. As described in Chapter 13, the recommendation is for a model based on the Health-Sector-Wide Disease-Based Model (HSW-DBM) but also incorporating some of the features of the refined version of PBMA (incorporating evidenced-based marginal analysis). The proposed application to be conducted over a 12-month period will provide a detailed case study of how to apply priority setting and also to yield recommendations for resource shifts in relation to the selected health problem area.

Results of the new case study, as well as the applications reported in Chapters 11 and 12 (the application of the HSW-DBM to NIDDM and of the refined PBMA to selected interventions for cancer) may be used to suggest options for funding under PHEBAM. The new case study could potentially constitute the first in an on-going commitment by the Department of Health and Aged Care to embark on a strategic priority setting work program. The aim of such a work program would be to determine resource shifts that would contribute to an efficient allocation of resources and the optimal service mix for the health and community services sector.

A possible fourth stage of the research program is the consideration of incentives and health system reform options that could be applied to facilitate recommended resource shifts.

SECTION I INTRODUCTION

Chapter 1 The Need for a Formal Approach to Priority Setting

1.1 Introduction

There is reason to believe that the current health service mix is sub-optimal. This is suggested firstly by the nature of the health market, which embodies characteristics of market failure and secondly from evidence of wide differentials in cost-effectiveness ratios for health interventions, and thirdly by evidence of highly variable procedure rates across the country and between population sub-groups. This evidence, which is presented in the remainder of the Section, underpins the quest for a priority setting mechanism able to identify desirable resources shifts.

Chapter 2 explores the desirable features of a model for priority setting and develops a set of criteria against which to assess the performance of competing models. Alternative approaches to priority setting are reported on in Section II. Covered are both the commonly employed non-economic (or planning) approaches to priority setting (Chapters 3 and 4), and key approaches based on economic principles (Chapters 5 to 9). When reviewed against the criteria developed in Chapter 2, the 'health planning' models are shown to be fundamentally flawed, in their failure to specify performance criteria and mechanisms for making choices. The economic approaches, while sound in theory, require in implementation, compromise to the theoretical principles, due to the size of the task. In Section III, the two models which involve least compromise, a modified form of PBMA and a 'Health sector-wide Disease-based model' are then described more fully through an application to cancer and non-insulin dependent diabetes respectively. This allows the suitability of these two models to be further explored.

In the final Section, contains a recommendation for a preferred approach to priority setting, for the health sector and for public health.

1.2 Context: Priority Setting within a Broader Health Planning Framework

Priority setting is one of the important health planning tasks that face governments in seeking to enhance the distribution of health care resources. As shown in Figure 2.1, there are two primary points at which governments can intervene to adjust the health service mix and access by the community to health services. These are i) the way health funds are allocated to populations, which can be primarily driven by supply or allocated through a needs adjusted funding formula to meet equity objectives, and ii) the way resources are allocated between programs and services which can be essentially adhoc or based on a formal priority setting mechanism, supported by complementary incentives.

Thus funds are allocated to regions and ultimately to services and consumers through a combination of program based payments and in response to service provision/demand, occurring through Health Insurance Commission (HIC) payment for medical services and drugs (listed on the PBS). The opportunity for determining the funding to regions or programs is identified with the current interest in the application of resource allocation formula, based on needs adjusted calculations. The second influence on resource allocation can occur through the setting of priorities and the adoption of incentives for their achievement. This is again illustrated in Figure 1.1.

The activities involved in setting priorities are described further in Figure 1.2, where the major inputs to that process have been identified. This identifies for instance the role for needs-based studies and randomised control trials.

This paper is primarily concerned with the allocation of the communities' resources at the regional or national level although some comments are made about the relevance of the models to priority setting at the agency level.

Figure 1.1 Health sector planning framework

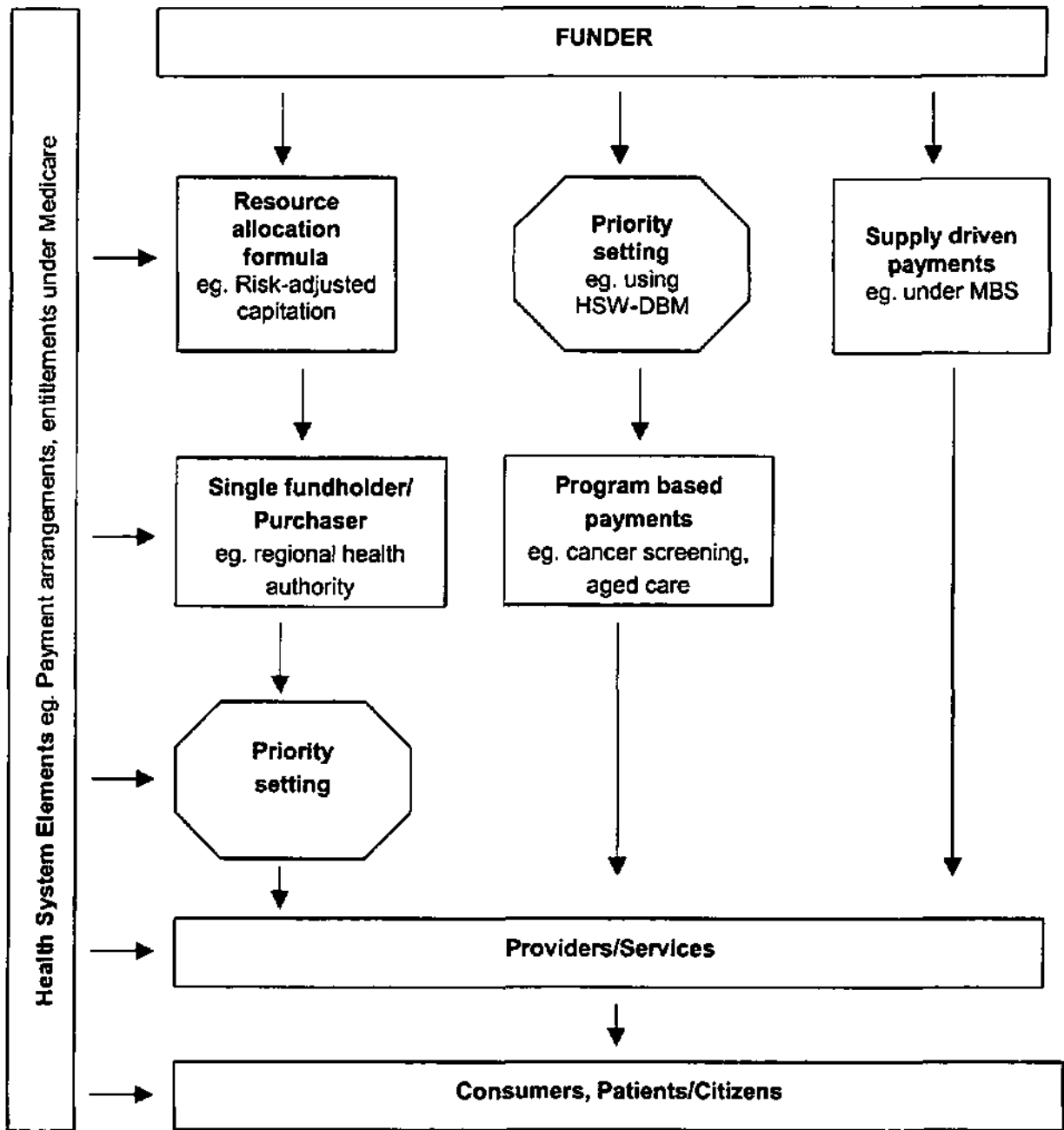
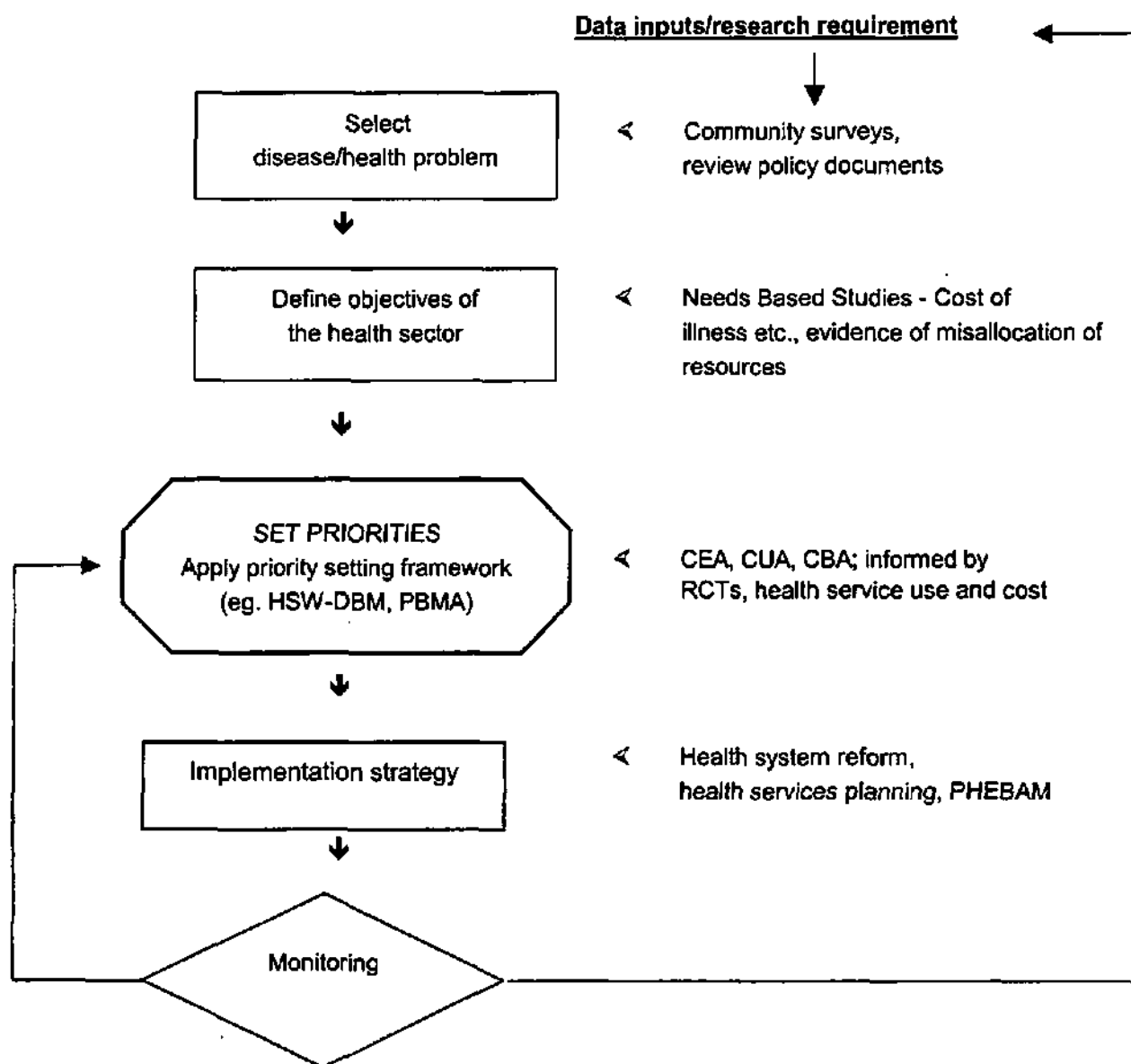


Figure 1.2: Health planning for priority setting



1.3 The Nature of Health and Characteristics of Market Failure

In the neoclassical theory of perfect competition, the assumed characteristics of profit maximisation, market contestability and independent and well informed consumers, ensure productive efficiency - least cost production, and allocative efficiency - the optimal mix of goods and services. (A large number of economic texts summarise these arguments, see for instance Le Grand et al 1992, McGuire et al 1988).

The central features of the competitive market are:

- i) supply side competition - many potential providers of (health) services and minimal restrictions on the nature of provision,
- ii) informed consumers able to give effect to their preferences – implying a capacity to determine their own health needs, make informed choices, and exercise control over 'their health budget', and
- iii) the absence of externalities - all costs of production are borne by the suppliers and all benefits of consumption are reaped by consumers. This requires, for instance, that an individual's consumption of additional health services has no influence on others.

In short, a perfectly competitive market in health would be characterised by informed consumers able to effect demand, and a competitive and responsive supply system. Taken together these two conditions enable consumers to influence the nature of service provision, a situation characterised as consumer sovereignty. A fundamental requirement of an efficient market is effective communication between consumers and providers of services. In the perfect market this is achieved through the medium of price, and the unimpeded movement of resources which allows resource shifts from 'lower valued' to alternative 'higher valued' activities.

The market in health does not meet these conditions, due to aspects intrinsic to health. Furthermore, government policies tend to exacerbate, rather than ameliorate these problems. There is a substantial health economics literature, in which the reasons for market failure in health are discussed (McGuire et al 1988, Evans 1984, Le Grand et al 1992). The common distortions in the health market are outlined below. These distortions underlie the need for a formal approach to priority setting. The market will not distribute resources for health efficiently.

A Intrinsic aspects of market failure

i Traditional Causes of Market Failure: externalities, public goods, merit goods, natural monopoly

Externalities – The failure to capture consumption benefits is a common feature of many types of health problems and possible solutions. For instance, drug and alcohol harm minimisation programs will typically yield benefits beyond that recouped by the individual, to encompass family members and the wider society. Benefits beyond the health sector may also be substantial, for instance through a reduction in crime. Purchase decisions based on benefit to the individual will thus be inappropriate when viewed from a society perspective. Immunisation against infectious diseases is another example where the benefit to society is beyond that recouped by the participating individuals.

Public goods – relate to goods or services for which there is a limited capacity to preclude persons from consumption, making private market supply problematic. Typical examples are clean air policy, food safety standards, public health promotion campaigns (to reduce the spread of AIDS, for road safety etc.). Many public health initiatives incorporate public goods features.

Natural monopoly: Engineering services, such as sanitation and clean water are an important contributor to community/public health, but are likely to be most efficiently supplied through a single provider. Combined with the need to ensure adequate access to all, and quality assurance concerns, government provision or at least government regulation may be desirable.

Merit goods: Most societies accept an obligation to dissuade individuals from behaving in away that is seriously damaging to their health. It is presumed that individual preferences, when it comes to health

are not sacrosanct. The use of harmful drugs is, in most societies, discouraged regardless of individual preferences.

ii Concerns about equity and access

Perhaps the most compelling reason for not relying on the market for resource allocation in health is the importance of ensuring 'fair' access to health services. Few, if any communities accept the proposition that access to health services should be determined entirely (if at all), by willingness to pay. Rather there is a widely held view that need, however defined, should be the primary determinant of access. (Further discussion of the concepts of equity and access and the objectives of the health sector, are provided in Section 1.3 below.)

Large differences in health outcomes between identifiable subgroups (age adjusted), are widely viewed as unacceptable. The distribution of health is of concern to society not just the sum (for instance as summarised in mean life expectancy). Furthermore the objectives of efficiency and equity must be *addressed simultaneously rather than sequentially*. The allocation of resources according to efficiency criteria, with equity achieved later through income transfers, acceptable elsewhere in the economy, is not appropriate in relation to health. Most would reject financial transfers as an incommensurate recompense for health degradation. Money is of no value to someone who is dead. Only health services can be purchased not health. The market cannot provide fair and equitable access to health services, so the acceptability of a market solution is undermined. A formal resource allocation process is required and one that allows efficiency and equity objectives to be pursued together.

iii Complexity of the relationship between health and the consumption of health services

People seek health services for the capacity of those services to contribute to their health and wellbeing. But the relationship between health and wellbeing, and the consumption of health services is complex. Outcomes can be highly variable, influenced by patient and provider characteristics and random variation.

Documentation of the effectiveness of even common health interventions is incomplete. Oxley and colleagues, OECD (1994) suggest the lack of evaluation of medical care, partly explains the massive differentials in observed procedure rates. While controlled trials are continually being undertaken, the pace of introduction of new technologies and adoption of alternative approaches to care means that practice is always ahead of evidence. Published information on the performance of individual service providers, at the clinician or hospital level is rare. In short, consumers will have difficulty in determining the real value to them of a particular health service.

The capacity for informed decision making and the practice of effective self-care is further compromised by the difficulty consumers have in accessing health information about themselves. Patient information typically resides with numerous individual service providers. No one is in possession of the complete picture of current patient care, health status, recent tests performed, test results, drug reactions etc. The issue of incomplete information while commonly recognised in health economics texts, tends to focus on the imbalance this creates between the consumer and the provider (see for example McGuire et al 1988). Less attention is accorded to the fundamental problem, which is the limited understanding of the relationship between health services and health, which affects both providers and consumers.

iv Provider as agent

Consumers invariably seek the advice of clinicians in making decisions about health care. The provider becomes, in effect, the patient's agent. But, a number of characteristics of providers impinge on their capacity to fulfil the agency role. The provider does not necessarily acknowledge or understand the role of agent and may have a vested interest in advice given.

v Moral hazard and adverse selection

Because of the unpredictable nature of health and ill health, and the possible size of health expenditures, insurance is a common solution to the sharing of risk. There is a substantial literature concerning the impact of insurance in removing the direct relationship between use of services and payment (McGuire et al 1988, Rosen 1995). It is postulated that there will be an incentive to over-consume (referred to as 'moral hazard'), although the evidence for this as a source of market failure is equivocal.

B The role of Government

Government in attempting to address the intrinsic attributes of health and health care, have created a set of institutional and regulatory arrangements which have restricted resource transfers between health services. Rather than solving the problems of the market these further impede the achievement of allocative efficiency.

i Preferential status of some services

Funding arrangements confer preferential status to certain types of services and providers. In relation to private professional health services, only those nominated in the Commonwealth Medicare Benefits Schedule, medical consultations (GP and specialist medical practitioner, pathology, radiology, medical procedures) and optometry are eligible for reimbursement. Other private health professional services (such as dietitian, physiotherapy, counseling, podiatry), no matter how central to patient care are ineligible for reimbursement.

The general practitioner also has a privileged status as 'gate keeper' to specialist services, and with other medical practitioners as the referral source for pathology, investigative procedures and pharmaceuticals. These arrangements promote a bias towards the use of medical services.

ii Funding support for particular health service delivery arrangements

The Medicare Benefits Schedule (MBS) provides, almost exclusively, for payment of private health professional services delivered through one-on-one provider/patient consultation. This discourages the provision of health services to groups or through multi-disciplinary teams. It inhibits dialogue between service providers and between the service provider and other family members, distorting the models of care that are offered.

iii Program based service provision with differential approach to budget caps

Health services are provided through numerous separate programs, each with their own legislative foundation and funding arrangements. This prevents resource shifts between programs and

discourages a coordinated response to care needs, creating distortions in the health service mix. The juxtaposition of uncapped funding of medical services and drugs, and capped funding of other programs, will increase the share of the former. Thus, between 1989/90 and 1996/7 the share of health expenditure spent on private medical services and pharmaceuticals increased from 27.7% to 31.9%, while the share spent on public hospitals fell from 34.3% to 29.6% (AIHW 1999b).

iv Shared responsibility for funding and delivery of health

Responsibility for health and other human services is shared between the Federal, State and local levels of government. No single agency or level of government has responsibility for the overall health of a community or commensurate control over the health budget.

The shared responsibility, combined with multiple funding sources and inadequate performance criteria encourages each agency to focus on its own financial targets, rather than the health outcomes for the community. The existence of perverse incentives and rewards for cost shifting is widely acknowledged (Patterson 1996, Macklin 1990, Butler 1999, Duckett 1998). Cost shifting is observed between levels of government, across sectors of the economy, and between the government sector and individuals.

Not only do differential funding arrangements create an incentive for cost shifting, but in an effort to minimise cost shifting, eligibility criteria are defined narrowly, limiting the capacity of programs to respond in a flexible way to needs. Cost shifting partly explains the large reduction in public hospital outpatient services that has occurred¹, transferring cost from the State to the Commonwealth, but also resulting in a loss of access to allied health services.

Decision making based on narrow financial consideration for the funder is unlikely to be efficient from the community perspective.

v Lack of control over budgets - multiple funders

Consumers rarely pay directly for all their health services, nor are health services funded through a single funder. Without the control over an entire health budget, the consumer and/or their agent is poorly placed to make an informed choice about the best mix of health services. If individuals were aware of the total expenditure on their health and had the capacity to redirect resources between different service types, a change in the health service mix is likely.

Overview of Health System and Funding and Delivery Arrangements

The intrinsic attributes of health and health care combined with the delivery and funding arrangements adopted by governments, generate incentives and barriers that restrict resource shifts and limit the active involvement of consumers in decisions about the health services they access. The achievement of an efficient mix of health services will only occur either through significant changes in health funding and delivery arrangements, or the application of an explicit health planning framework for priority setting. This conclusion is also supported by highly variable procedure rates and massive differentials in marginal cost-effectiveness ratios.

¹ Between 1987/8 and 1993/4, non-admitted patient services fell from 44 million (3.6/person) to 31 million (1.7/person), while private medical services funded through MBS increased by 45 million, Butler 1998.

1.4 Evidence of market failure in health: differentials in cost-effectiveness ratios and in procedure rates

In a major study by Tengs and colleagues (1995), estimates of the cost-effectiveness of 500 life saving interventions, drawn from across the health, transport, industry and environment sectors have been brought together. Substantial variation in cost-effectiveness ratios is identified. Programs range from cost saving, for some drug and alcohol treatment programs, prenatal care and well targeted public health programs, to over US\$200,000 (~A\$333,000) per life year gained, for some interventions (eg poorly targeted intensive care services and some screening programs).

A subset of results, reflecting the wide range in program performance, is reproduced below, in Table 1.1.

Table 1.1 Performance of 'life saving' programs: examples

| Cost/life year \$US | Number of programs | Typical programs in category |
|---------------------|--------------------|--|
| Cost saving | 61 | Public health/legislative preventative programs: mandatory motor-cycle helmets, flammable standards for children's' sleepwear, reduction in lead content of petrol, childhood immunisation (measles, mumps, rubella polio etc.), drug and alcohol treatment programs, prenatal care. |
| 0-\$10,000 | 110 | Neo-natal intensive care babies 750-1500gms, PTCA for men 55+ with severe angina, pneumonia vaccine for people 65+, smoking cessation advice for persons 35+, sickle cell screening for black newborns, coronary care for patients <65 with cardiac arrest, influenza vaccination. |
| \$10-20,000 | 55 | Anti-hypertensive drugs for mild/moderate hypertension, medical vs surgery for duodenal ulcer, advanced life support paramedical equipped vehicle. |
| \$20-\$50,000 | 85 | Renal dialysis, use of ACE inhibitors in people 35-65 with mild hypertension. |
| \$50-\$100,000 | 52 | Renal dialysis, poorly targeted intensive care, sicklecell screening for all newborns. |
| \$100,000+ | 184 | Toxin control, (benzene, arsenic, asbestos), school bus safety, screening/management of low risk populations (various), intensive care various conditions, upper gastrointestinal X-ray and endoscopy (as alternative to antacids or ulcer therapy) for gastric ulcer. |

Source: Tengs et al 1994

While resource redistribution should reflect marginal not average cost-effectiveness ratios (the Tengs study reports a mix of both), it is most likely that such large differences reflect an inefficient distribution of resources. A reduction in poorly performing programs and an expansion of programs with a more favourable cost-effectiveness ratio should result in a net gain.

Differences in cost-effectiveness ratios are reported for Australian health services, with some interventions potentially cost saving and others costing over \$50,000/life year. In a review of drugs submitted for reimbursement under the PBS, approvals were given to drugs that vary in cost/life year saved (incremental cost-effectiveness ratio) from \$5,050 to \$68,900 (George et al 1999). Research reported by Segal (2000) and Carter, Stone et al (2000) also indicate highly variable cost-effectiveness ratios.

Further evidence of market failure is provided by massive differences in management patterns and procedure rates across Australia, not explicable by differences in population characteristics. For example, the Australian Women's Health Study (Brown et al 1997) reports on procedure rates by region and income (based on self-report) and documents, in relation to hysterectomy, a rate in the ACT which is only half that in Western Australia and a rate in the lowest income quintile, more than 3 times that for women in the highest income quintile (age adjusted).

A recent review of cardiac surgery, following emergency admission for acute myocardial infarction (AMI), demonstrates substantial differences in rates of surgery apparently unrelated to level of need (Richardson et al 1998). Marked differences were observed by region, gender and health insurance status².

A study of procedure rates by statistical local area in Victoria (Richardson and Robertson 1998), also found wide variations in 15 common procedures. After allowing for the variance expected due to differences in age, sex and sample size, unexplained variation for colonoscopy was 45 times expected, tonsils and adenoids 7.5 times expected. The smallest differential was for exploratory laparotomy at 1.7 times greater than expected.

1.5 Role for a Priority Setting Framework

The lack of the preconditions for allocative efficiency, in the intrinsic attributes of health and in the government response, together with evidence of such failure in the small area variation in procedure rates and differential cost-effectiveness ratios, supports the hypothesis that the health service mix is sub-optimal. It means that there is opportunity for health gain, through the redirection of resources from services which perform relatively poorly, to services and populations which will yield greater benefit per unit of cost. The potential gains from addressing allocative inefficiency are not insubstantial. Consider two programs with vastly different performance: the transfer of resources from a program that yields one life year gain per \$50,000 (performance consistent with currently funded programs), to an alternative program that yields one life year gain per \$5,000 (equivalent to many under-funded health programs) would achieve a net gain of 9 life years for each \$50,000 transferred.

It is also significant that developments in health delivery systems have not obviated the need for models of priority setting. While, Purchaser-Provider, Managed Competition and Managed Care *models of health care funding and delivery aim to promote both allocative and technical efficiency*, these arrangements both demand and facilitate a formal priority setting activity.

With responsibility for the total health care of a community or constituency and in receipt of pooled funds to purchase services on behalf of the community the separation of the purchasing function from health care provision creates a clearly defined planning and purchasing role, which needs to be informed. Under the 'purchaser-provider' framework, purchasers require advice on how to select between competing health interventions. Thus, such models of health service funding and delivery are complementary to, and not an alternative to a formal approach to priority setting.

In short, there is a need for a formal model for priority setting. This report contains a critique of the dominant approaches. However, before proceeding to describe and assess the performance of the

² For example the rate of coronary angioplasty in Queensland (adjusted for admissions for AMI), was less than one third of the rate in Western Australia. Private patients in private hospitals in Victoria were more than twice as likely to have coronary angiography than public patients in a public hospital, and more than three times as likely to receive coronary revascularisation.

various models, a set of criteria by which to judge performance is developed. In developing these criteria the particular research question which the priority setting task is presumed to address is that of the optimal allocation of resources across the health sector, or more broadly to meet the health needs of the community. The primary concern is not with setting research agendas for health, or determining health priority areas, or allocating budgets of a health provider, but rather to determine desirable resource shifts within the health (and community services) sector, to identify programs and services that should be expanded and those that should be contracted.

Chapter 2 Development of Performance criteria

2.1 Introduction - Recognition of Resource Scarcity

The primary characteristic of a genuine priority setting model is the explicit recognition that resources are scarce relative to the potential health services to which they could be applied. The need to make choices is inevitable. Priorities can either be implicit, the outcome of the various pressures on providers, government agencies, purchasers and patients, or they can be explicit. An explicit approach to priority setting requires the development of a framework or model, and a set of protocols for decisions about which services and programs are to be provided (or expanded), and which services are to be contracted.

2.2 Objectives of the Health Sector

The welfare economics tradition defines the objective of economic activity, as the maximisation of wellbeing of society, given the prevailing income distribution. What this might mean in relation to the health sector is still the subject of debate. The key unresolved questions relate to i) the constituents/meaning of 'wellbeing', ii) whether individual wellbeing is uniquely reflected in individual preferences, iii) *whether the wellbeing of society is encapsulated entirely in the wellbeing of individuals*, and iv) whether society wellbeing is a simple sum of individual wellbeing. There is a dialogue in the health economics literature in which these matters are debated (for example by Culyer 1989, Sen 1977, 1979, Margolis 1982, Wagstaff 1991).

The debate about objectives of the health sector is frequently characterised as an argument between welfarists and extra-welfarists. The extra-welfare position is typically represented as a concern with health, as an end in itself (however defined), which is contrasted with the welfare position - that defines benefit by individual preferences. The welfare position does not preclude a range of factors entering into the preference function, such as consumption by others, option demand (potential access to services), the personal experience of the service (how the service is delivered, how one is treated as a patient, etc.), and information gained. Concern with the distribution of health and access to health services may also contribute to individual utility. Community concern with the adoption of behaviours known to be damaging to one's health, such as excessive drinking, or failure to access critical care facilities when needed, is also potentially covered in the welfare tradition through the designation of merit goods and externalities.

In the development of a model of priority setting a definition of the maximand, what is meant by 'society wellbeing' is of central importance. It is not possible to operationalise the concept of efficiency - allocative or technical - without defining the concept of benefit. The definition needs to cover both what 'wellbeing' means at the individual level, and how individual values are to be combined into a societal value.

Access to health services and inequality in health outcomes are widely documented as objectives of the health sector. Concern to ensure access to health services based on need, rather than capacity to pay is a dominant reason for the near universal involvement of governments in health funding (either directly or through supported health insurance arrangements). Government health policy documents also confirm a concern with equity as well as efficiency. In the report on Better Health Outcomes for Australians, the goals of the health sector are: 'improving health and wellbeing through reducing the burden of illness, reducing inequality, increasing community participation and creating healthier environments' (Commonwealth Dept. Human Services and Health, 1994). Similar aims are articulated

in health documents from the U.K. The adoption of a higher weighting for the Aboriginal and Torres Strait Islander population in the Queensland resource allocation formula for the distribution of health resources 'to allow for the additional health services required by this population due to their unacceptable morbidity and mortality rates' (Queensland Dept of Health 1994), reflects a concern with health inequalities.

Studies that explore the preferences of the community, consistently suggest a concern with distributional issues, not just maximisation of health gain (for example, Nord et al 1995a,b, 1999). Thus access to health services and the distribution of health and wellbeing, not just the 'average health' of a community is important. The implication is that an ideal priority setting model will provide for the consideration of both efficiency and equity. In theory, this could be accomplished either through an additional stage in the priority setting process, or through a suitably comprehensive definition of benefit, able to encompass the distribution of wellbeing, as well as the sum. The persistent references in needs studies and health policy and planning documents to the principle of universal access to health services, and to inequalities in health status, suggest that both are important.

It is not the role of this Paper to establish a precise meaning for 'equity and access', but rather to note their importance and the desirability of their incorporation into the model of priority setting. The challenge, in the context of a priority setting Framework, is to include equity within the definition of benefit, or to establish a process that acknowledges the dual objectives of equity and efficiency. The challenge is more one of practical application than with the theory.

While in theory, equity objectives could be encompassed within the individual utility function, in practice the capacity to do this is limited. Without a mechanism to incorporate the effect on individual utility of a change in the wellbeing of others, society welfare measured as the sum of individual wellbeing will fail to encompass the interdependence of utilities.

A quite separate argument is made within the community development and community health literature about the components of society wellbeing. This literature refers to a distinct concept of 'community health', which it is postulated is different from the sum of the health of the individual members of the community. (See for example Harris and Wills 1997, Peacock et al 1997a, Hawe 1994, WHO 1986).

Underlying the distinction seems to be a desire to shift the concept of health and health care away from a highly individualised disease/risk factor approach, to a social view of health, which recognises the importance of social determinants, encompassing the physical, social and economic environment.

However, even where community health is proposed as an independent objective of the health sector, its primary value is its capacity to make an on-going contribution to the health of members of the community. This is typical in the literature on healthy communities, social capital and capacity building. (See for instance Harris and Wills 1997, Hawe 1994, Wallerstein 1992, Rissel 1994). Attributes of healthy communities, such as strong and diverse social networks, democratic decision making processes, control over resources at the local level and support for sharing of knowledge and skills will, it is argued, contribute to the current wellbeing of members but also support an on-going contribution to their wellbeing. It is not apparent that this argument supports the proposition that society wellbeing is beyond that embodied in the wellbeing of the individuals of the community. Rather it seems to be an attempt, by non-economists to enunciate the concept of capital. If the central value of 'community health' is its capacity to deliver on-going health gains to members of the community, no modification to the basic principle of individual wellbeing, as the nucleus of community wellbeing is required.

The implication for priority setting are more prosaic and relate to the conduct of cost-effectiveness analyses. Specifically, that long term program impacts should be included, and that the choice of program options should be wide-ranging and encompass both traditional health programs but also possibilities from outside the health sector, and options that focus on communities as well as the individual.

2.3 Conditions for Optimality

Two important implications can be drawn from this discussion pertinent to the criteria for priority setting: firstly it is desirable that equity and access objectives, as well as efficiency, are incorporated into the priority setting process; and secondly, that the Model should be able to accommodate alternative definitions of benefit, or to derive objective(s) which reflect the concerns of the community.

If society has a clearly defined equity objective (such as access by all to 'core' health services, or the reduction in health inequalities) then efficiency could be pursued, with that equity requirement as a constraint. In that case, the optimal health service mix will occur with the achievement of the nominated equity objective, when at the margin, benefit per unit cost is equal across all services or programs.

The traditional condition for allocative efficiency, given resource scarcity would apply, as expressed by Equation 1:

$$MBa/MCa = MBb/MCb = MBc/MCc = \dots MBi/Mci \dots = \dots \dots \dots 1$$

where MB_i , MC_i refer to the marginal benefit cost ratio³ of program or service i .

And given the achievement of the equity goal (replacing the traditional - given the existing income distribution).

It is also plausible that equity and efficiency will at times be complementary, that is strategies will jointly contribute to both, while at other times, equity and efficiency will be competitive, with each pursued at the expense of the other. In the latter case a trade-off will occur, which can be implicit or explicit. If the equity objective were defined in terms of inequality in health outcome, maximisation of society wellbeing would need to incorporate the trade-off accepted by society between health inequality and total health.

If the concept of an equity/efficiency trade-off is to be incorporated, this might be expressed as shown in Equation 2. Within each population subgroup, the marginal benefit cost ratio of services targeted at the population sub-group is equalised, but the MB/MC ratio of services addressing different population subgroups may differ. The extent of difference would be determined by the equity-efficiency trade-off established for that society.

$$MBaj/MCaj = MBbj/MCbj = MBcj/MCcj = \dots MBij/Mcij \dots = \dots \dots \dots 2$$

where MB_{ij} & MC_{ij} refer to the marginal benefit & marginal cost of program i delivered to sub-population j , and

³ The concept of the margin is central, and has several dimensions, relating to the expansion or contraction of services, scale of activity, the sub-population to which the service is addressed, the marginal individual in receipt of, or just denied the service, alternative service design features.

MB_{ij}/MC_{ij} may be greater or less than MB_{ik}/MC_{ik}

with the extent of inequality dependent on the relative health status of the sub-populations and the efficiency/equity trade-off determined from society values.

Alternatively benefit could be defined comprehensively to encompass both efficiency and equity, (that is both total societal wellbeing as well as its distribution). In this case the condition for optimal health service mix can simply be described as in Equation 3:

$$MB_a/MC_a = MB_b/MC_b = MB_c/MC_c = \dots MB_i/MC_i \dots = \dots \dots \dots 3$$

where MB_i refers to the marginal benefit of program i defined in terms of the contribution to societal wellbeing which incorporates both an efficiency element (individual benefit summed across all individuals) and an equity dimension (relating to the distribution of benefits), and

MC_i refers to the marginal cost of program or service i .

This latter model while simple in conceptualisation does not provide specific guidance for measuring benefits. Thus while this latter concept has some attraction it may prove impractical.

All of the formulations of the conditions for optimality, involve a comparison of intervention options, in terms of their marginal benefit cost ratios. Thus it presumes a priority setting process which can derive a set of intervention options for comparison and incorporate a mechanism to measure program impacts, which can be used to calculate a marginal benefit cost ratio. The above description also presumes a societal perspective.

2.4 Set of Criteria for Assessing Performance

The theoretical requirements of a model for priority setting arise out of the conditions for allocative efficiency - the equalisation of marginal benefit/cost ratios (across all possible programs and services across the entire health sector), where benefit incorporates both efficiency and equity objectives. Only then is it impossible to enhance wellbeing without the application of additional resources - presuming technical efficiency is simultaneously pursued.

This implies a number of essential characteristics, against which the performance of a priority setting model can be assessed:

I A decision rule is specified: The decision rule and process for setting priorities are specified:

The most basic requirement is that resource scarcity is recognised and precise criteria for the redirection of resources, for making choices, is enunciated.

II There is a logical relationship between the decision rule and the community's objectives

The theory of welfare economics suggests this will be achieved when:

The research question and analysis perspective is that of society:

A societal perspective is adopted – (or as a second best the perspective is explicit), and the research question is broadly defined to encompass the entire health/community services sector.

The selection of program/service options is comprehensive and precisely defined:

Program selection is critical. Any 'prior filtering' may limit options for consideration in a way that is not explicit. Intervention options should not be constrained by existing services, or by current program boundaries. The model should facilitate identification and comparison of interventions offered through different delivery settings, for different stages in the disease process, delivered by various agencies, supported through different funders. It should also allow consideration of options outside the narrowly defined health sector. A precise description of service options is also critical to include details of population target, service elements, form of delivery etc.

Objectives are well defined:

The theoretical requirement to equalise marginal benefit/cost ratios presumes that agreement is reached concerning the definition of benefit by which performance of interventions is to be evaluated. The model seeks to incorporate community objectives in relation to health into the decision criteria.

A marginal perspective is adopted:

In principle, the achievement of allocative efficiency requires the evaluation and comparison of every possible health intervention, at the margin. Not just covering program decrements or increments but also relating to different sub-populations (down to the individual patient/member of society), different locations, and alternative program characteristics. The margin can also refer to the adoption of an iterative approach (whereby the impacts at the margin are recalculated after each presumed resource shift). Average benefit and cost will often poorly appropriate values at the margin. Interventions may be very effective for some patient groups, but ineffective for others. Similarly cost alters with size of program or patient groups targeted.

There is rigour in measurement of costs and benefits:

The use of high standards of evidence in the measurement of program impacts - costs and benefits - is essential for confidence in the resulting analysis. Sensitivity analysis cannot replace objective evidence, but requires knowledge of the expected range within which parameter values will fall.

III Capacity for implementation

There is capacity of implementation:

The requirement is not simply about the demands of the model relative to current resources available to implement a particular priority setting exercise, but rather about the resource implications relative to the purpose and the potential benefits of implementing a rigorous approach to priority setting.

Compromise in order to work within available budgets is unacceptable where this involves loss of integrity and undermines confidence in the Model. Thus while the requirements of the theoretical ideal imply a substantial research task, with large data demands - in terms of evidence on effectiveness and cost of alternative intervention options, this should not be used indiscriminately to justify inferior approaches. Rather it should be used to seek realistic budgets for the purpose of health planning and

priority setting and to support a strategic research effort to gather evidence critical to the priority setting task.⁴

A number of Models have been reviewed in this report to assess their integrity relative to these criteria. The models evaluated are:

- i) the implicit approaches of historic decision rules and best practice guidelines,
- ii) a set of health planning models, that are focused on the description of health needs and health problems including:
 - community surveys, goals and targets,
 - cost of illness/burden of disease, and
 - avoidable mortality/morbidity,
- iii) a set of models based on economic principles; including:
 - the Health Sector-Wide Disease-Based Model,
 - the Health Benefit Group/Health Resource Group approach,
 - Program budgeting with marginal analysis (PBMA),
 - QALY League Tables - large scale - as exemplified by the Oregon experiment, and a planning exercise of the Illawarra Health Region, NSW,
 - Program evaluation— as exemplified by the work of the Pharmaceutical Benefits Advisory Committee (PBAC).

The description and critique of these models is the subject of Section II of this paper. Resource allocation formulae/weighted capitation models are not discussed in this report as they represent an approach to changing needs of total funding to populations based on risk adjusted need and to meet equal objectives. They are not concerned with the mix of services purchased with those funds, thus not within the topic of this paper.

⁴ For instance, the total health services expenditure for 1997-98 was \$47,267 million, (AIHW Health Expenditure Bulletin No 15). Given the evidence concerning inefficiency in resource allocation, it is almost certain that a redirection of health resources could add substantially to the value to the community from their application. There would seem to be a prime face justification for a substantial budget for priority setting - \$10 million p.a. would represent only 0.02% of the total health budget.

Section II MODELS FOR PRIORITY SETTING - DESCRIPTION AND CRITIQUE

Chapter 3 Implicit Models

3.1 Historic-Based Model

Historic-based decision rules have been the most common approach to health services planning, especially at an agency or program level. Under the historic-based model, program funding is based on the previous year's allocation, with a nominated adjustment. The adjustment will often reflect a change in costs or a change in the population base. Adjustments tend to be relatively uniform, with all program areas treated alike, regardless of performance. Differential adjustment may occur, but in an ad hoc way, for instance in response to interest group lobbying or partial reviews.

Historic funding is a traditional public finance approach. It can be highly effective in achieving a nominated financial outcome such as the capping of spending on particular programs. It fits the conventional agency culture. It imposes low transaction costs for decision making and training. However, it does not incorporate mechanisms or decision rules for maximising community benefit from a predetermined budget, and explicitly discourages the redistribution of resources between program areas.

The use of historic-based decision rules assumes that existing priorities, as embodied in current resource allocations between program areas are optimal, and that any reduction or increase in program funding will be equally effective, regardless of where additional resources are allocated to, or from where resources are withdrawn.

3.2 Best Practice Guidelines

Best Practice Guidelines are developed by clinical groups often in the context of a consensus conference, (eg NHMRC 1991, NHMRC 1992, Hypertension Guidelines Committee 1991; AHMAC 1990, Consensus Panel 1992). The primary purpose of developing Best Practice Guidelines is to contribute to the adoption of best practice care, within clinical practice. Guidelines are defined essentially based on evidence of clinical effectiveness. They represent an important influence on the pattern of patient care and management. Despite concern that adoption of best practice care as dictated by the Guidelines is poor, over time they influence patterns of management.

Though Best Practice Guidelines are not usually considered a formal priority setting mechanism, they may have a major influence on the health service mix. Especially now they are being used increasingly in the context of 'Coordinated Care' or 'Managed Care' in defining protocols of care that will be funded. They have the potential to contribute to (or detract from) the achievement of allocative efficiency.

Best Practice Guidelines are normally developed with little regard to the resource implications or the capacity of the health system to deliver best practice care. For example, often new treatments offer a very small improvement in outcomes over current treatments, but incur a substantial cost penalty. But on clinical criteria it is appropriate to support the use of the more effective higher cost treatment. Guidelines may highlight those groups most able to benefit and for whom any side effects may represent an acceptable risk, and others for whom the possible side effects cannot be justified by the

potential for benefit. If there is a priority setting principle it is implicitly about providing care to those with greatest capacity to benefit, or that all those with capacity to benefit should receive care. While this works well in relation to one particular treatment, it provides little guidance about the level of resources that should be allocated across the whole range of health services that may generate benefits, given resource scarcity.

In short the approach does not provide an adequate basis for priority setting because it has no mechanism to incorporate cost. It cannot be translated into service implications and recommended resource shifts in the context of resource scarcity. It has no process to establish priorities if resources are insufficient to provide best practice care to all those who meet the relevant clinical criteria.

On the other hand Best practice guidelines can provide a useful input into a priority setting process, contributing to the definition of possible intervention options. They can also contribute to health planning, providing the basis for estimates of resource implications and manpower requirements of universal access to best practice care.

Chapter 4 Needs-Based Approaches

4.1 Introduction

The health needs assessment approaches are primarily concerned with defining, quantifying and estimating the size of health problems, and in identifying health inequalities between age, gender, ethnic groups, and geographical areas. Epidemiological studies of comparative health status, measured by all-cause or disease specific mortality and morbidity or by life expectancy, consistently report substantial and significant differences in the health of sub-populations.

Various studies provide evidence of a relationship between socio-demographic and economic parameters and health status. This finding seems universal. (See National Health Strategy 1992, Lynch et al 1997, Kawachi and Kennedy 1997, Wilkinson 1997, AIHW 1998, Murray and Lopez 1996, World Bank 1993, Streeton 1989, 1994; Phillips et al 1995). In these studies sub-populations are typically classified by income, gender, age, geographical location (eg urban, rural and remote), and ethnicity/country of origin. Poorer health status is consistently identified for populations identified as socio-economically disadvantaged. Needs based studies are essentially descriptive. Analysis is usually restricted to an attempt to explain observed differences in health status.

However, the results of needs based assessments are sometimes used in support of particular types of policy initiatives. For instance, Syme (1996) and others argue that in the development of health policy and in selecting health interventions, the importance of the relationship between socio-economic status and health should be reflected. The results of epidemiological studies have been used to support health promotion interventions directed at life style change but also broader community based interventions targeted at the social, physical/environmental and economic influences.

A number of specific needs-based approaches are now described, and considered for their suitability for priority setting against the criteria nominated in chapter 2. The 'models' considered are; community surveys, burden of disease and injury/cost of illness studies, avoidable mortality and morbidity and Goals and targets. These types of studies are promoted as health services planning tools and thus warrant consideration in this Paper.

4.2 Community Surveys

Needs assessments, based on community surveys are commonly undertaken by agencies with a regionally defined constituency. They are a requirement of Local Government Health Plans in Victoria.

Community surveys tend to highlight a wide range of health concerns to communities, encompassing such issues as personal safety, the physical environment, opportunities for productive use of time. Disease or ill-health is rarely identified as the over-riding concern (Summers 1992, Higginbotham et al 1993).

Even though community surveys are relatively common, there is little documentation about how such surveys might be used. Brown and Redmond (1995) describe a process for the selection of priority health promotion targets for women in the NSW Hunter Region. They recommend combining data from community surveys, epidemiological data on health status and the views of key informants from the health and community services sector, to rank health issues in terms of, importance of health

problem, capacity for health promotion to reduce burden, and amenability to monitoring. The ranked set of health issues is then to be passed on to the regional health planner to devise a set of priority programs. The community survey approach does not incorporate a process for developing a priority set of programs or recommending resource shifts. It fails the basic requirement - a protocol for resource allocation decisions. However community based surveys can identify areas of concern and thus potential gains.

4.3 Cost of Illness Studies

Cost of illness or burden of disease studies refer to the studies that measure the impact of a particular disease on the community, usually in terms of mortality, morbidity and health service use and cost. These studies are used in policy forum to advocate for the allocation of health service resources to a particular health problem or disease.

Cost of illness is commonly defined to include three components:

- i. *Direct costs* - health service costs for management (and prevention) of the subject disease including complications;
- ii. *Indirect costs* - the value of lost production (economic activity) through illness and premature death attributable to the subject disease; and
- iii. *Intangible costs (or direct health burden)*: the loss in wellbeing through the impact of the subject disease on health related quality of life and premature death. While neither ill health nor premature death is intangible, the valuation placed on this loss is.

There is a fundamental difference between the direct health service costs for disease management and prevention, and the latter two cost categories. Intangible cost and loss of production reflect the burden of disease that is incurred, while the cost on the health system reflects the costs incurred to reduce that loss. There is substantial debate about the appropriate techniques to use to estimate costs within each of the three categories, (especially the impact on economic activity). There are two basic methods to undertake disease costings:

The case study approach: a bottom-up approach in which the various costs associated with a specific disease are calculated directly and summed, see for example Box 4.1.

The satellite national accounts approach: a top-down approach in which total health expenditures and morbidity and mortality for a population are apportioned between diseases, on the basis of plausible attributable fractions, using national data sets.

The Australian Institute of Health and Welfare (AIHW) has undertaken a series of Cost of Illness studies using the national satellite approach to estimate the impact of disease on the community; by major disease class and subclass, by risk factor, age and sex Mathers 1996). The AIHW discussion papers detail the methodology in calculating both direct and indirect costs. Direct costs include, hospital inpatient services, pharmaceuticals and medical services nursing homes and allied professional services. They use known aggregate expenditures and apportion these on a disease-specific basis using Australian data, (the hospital morbidity series, the National Survey of morbidity and treatment in general practice and the National Health Survey). Indirect costs are based on an implied production loss of time in the work force due to hospitalisation and premature death. Indirect costs are measured in life years lost, to a nominated age (65 or 75 years). More recent work by Mathers has focused on measurement of intangible loss in terms of disability adjusted life years, (see Section 4.4 on the Australian Burden of Diseases Study).

Box 4.1 The Model of Resource Utilisation for Costs and Outcomes of Stroke (MORUCOS)

Commissioned by the National Stroke Foundation to assist with costing and economic evaluation of stroke care in Australia, the Centre for Health Program Evaluation is currently developing 'The Model of Resource Utilisation, Costs and Outcomes for Stroke' (MORUCOS) (Mihalopoulos, Carter and Dewey 2000). The model aims to combine epidemiological data; demographic data on stroke incidence and population trends, service utilisation patterns, direct costs across the continuum of care, lost production (indirect costs), and economic data on costs and outcomes, thus to describe stroke incidence, project stroke incidence and costs, and evaluate new interventions in the areas of prevention, cure and care.

The model has been applied in Western Australia, which has so far only accomplished the first two phases of the model, possibly proceeding to the evaluation phase depending on funding. The study relies heavily upon research results of previous stroke studies. It uses 1997 as reference year adjusted by 5% discount rate using the AIHW deflators (1997). The model is disease (stroke) specific. As the authors acknowledge, it can be used as a stand-alone costing model (in this sense, it can be seen as a cost of illness study by the bottom-up approach), or alternatively, as an adjunct to economic evaluation studies of stroke care. When the evaluation phase is conducted, it can inform stroke service planning, and contribute to priority setting exercises.

The role of cost of illness studies has been the subject of on-going debate. While some claim cost of illness studies provide a justification for expenditure on prevention and management, others recognise a more limited role. Disease costings can be used to estimate the potential savings of a reduction in disease incidence. Although more detailed analysis may be required than is normally available through traditional cost of illness studies, particularly to differentiate by disease stage. It can also highlight diseases responsible for a high level of disease burden that may warrant greater attention. Others believe that cost of illness studies tend to be misused and may distort resource allocation decisions. For instance, cost of illness estimates might lead to priority being given to those health program which already have a large amount of resources devoted to them (Drummond et al 1986). The size of a problem is not necessarily a reason for allocating more resources to a problem area. We should instead be considering the marginal returns gained from allocating those additional resources, that is, the benefits generated. For example, substantial resources are spent on CHD to great effect, however, it is not clear that additional resource would generate further benefit, compared with allocation of additional resource to alternative lower profile diseases.

4.4 Burden of Disease Studies

The Global Burden of Disease (GBD) Study

Most prominent of all cost of illness/burden of disease studies is the study initiated in the early 1990's by the World Health Organisation and the World Bank (1993), commonly known as the 'Global Burden of Disease Study'. The GBD study is the first attempt to quantify disease, injury and health risks worldwide. It has quantified the burden of 486 sequelae of 108 major causes of death and disability,

dis-aggregated by eight geographic regions and ten age-sex groups and attributable to identifiable risk factors, for 1996 and projected to the year 2020. (Results are presented in Murray and Lopez 1996).

The Global Burden of Disease study has used the Disability-adjusted Life Year (DALY) as the primary measure of health status, in response to the inadequacy of mortality in the context of the rising importance of chronic non-communicable diseases. The aim was to shift health status description from mortality and morbidity to measures of quality of life and well-being (Murray and Lopez 1996). The DALY is designed as a single measure of disease burden, to capture the impact of both premature death and disability.

The DALY is a particular form of the quality-adjusted life year (QALY), but where 1 represents maximum disability and 0 full health. While with the QALY, 1 represents full health and 0 death. (States worse than death are considered possible and take on a negative value). A DALY comprises years of life lost (YLL) (to a nominated life expectancy), plus years lived with disability (YLD). In calculating the DALY, for each condition studied, disease experts were invited to provide information on incidence, mortality, most common sequelae and the duration of sequelae.

Disability weights were derived by an international group of health care providers by applying the Person-Trade-Off⁵ approach to 22 indicator conditions. These conditions were classified into seven disability classes, which were then used as makers to allocate disability weights to all other disabling sequelae (Murray and Lopez 1996).

The GBD study also incorporates age weights. Positive weights are applied to ages 10 to 55 years (with a maximum of 150% at age 25), with negative weights up to age 10 and beyond age 55, down to zero for a newborn and 40% for a person of 90. A 3% discount rate is applied to years of life lost in the future.

The GBD study has attempted to provide comparable and timely information on:

- the relative contribution to disease burden from premature mortality and from non-fatal health outcomes;
- the contribution of different diseases, injuries and risk factors to ill-health; and
- projections of premature mortality and non-fatal health outcomes.

Apart from providing a new and consistent measuring of the health status of populations, there is an expectation by some, that the GBD will contribute to priority setting. In 1998, in her 'Speech on Burden of Disease Concept' (WHO 1998), Dr Brundtland, the WHO Director-General, declared that when resources are scarce, we need methods to define what is more important and we need priorities. She states that the purpose of the burden of disease concept is *'to provide a comprehensive assessment of health challenges to help inform public debate on the priorities for health action'*, and that *'a key component of the burden of disease approach is to make the ethical values underlying an assessment of health priorities transparent and available for public debate'*.

The WHO report on Investing in Health Research and Development (WHO 1996) also claims that 'the (GBD) methods are intended to provide some systematic steps that investors might use to help guide their decisions about resource allocation.' This report provides a discussion of priorities for research

⁵ Under the person trade off approach experts (or members of the public) are asked to determine the number of people with a specified condition for whom life could be extended by one year, to be equivalent to an extension of life by one year of 10 persons in full health.

and development based on size of problem and amenability to effective intervention through research efforts.

Murray and Lopez (1996, p39) also note in the summary to the GBD study report that

'The study's impact will be judged in two ways: first, by the degree to which it stimulates other researchers to apply the same rigorous methods of measuring disease burden in all regions; and secondly, to the extent that it changes priorities for public health in the decades ahead.'

However, the report does not specify exactly how the GBD might be applied to resource allocation decisions in a situation of resource scarcity. Those involved with the GBD studies suggest it provides; a uniform measurement unit, timely health information, and a means to set research and development priorities and assist resource allocation.

Australian Burden of Disease Studies

Responding to the WHO initiative, the Australian Institute of Health and Welfare, with part-funding from the Commonwealth Department of Health and Aged Care set up the Australian Burden of Disease Study in June 1998. At the same time, the Victorian Department of Human Services also commenced a parallel analysis of the burden of disease for Victoria. Both studies have completed a wide range of disease and injury estimates and published the research results (Mathers et al 1999, DHS 1999a, 1999b).

The two Australian studies adapted the GBD methodology to suit the Australian context and the need for greater detail in measuring the size of health problems important in Australia. Several changes were incorporated into both the national and Victorian burden of disease studies. No age weights were used, which means that a year of life is valued equally at all ages. A set of Dutch disability weights was used for many conditions for their greater detail in relation to disabilities more common in Australia. There was also an adjustment of YLD estimates for comorbidities between mental disorders and between physical disorders at older ages (Mathers et al 1999; DHS 1999a, b).

The debate over cost of illness/burden of disease studies

The performance of cost of illness/burden of disease studies is explored against the nominated criteria at the end of this Chapter, but some of the concerns with this method are noted here.

There has been a lively debate over the use of BOD estimates as a tool in priority setting. Mooney and others have been highly critical, arguing that burden of disease studies have no role in the setting of health service priorities, (Mooney and Creese 1994; Mooney, Irwig and Leeder 1997).

There is a concern expressed that such studies:

- divert scarce analytical resources away from more valuable research tasks, such as calculating the marginal cost-effectiveness ratios for various interventions;
- distort priorities by placing the emphasis on the big problems rather than best buys;
- focus on diseases rather than interventions.

Advocates of the BOD studies (Vos and Mathers 1998) argue that the GBD study is a major step forward in operationalising and promoting the use of rigorous approaches to priority setting. It is also recognised that in setting priorities based on BOD the use of size of burden as the only criterion is not appropriate. Reference is also made to the need to introduce cost-effectiveness analyses. Others have used the GBD together with additional data to determine how to maximise the DALYs averted per dollar for interventions for specific diseases or health problems (Bradshaw and Schneider 1998).

Vos and Mathers (1998) argue that cost of illness estimates are useful as part of the priority setting process:

- to identify those disease areas about which to conduct of cost-effectiveness analyses due to potential for large health gains;
- knowing the size of health problem by population sub-group is critical to setting priorities to achieve equity objectives.

While academics argue over the value of cost of illness studies in priority setting it is not clear from the literature that burden of disease estimates have been used directly in priority setting exercises. A discussion about the DALY, a contentious element of the GBD is discussed in Chapter 13.

4.5 Avoidable Mortality and Morbidity

The concept of 'Avoidable mortality and morbidity' relates to a potential responsiveness to health sector interventions through prevention, early diagnosis or treatment and has been used to classify all disease and injury codes. It has been argued that this concept is pertinent to determining the size of 'potential' health gain, and may of value in priority setting.

'Avoidable mortality' is defined as (New Zealand Ministry of Health 1999):

'A potentially avoidable death is one that, theoretically, could have been avoided given current understanding of causation and currently available disease prevention and health care technologies.'

and '*avoidable morbidity*' (*avoidable hospitalisation*) as:

'one involving an individual aged 0-74 years that could in principle either have been prevented altogether (preventable hospitalisation) or could have been successfully treated at an earlier stage in the primary health care setting (ambulatory sensitive hospitalisation).

Avoidable mortality analysis emerged in 1976 when Rutstein and colleagues proposed the categorical attribution of diseases and injuries using 'sentinel-health-events' (Rutstein et al. 1976, 1980). This was expanded by Charlton and colleagues (Charlton et al. 1983), whose lists of avoidable mortality included causes amenable to medical or surgical treatment to age of 65 years, and was intended to serve as a health care system performance indicator (Holland, Fitzgerald et al. 1994). The 'avoidable mortality' concept was later extended to cover hospitalisation (Weissman et al. 1992, Billings et al. 1996).

The New Zealand 'Avoidable Mortality and Morbidity' Study

The New Zealand Ministry of Health has extended the 'avoidable mortality and morbidity' approach, altering Charlton's list of avoidable mortality and extending the age limit to 75 years (Marshall and

Keating 1989, Malcolm and Salmond 1993, Jackson et al. 1998). Both mortality and morbidity have been subdivided into three categories, as described by New Zealand Ministry of Health (1999):

- **Primary avoidable mortality (PAM):** conditions that are preventable, whether through individual behaviours change (lifestyle modification) or population level intervention (healthy public policy). The condition is preventable by addressing its risk or protective factors: primary prevention.
- **Secondary avoidable mortality (SAM):** conditions that respond to early detection and intervention, typically in a primary health care setting. As well as clinical preventive services such as cancer screening, it includes chronic disease management of high blood pressure. This approach constitutes 'secondary prevention'.
- **Tertiary avoidable mortality (TAM):** those conditions whose case fatality rate can be significantly reduced by existing medical or surgical treatments (typically, but not necessarily, in a hospital setting), even when the disease process is fully developed. This constitutes 'tertiary prevention'.

Proportions/fractions contributing to each of the three levels for each cause of death have been estimated and assigned, such that the fractions sum to <1.

Preventable hospitalisations, adopted as a proxy indicator of morbidity, were subdivided into three similar sub-categories:

- **Preventable hospitalisations (PH):** hospitalisations resulting from diseases preventable through population-based health promotion strategies
- **Ambulatory sensitive hospitalisations (ASH):** hospitalisations resulting from diseases sensitive to interventions delivered in a primary health care setting
- **Hospitalisations avoidable through injury prevention (IP)**

The estimates of avoidable mortality and morbidity and the allocation to the three sub-classes was determined through a bargaining process. Two public health specialists created an initial allocation, based on population attributable risks and expert opinions. This was revised by a team from the NZ Ministry of health, and subject to external peer review.

The resulting estimates appear in the Ministry of Health Report 'Our Health, Our Future: the Health of New Zealanders 1999', and cover the period from 1981. 'Avoidable mortality' (to age 75) was estimated to have declined by 38% from 1981 to 1997 while 'unavoidable mortality' declined by 9%. In 1996-7 almost 70% of deaths to age 75 were assessed as being potentially avoidable, with about 50% potentially responsive to primary prevention and 25% to each of secondary and tertiary interventions. Almost 80% of all avoidable deaths were reported in the 45-74 age group, dominated by chronic diseases such as IHD, diabetes and smoking related cancers. Among younger age groups, most avoidable deaths are injury related. Males bear a higher proportion of avoidable deaths, (which is hardly surprising given their lower mean life expectancy).

Both avoidable and unavoidable rates of hospitalisation (age-standardised) have increased. While hospitalisation avoidable through primary prevention is estimated to have declined by 40%, hospitalisation avoidable through primary care has increased by 25% and due to injury by 6%. In 1997-8 almost one third of total hospitalisations (to age 75) for reasons other than maternity, mental and disability support services, were assessed as potentially avoidable, through primary prevention (approximately one third) and through primary care around two thirds. This analysis has been used to

provide information about inequalities in health status by age, gender, ethnicity and socioeconomic status (N.Z. Ministry of Health 1999, P315).

Use of DALYs in the avoidable mortality and morbidity studies

A recent UK study (Hollinghurst et al 1999) has used DALYs in determining the 'avoidable' burden of disease in the South and West of England.

Substantial technical and conceptual problems are acknowledged in the application of the avoidable mortality and morbidity approach. Hollinghurst and colleagues note reliance on subjective judgement in incorporating the DALY and the difficulty of accessing data on which to base the estimates of avoidable burden. An informed dialogue is still required around key conceptual issues. For instance, how is 'avoidability' allocated when a condition can be modified through primary prevention, primary care and tertiary prevention. How is the role for cutting edge medical technology to be treated? How are results to be interpreted? For instance an increase in avoidable deaths, could reflect new possibilities for control, or reflect deterioration in the quality of management.

As a method for setting priorities, the avoidable mortality and morbidity approach suffers from precisely the same limitations as the cost of illness studies, in that it does not incorporate any decision process for choosing between competing health care demands. Furthermore the methods used to classify what is avoidable and how avoidability is to be allocated across primary prevention, primary care and tertiary prevention are questionable at best and there is no formal examination of the costs and effectiveness of possible interventions. The interpretation of results is also unclear. For instance an increase in avoidable deaths might reflect new possibilities for control, or deterioration in the quality of management. Performance of the method, in terms of its potential value for priority setting, are discussed further in Section 4.6 with other needs based approaches.

4.6 Goals and Targets

The use of a 'Health Goals and Targets' approach to make more health care decisions more rational was initiated by WHO in the late 1970s, under the slogan of 'Health for All by the Year 2000'. In Australia, the setting of goals and targets has been used at the national level as a health planning and priority setting framework (Commonwealth Department of Health and Family Services 1997), and applied in the health planning document 'Goals and Targets for Australia's Health in the Year 2000 and Beyond' (Nutbeam et al 1993). Targets are set for reduction in incidence and prevalence of selected diseases and risk factors after a brief description of disease burden and consideration of 'preventability'.

Health goals and targets were also devised for sub-populations as reported in 'Health Goals and Targets for Australian Women' (Working Party of the Australian Health Ministers' Advisory Council Subcommittee on Women and Health 1993, and for diabetes (Colaguri et al 1998). Goals and targets are often expressed in the most general terms; for example to 'reduce the incidence of osteoporosis in older women (Nutbeam et al 1993a, P93), or more precisely but without clear justification; for example to 'reduce mortality from heart disease in males aged 30-64 years by 50% by 2010' (Nutbeam et al 1993a, P34).

These studies attract limited resourcing yet tend to be vast in scope, resulting in analyses that lack depth. More importantly there are no defined criteria for the setting of goals and targets. There is no explanation of the methods by which the goals and targets are derived, and which might be replicated by others. There is also no discussion of how the goals and targets are to be achieved and no process

to prioritise recommendations, given that not all goals and targets can be achieved with the resource allocated to the health sector.

In this fundamental sense then, the Goals and Targets approach does not constitute a model for the setting of priorities or advising on desirable resource shifts. Such studies may even mislead policy makers, by suggesting that priority setting can be accomplished through minimal research effort, possibly redirecting limited health planning resources away from more rigorous approaches to priority setting.

4.7 Overview of the Performance of Needs-Based Approaches

i The decision rule and process for setting priorities are specified

The needs-based approaches described in this Chapter represent a dominant thrust of health services planning. Without exception they fail to incorporate decision rules for priority setting in a situation of resource scarcity. Therefore they cannot and do not provide a mechanism for adjusting the health service mix towards optimal. They can at best provide an input to a priority setting exercise, where decision rules are introduced from elsewhere.

These common approaches to health services planning, while possibly acknowledging resource scarcity, do not incorporate mechanisms for making choices between competing uses of health care resources.

The needs based approaches are useful as descriptors of comparative health status and to highlight the relative magnitude of health problems. This does not however constitute a priority setting process. At their best these models provide information that can be used by health planners in determining where to focus a priority setting work program.

Brief consideration of the other performance criteria is undertaken, but given the failure of the primary criteria, the failure to specify a process for making choices, their performance with respect to the other criteria is largely irrelevant.

ii The research question and analysis perspective is that of society:

Most needs based studies take a broad societal perspective, except for some community based surveys which may focus on the concerns of a sub-group who represent the constituency of the particular agency. In fact probably the strength of the GBD is its very breadth and the attempt to consider a wide range of health problems and wide ranging risk factors. Certainly the World Bank Report (1993), in which the original GBD material was published, takes an extremely broad view of health, with considerable attention devoted to environmental health matters as well as education and poverty. However the GBD work itself is focused on disease rather than interventions. The avoidable morbidity and mortality work is also pertinent in focusing attention on the possibility for reducing disease burden by intervening across the disease spectrum. Unfortunately the approach taken for defining and classifying 'avoidability' is extremely weak, and lacking in any process for using results in decision making.

iii The selection of program/service options is comprehensive and precisely defined:

All the needs based studies - the cost of illness, burden of disease, epidemiological surveys, etc, focus on an assessment of the size of the health problem. They fail to describe interventions at all, let alone in the type of detail needed to develop cost-effectiveness estimates. It is only by calculating the cost-

effectiveness of interventions that it is possible to determine where limited resources can be allocated to best effect.

In theory, the avoidable mortality and morbidity approach would need to incorporate an extremely thorough and detailed assessment of all the thousands of possible intervention options for reduction in disease burden, through primary prevention, primary care and tertiary prevention in order to derive the estimates of avoidable mortality and morbidity. However there is no evidence that this has occurred. In short, all of these methods focus on health needs and burden of diseases and injuries, with no process for identification of intervention options.

iv Objectives are well defined:

Few of the needs based studies explicitly address the issue of the objectives of the health sector, although community based surveys depending on their focus may provide some insights into those matters of concern to the community which could potentially be used in understanding what might be the objectives of the health sector. The GBD in using the DALY as the measure of outcome implicitly is adopting the maximisation of DALYs as the objective of the health sector. The use of age weights introduces a judgment about the relative value of DALYs accrued at different ages. The adoption of the longest world mean life expectancy as the target for all, also incorporates elements of distributional equity, while the Australian Burden of Disease study does not incorporate age weights or the adoption of the longest world mean life expectancy. The debate around the choice of DALY and the means for its summation and means to accommodate access and equity issues is underdeveloped.

It is acknowledged that in describing health status across different populations, defined by region, sex, age, ethnicity etc., needs based studies can identify differences in health status, which may both inform equity objectives and enable their achievement (or failure there-of) to be monitored.

v A marginal perspective is adopted:

None of these approaches are based on economic principles. They fail to adopt a marginal perspective in its most basic meaning, that of considering opportunities for changes from the status quo.

vi There is rigour in measurement of costs and benefits:

Needs based approaches vary in terms of rigour in measurement and levels of evidence. Because of the very wide scope of most cost of illness/burden of illness studies this invariably is at the expense of confidence in the data. The method for calculation of DALYs in the GBD and the Australian burden of disease studies, as well as the approach to measurement of avoidable mortality and morbidity, involve substantial use of expert opinion.

This raises considerable doubt as to the robustness of estimates generated.⁶ The use of the EuroQol in the Australian burden of disease study is also of concern, as it is an extremely insensitive health utility instrument, as it only has three levels for each field (Hawthorne, Richardson et al 2000; Richardson 1999).

⁶ Concerns also relate to the quality of data at the most basic level. (Carr-Hill and colleagues (1987) note that coding of cause of death may be confounded, as the quality of the medical records from which cause of death is derived may be correlated with the quality of the associated medical care.

This lack of confidence in the data and approach to deriving estimates also means that the claim that these studies provide a uniform health outcome measure is weakened. It is the case that problems with data availability, relevance and reliability are common to all health planning approaches.

vii There is capacity of implementation:

The various needs based approaches can be implemented as illustrated by the various reported examples. Further where they can rely in large part on existing data sets they can be completed with surprisingly few health planning resources. The Victorian burden of disease study has been completed with less than 3 FTE person years.

Needs based studies have been undertaken primarily to describe the health of communities. They meet that requirement extremely well. Community surveys and data on health status also enhance our understanding of the nature and extent of health inequalities and can contribute to the debate about the objectives of the health sector.

However as noted above such studies are not directly relevant to the allocation of resources. While needs assessments may provide insights into the nature of health inequalities and of the health problems to which health services and health policies might be addressed, this literature does not specify a method for translating problem identification into a resource allocation process. They may however, contribute to the selection of health problem areas for the conduct a priority setting study.

Chapter 5 Health-Sector-Wide Disease-Based Model

5.1 Model Development

The Health-Sector-Wide Disease-Based Model (HSW-DBM) was developed in 1993 as a framework for priority setting that would meet the formal requirements of an 'ideal model', as described in Chapter 2. In contrast with the needs-based approaches, the focus was that of resources and interventions, and describing a process for making choices under scarcity, not disease burden. As with all the remaining models considered in this Paper it is based in the discipline of economics. Within health economics the common approach for priority setting was that of comparative cost-effectiveness analyses, with interventions selected for inclusion in studies adhoc and often reflective of the responsibilities of one agency or level of government. In developing the Health Sector Wide Disease Based Model a particular concern was to extend the scope to the entire health sector and seek a more rigorous and comprehensive approach to the selection of interventions for analysis.

A priority setting exercise designed to achieve allocative efficiency (the optimal health service mix) must disregard existing program boundaries. To do otherwise is to perpetuate existing inefficiencies. Resources allocated through different health service providers, by different funders, through various modalities, and targeted at different sub-populations jointly contribute to the wellbeing of the community. Thus, framing of the research question, to encompass the entire health and community services sector and ensuring comprehensiveness in the selection of interventions for comparison were important in the development of this Model.

This, however, implied a very large research task and the need for a strategy to make the task manageable. The solution was to stage the priority setting activity, in such a way, that intermediate conclusions (local optima) would be consistent with the global optimum. This is most likely to occur where the research question is structured by health problem/client/patient group and not by service type or health delivery setting.⁷

The possibility of using the simpler evaluation method, of cost-effectiveness analysis rather than cost-utility analysis, for a part of the priority setting task was also explored.

5.2 Key Features of the Health-Sector-Wide Disease-Based Model

The Health-Sector-Wide Disease-Based Model is described with reference to Figures 5.1 and 5.2. Figure 5.1 depicts the total health (and community services) sector. (The scope of 'the health sector' is not resolved as part of the Model definition, but is a matter for interpretation in the particular application. Potentially scope could be extended to encompass ultimately the full range of human services that contribute to health related wellbeing). The health (and community services) sector is subdivided into broad health problems or disease groups. As discussed below, this provides a means for staging the priority setting task, while minimising the risk of recommending resource shifts, inconsistent with allocative efficiency.

⁷ For instance if the focus is pharmaceuticals, as with the Pharmaceutical Benefits Advisory Committee in recommending drugs for listing on the Pharmaceutical Benefits Schedule (PBS), the research question is circumscribed. The aim is to identify drugs that are at least as cost-effective as those already on the PBS. However if the research question were refocused around the health problem, (such as sleep disturbance, or asthma), the best solution might be a behavioural approach, and a reduction in the use of all drugs. Subsidising even the more cost-effective drug treatments might not be part of the efficient solution.

The framework illustrated in Figure 5.1 provides for the grouping of all health services, actual and potential, by health problem and population sub-group. This is shown as a two way classification; i) health problem or disease class along the horizontal axis and ii) population subgroup at key stages in the disease process/health problem development, along the vertical axis.

Figure 5.1 Health problem/disease based approach to allocative efficiency

| Disease Stage/ Population or patient target | Health problem or Disease class (partial list) | | | | | | Total resource use |
|--|---|--------------------|--------------------|-------------------|---------------------|-------------------|--------------------------|
| | Endocrine Disorders | | Cancers | Neuro- logical | Cardio- vascular | Family at risk | |
| | type 2 diabetes | type 1 diabetes | breast lung etc | stroke, | CHD etc | Alcohol etc. | |
| Primary prevention <i>Population at risk</i> | | | | | | | |
| Early identification. <i>Persons with un- diagnosed disease</i> | | | | | | | |
| Disease management and prevention of complications <i>Persons with established disease</i> | | | | | | | |
| Treatment of end stage disease, palliative care. <i>Persons with advanced disease</i> | | | | | | | |
| Total resource use | | | | | | | |

Each column in Figure 5.1 encompasses all the potential interventions that may address the health problem or disease of interest, grouped by stage of disease/population group. Four distinct population sub-groups are identified:

- the healthy community or persons at risk - a possible target for prevention services,
- persons with early stage disease/health problem development - potentially suitable for screening and early case finding,
- persons with diagnosed disease or health problem - suitable for management,
- persons with intractable disease suitable for end stage management or palliative care.

A description of the Model, through a list of the tasks involved in the priority setting process is provided below. Broadly, the Model proposes each disease/health problem area is studied separately. The first stage involves the comparison of interventions for the selected health problem or disease, at each disease stage. This is followed by comparisons between disease stages using cost-utility comparisons of the most cost-effective and least effective interventions at each stage. The final research phase is the comparison across disease/health problem areas, to eventually cover the entire health and community services sector.

5.3 Reason for Health Problem/Disease Focus

Prior to a detailed description of the tasks, the reasons for adopting a disease/health problem focus with the associated population grouping as the structure for the priority setting task is explained.

i To ensure a focus on resource allocation between disease stages

An explicit objective of the Model is to focus attention on the allocation of resources between disease stages, recognising the comparative neglect of this issue. Health systems typically have separate budgets and separate planning bodies for broad program areas such as public health, acute health, nursing homes and residential care, mental health and primary care. Resources tend to be locked into program streams, with little opportunity to consider the current distribution between program streams. The focus on disease/health problem not just enables, but ensures an assessment of allocative efficiency between disease stages. This is because the Model requires options at each disease stage: primary prevention, screening/early diagnosis, management and palliative care to be compared. It also encourages comparison of services offered by different agencies, in different settings, supported through different funders. The proposed structure also supports consideration of the widest possible choice of intervention options.

ii It supports a staging of the research task with little risk of sub-optimisation

In structuring the analysis by disease or health problem, the allocative efficiency question becomes minimisation of disease burden, for each disease and health problem taken in turn.

Each stage of the priority setting task has a definable research question:

- firstly in relation to a selected disease/health problem, to ascertain resource shifts at each disease stage that would contribute most to health and wellbeing given the current level of resourcing at the disease stage,
- secondly to ascertain resource shifts that would contribute the greatest reduction in burden in relation to the subject disease or health problem, with no constraint on possible solutions, and
- finally to ascertain resource shifts across diseases, that would contribute greatest to health and wellbeing.

iii Capacity to observe distributional impacts

In addressing programs to prevent and manage a nominated disease/health problem, there is a sense in which the analysis is focused on a particular population – those at risk of, or diagnosed with the subject health problem/disease. This may reduce the potential for unintended distributional consequences. The identification of population subgroups with a disease/health problem at each stage will facilitate the observation of distributional impacts of resource shifts and if desired incorporate weightings to reflect community preferences.

iv Opportunity to use intermediate outcome measures

In the first stage of the priority setting task, where the interventions being compared are addressed at a single disease stage, there is the possibility of using intermediate health outcome measures. In the comparison between disease stages, there is the prospect of translating outcomes of early intervention into outcomes pertinent to later disease stages using knowledge of normal disease progression. It may be possible therefore to use cost-effectiveness analysis, an economic evaluation technique with less demanding data requirements than cost-utility analysis.

v Research efficiency

The priority setting task will need to draw on published research about the subject disease. But, much of the knowledge about a disease or health problem required to assess performance of intervention options will be pertinent to the various disease stages. The disease/health problem focus may provide a valuable role in pulling together all the literature pertinent to a reduction in disease burden, and generate efficiencies in the research task.

5.4 Model Description - Research Tasks

The DBM involves the staged comparison of health interventions to eventually cover the entire 'health' sector, through a structured approach involving:

1. **Selection of disease/health problem** - to commence the priority setting activity;
 - i. **Ranking at each disease stage** – comparison of all interventions at the disease stage, equivalent to a within cell analysis, for all the cells down a column (see Figure 5.1). The aim is to identify the most marginal programs, the least and most cost-effective (see Figure 5.2), at each disease stage, and desirable resource shifts at each disease stage;
 - ii. **Comparison across disease stage** - comparing the most marginal services, a comparison between cells of a single column. It would result in conclusions about desirable resource shifts (from least cost-effective to most cost-effective interventions) across disease stages;
 - iii. **Replication of steps i to iii for all diseases and health problems** - to eventually cover the entire health sector;
 - iv. **Comparison between diseases** – through a comparison of the most marginal programs (best and worst) from each cell, possibly commencing with a particular stage, between cells along a row.

This broad approach is implemented via a set of research activities.

Activity 1 Select a health problem, disease group/sub-group for analysis

The first task is to select a disease grouping or health problem for study. A number of criteria are suggested for this purpose as listed in Box 5.1. These reflect a combination of importance of the health problem and likelihood that the current health service mix is inefficient. The criteria might be thought of as cumulative, the more criteria that apply the better.

Box 5.1 Criteria for selecting health problem/disease for priority setting task

1. The health problem is of 'sufficient' size: The disease burden is high - measured by attributable disability or quality adjusted life years and/or in terms of health budget allocated for prevention and management, and the health problem has been identified as an area of concern to the community and
2. There is evidence of misallocation of resources: The current health service mix is apparently sub-optimal - indicated by substantial variation in management practices, large differences in cost-effectiveness ratios, major departures from best practice care.
3. Consistency with stated government priorities.
4. There are opportunities for primary and secondary prevention.
5. Issues of equity and access: The optimal mix of services has both an equity and efficiency dimension.

Access to data - on costs and effectiveness of existing and possible interventions.

While it is desirable that the choice be explained and justified, in view of limited health planning resources, the starting point is not critical to the integrity of the Model. The Model proposes that progressively, all areas of the health (and community services sector) would be reviewed; thus the

choice of where to start is less important than the commitment to a staged priority setting research program.

Activity 2 *Devise a structure for analysis of the disease/health problem - determine appropriate classification into disease stages or problem development*

A thorough understanding of the selected disease/health problem is required. This would cover aspects such as, normal disease progression, risk factors for development of disease and of complications, possibility for prevention or delay of disease onset, opportunities to ameliorate disease burden through early diagnosis and management.

Data sources include the medical literature, (journals, published reports, best practice guides), public health, health promotion and health education literature and health economics studies. Discussions with clinicians, other service providers and consumer groups may be valuable.

Based on an understanding of the potential role for primary prevention, for screening and early case finding and of alternative approaches to management; disease progression/health problem development would be broken into pertinent stages, that define sub-populations or patient groups to whom interventions could be targeted. This provides the structure for the analysis. It should not be limited by current approaches to prevention and management, but reflect the full range of options suggested by disease aetiology and published trials.

Activity 3 *Select disease stage to commence analysis and identify all possible intervention options at that stage*

Identify and describe for the selected disease stage, all intervention options that could potentially reduce disease burden for each population/patient group. The list should be as comprehensive as possible and include existing as well as potential services and interventions from outside the health sector. The source of funding or responsible agency should not be relevant in developing the list. The options will essentially be deduced from the understanding of the disease gained in Activity 2. Key dimensions to be covered in developing the list are:

- modality - eg surgery, physician care, support for more effective self-care, population based health promotion, health system reform;
- health delivery setting - such as hospital in-patient, out-patient, community care setting, private clinical practice etc.,
- philosophy of care - such as patient empowerment, traditional medical model,
- patient/population targets - identified at-risk groups, pertinent clinical presentation,
- initiatives from outside the health sector.

In defining intervention options, program characteristics - such as target patient/population group, health professional mix, delivery location, should be described in detail, as these are likely to influence cost and outcome. It will probably be necessary to describe several versions of each broad service type, incorporating different service characteristics.

Activity 4 Rank interventions at the disease stage, to identify the most marginal programs - best and worst

Before interventions can be ranked, the criteria for ranking must be established. This involves selection of an appropriate definition of benefit pertinent to the disease stage/set of services being compared and reflective of community views.

It is presumed that the way the disease stage/population/patient group has been defined will suggest a simple, possibly intermediate outcome measure common to all interventions. A more complex concept of benefit is introduced in Activity 6 in the comparison between disease stages, and in Activity 7 where issues of equity and access are considered in developing recommendations about desirable resource shifts. The aim is to rank all interventions addressed at the particular disease stage from least cost-effective to most cost-effective, as illustrated in Figure 5.2 (where each asterisk represents a potential intervention).

Figure 5.2 Ranking of interventions

| Disease Stage | | | | | | | | | | |
|--|---------------------|----------------|----------------|----------------|----------------|---------------------|----------------|----------------|----------------|-------------------------------|
| Population target | less cost-effective | | | | | more cost-effective | | | | |
| Primary prevention population at risk | | | A _w | A ₂ | A ₃ | A ₄ | A ₅ | A ₆ | A ₇ | A ₈ A _b |
| Early diagnosis population at risk | B _w | B ₂ | B ₃ | | B ₄ | B ₅ | | | | |
| Disease management persons with established disease | | | | | C _w | | C ₂ | | C ₃ | C ₄ C _b |
| End stage care persons with advanced disease | | D _w | D ₂ | D ₃ | | D ₄ | D ₅ | | | |

Notes:

- A_i is the ith primary prevention intervention option addressed to the at risk population, ranked from least cost-effective (A_w) to most cost-effective (A_b).
- B_i is the ith screening/early case finding intervention option addressed to the at risk population, ranked from least cost-effective (B_w) to most cost-effective (B_b).
- C_i is the ith intervention option for management of persons with established disease, ranked from least cost-effective (A_w) to most cost-effective (A_b).
- D_i is the ith end stage care program for persons with advanced disease, ranked from least cost-effective (D_w) to most cost-effective (D_b).

This represents the major research task and will involve the conduct of several cost-effectiveness (cost-benefit) analyses of the identified interventions. Ideally the analysis will be conducted at the margin, relative to the status quo. Objective evidence, taken from the published and unpublished literature is to form the basis for estimates of program costs and outcomes (immediate and long term) and the impact on downstream resource use. Expert opinion and modelling of costs and effects may be able to be applied to extend observations to other settings or outside the range of observations. The need to gather data on costs and effectiveness not just for a 'typical' program targeted at a defined client group, but to reflect many possible variations for instance, encompassing different settings and

alternative patient groups, extends substantially the data requirements. The aim is to rank interventions on the basis of the marginal cost-effectiveness ratios.

Based on this analysis preliminary conclusions could be drawn of the type: Given current resource allocation to the particular disease and stage, net benefit will be increased by transferring resources from service Aw to service Ab. It may also be possible to comment on desirable resource shifts between intra-marginal programs.

Activity 5+ Tasks 3 and 4 are repeated for each disease stage, to define and rank all interventions to identify the marginal programs at each disease stage.

Possible interventions are identified and ranked at each disease stage, using cost-effectiveness as the analytical model. The analysis outlined in tasks 3 and 4 is repeated to cover progressively all stages of the disease and possible target populations. This will involve the conduct of many, perhaps thirty or more, cost-effectiveness analyses. The aim is to identify the marginal interventions at each disease stage - the best actual or possible and worst actual or planned intervention at each stage. (This is illustrated in Figure 5.2 as services Ab, Bb etc., best possible and Aw, Bw etc., worst existing or planned.

Activity 6 Comparison across disease stages

If the initial comparison at the disease stage is a cost-utility analysis (or cost/life year) direct comparison of interventions across disease stages will be possible without the need for further analyses. Otherwise it will be necessary to select a universal outcome measure to allow for comparison across disease stages. The options are:

- use of known epidemiology to translate health outcomes achieved through early intervention into outcomes achieved at later stages in the disease,
- use the quality adjusted life year, or where quality of life data is unavailable adopt the life-year,
- ascertain the dimensions of benefit of relevance to the community, and determine an acceptable means of combining these.

This analysis can be limited to the most marginal programs from each disease stage to establish the most marginal projects, best and worst to address the disease/health problem - not restricted to a particular disease stage or population target. As illustrated in Figure 5.2 the worst performing program for screening Bw is identified as the least cost-effective program overall and Ab the best performing primary prevention intervention as the best. The implication is that for the subject disease, a shift in resources from Bw (screening) to Ab (primary prevention) would result in the greatest net gain to the community.

Theory would dictate that the analysis proceed in an iterative fashion, with the evaluation repeated after allowing for the recommended resource shift from worst to best, to identify the next most marginal service, and so on. In practice information gained in the first round analysis should provide sufficient insights into the magnitude of costs and benefits of some intra-marginal projects/services to permit other resource shifts to be recommended.

Activity 7 Develop conclusions about desirable resource shifts – incorporate equity and access issues

The ranking of interventions, firstly at the disease stage (patient/population group) and secondly between disease stages, provides the basis for provisional conclusions about services to be expanded and those to be contracted. Prior to the development of final recommendations, equity and access issues should be considered. If the description of benefit has incorporated equity and access, then the rankings will already reflect this dimension. The provisional conclusions about desirable resource shifts can then be adopted as the final recommendation. Otherwise, issues of equity and access will need to be explicitly considered.

One possible approach is to ascertain the impact on particular sub-populations of the resource shifts indicated by the cost-effectiveness/cost-utility analysis, and consider whether the distributional implications are likely to be consistent with community values.⁸ If for instance the community is concerned with disparity in health status, then the impact on health inequality would be pertinent. Where no conflict arises between the equity objective and allocative efficiency, resource shifts indicated by the cost-effectiveness/cost-utility analysis could become recommendations. Where a conflict does arise, consideration of the acceptability of the trade-off between equity and allocative efficiency would need to be established.

Activity 8 + Health-sector-wide analysis

The Model provides a Framework for a research program to be implemented progressively over the entire health sector. This is achieved by repeating Activities 1 through 7, until all disease categories and health problem areas have been covered.

The final phase of the analysis is to draw conclusions about desirable resource shifts between disease categories and health problems. The task would involve comparison of the most marginal interventions, regardless of disease stage addressed at different disease categories. The procedure would be similar to that outlined in Activity 6, with comparisons based on cost-utility analysis (or alternative measure of benefit). The analysis would in theory, proceed in an iterative fashion, firstly comparing the most and least cost-effective interventions and then proceeding to the next most marginal interventions, within and across stages of disease and population groups.

The Model presumes an on-going analysis with continual revision. Revision would occur in response to new information and to reflect changes in the cost and effectiveness of interventions - associated with resource shifts, new health technology, change in disease patterns and population attributes and to reflect changes in community values. It would be desirable for a complementary research program to be in place to meet critical data gaps about the costs and effectiveness of key health interventions, to support the implementation of the priority setting framework.

5.5 Assessment of the Model against the Performance Criteria

In broad terms a model for priority setting needs to meet three primary requirements:

- Firstly, that there is a specified process for setting priorities and recommending resource shifts that recognises the reality of scarcity and the need to make choices;
- Secondly, that there is a logic relating the priority setting process to the communities objectives; and
- Finally that the process is capable of implementation in the context of a 'reasonable' health planning budget.

⁸ If community values are not known, a complementary research program may be required to establish such values.

The logic between the priority setting process and the community objectives derives from the discipline of economics - specifically welfare economics. The economic principles have been reinterpreted (as described in Chapter 2) to yield five distinct criteria that a model for priority setting should meet. It is against these criteria that the Disease Based Model is assessed, together with the final criterion related to tractability.

i The decision rule and process for setting priorities are specified:

All the economic models, including the Disease Based Model meet the first requirement, that of an explicit process for setting priorities and decision criteria for resource shifts, that recognises resource scarcity. This is not therefore dealt with further. As noted in Chapters 3 and 4 the fundamental weakness of the non-economic approaches is their failure to specify any such criteria.

The second broad set of criteria is concerned to ensure that there is a logical relationship between the process for setting priorities and the communities objectives. This is explicit in the reference to economic principles for all the economic models, including the Disease Based Model. Performance is defined in terms of marginal/benefit cost ratio, or net benefit, with resource shifts driven by the objective of maximising net benefit. Five criteria have been nominated which encapsulate this requirement:

- the adoption of a societal perspective/breadth of scope – the research question and costs and benefits are to be defined from the perspective of society;
- a focus on intervention options to reduce disease burden/health problem – and a mechanism to ensure comprehensiveness in the description of these options;
- incorporation of the community's objectives in the definition of benefits/performance;
- a marginal perspective is taken - reflecting a focus on change, and on the way program and patient/community attributes are defined;
- the adoption of objective evidence in the measurement of costs and benefits, to minimise the use of 'opinion'.

The performance of the Disease Based Framework against each of these criteria is now assessed in turn.

ii The research question and analysis perspective is that of society:

The Disease Based Model specifically defines the health problem in terms of the entire community (at the regional or national level). A major objective of the model is to avoid the limitations that arise from a focus restricted by the viewpoint of a particular agency or funder, or one that is restricted by existing health system funding and delivery arrangements. The model dictates that the community perspective is taken in the way benefits and costs are conceptualized and measured and through the emphasis on comprehensiveness in the description of intervention options.

iii The selection of program/service options is comprehensive and precisely defined:

The Health-Sector-Wide Disease-Based Model, through its structure and task statement has a focus on intervention options and reduction in disease burden, in the context of a defined health problem. The requirement to define intervention options as comprehensively as possible is explicit, with a suggested approach for its achievement. The achievement of comprehensiveness represents a major challenge of any priority setting model, due to the great variety of ways of addressing even quite narrowly defined health problems.

Even where the number of broad program types is not excessive, within each program type there can be innumerable variations in possible program characteristics that are non-trivial.

It is inevitable therefore that comprehensiveness is compromised. However, this should be less so if the task is staged, as with the Disease Based Model. But, even here choices must be made of the intervention options selected for review. How this selection is made is critical to the chance of including the most marginal programs. The steps proposed for this task are outlined in Box 5.2.

Box 5.2 Process for selecting interventions for comparison

1. Gain an understanding of the disease, in terms of incidence/prevalence, rates of disease progression, risk factors etc.;
2. Define opportunities to intervene by disease stage based on theoretical possibilities, published trials, current service provision;
3. Develop a classification system for describing interventions, pertinent to the disease and stage, to include:
 - target group – age, ethnicity, family history, co-morbidities, lifestyle attributes etc.,
 - health delivery setting - hospital-in-patient, out-patient; community-health centre, patient's home, private rooms, residential care facility, etc.,
 - health professional, whether sole professional or multi-disciplinary team,
 - philosophy of care – such as empowerment or medical model,
 - approach to care - behavioural, surgical, drug, media etc.
4. Select program options for review to cover the widest possible range of options, and including the major funded and proposed programs, to include examples of 'best practice' and programs suggested by 'experts' as probably highly cost-effective or highly cost-ineffective.

iv Objectives are well defined:

The model seeks to incorporate community objectives in relation to health into the decision criteria.

The Model provides a mechanism to incorporate societal objectives into the priority setting process. However, if there is no agreed understanding of the communities objectives in relation to health, a formal activity to explore these matters as a complement to the priority setting task would be desirable. The model also highlights the need to explicitly consider the impact on different segments of the community and to identify desirable resource shifts in relation to identifiable population subgroup. This reflects a concern to address distributional objectives and not just efficiency. The possible need to trade off various dimensions of benefit is also acknowledged.

v A marginal perspective is adopted:

The concept of the margin applies along several dimensions and the health sector wide Disease Based Model (DBM) is well designed to incorporate all these elements:

- *Recommendation for change based on marginal benefit cost ratios:* The DBM is explicitly designed to identify the most marginal programs in order to recommend resource shifts. The aim is to identify intervention options with the highest marginal benefit-cost ratio for expansion, and those with the lowest marginal benefit-cost ratio for contraction;

- *Level of activity* - the calculated benefit-cost ratios for each project, should reflect the impact of the last dollar added to, or subtracted from the project relative to the existing level of activity. While, the Disease Based Model in theory, reflects the margin in terms of program size, the available clinical trial data constrains this interpretation. It will often be necessary to use average data from clinical trials to approximate the margin, whatever the current level of activity;
- *Incremental costs and benefits* – performance is to be compared with a nominated alternative 'base case' usually the current situation. The structure of the Disease Based Model allows for costs and benefits to be determined against 'current practice' or any base case. The issue here is not a theoretical one, but a practical one to do with data limitations and the number of alternatives that can be analysed. How the base case is defined is important and should be clearly specified. This is facilitated in the requirement for precision in description of intervention options;
- *The marginal 'case'* – the program recipient who will gain most from program expansion or lose least from program contraction is in theory the focus. As costs and outcomes vary with patient/client subgroup and individual patient characteristics, the analysis should ideally aim to identify these truly marginal cases. The extent to which this can be done will depend on data availability and the resources that can be applied to the priority setting task. In ensuring a focus on population subgroups, the Disease Based Model supports identification of the truly marginal case.

vi There is rigour in measurement of costs and benefits:

The Disease Based Model requires costs and benefits to be based on objective evidence. While modeling can extend the range of program impacts and costs that are analysed, it relies on a sound data source for the selection of parameter values. The use of expert opinion to establish matters of fact is explicitly discouraged. One advantage of the requirement for objective evidence is the possibility of developing a research agenda from the key information gaps identified.

vii There is capacity of implementation:

The final requirement is that the Model is capable of implementation in a way consistent with the theoretical principles given a 'reasonable' budget for health planning. This should not be taken to mean that the Model can be implemented whatever the resources allocated for the task. Given the inherent complexity of the task and its importance, a substantial resource commitment is not inappropriate. The Disease Based Model addresses the challenge through the structuring of the analysis by disease or health problem and disease stage/patient group, which permits the staging of the analysis. This means that research activities of a more manageable size can be defined, that can be accomplished by a small research team over a 12 month period. The staging is defined in such a way that local optima should contribute to the global optima, that is conclusions reached in relation to each sub-study will contribute to the whole.

In this way adherence to economic principles is retained whilst allowing the research task to be progressed incrementally. The focus on the disease or health problem also provides for efficiency of research effort. In an application of the Model to NIDDM, these efficiencies were apparent. The literature and analysis relevant to primary prevention was useful in considering screening and patient management and vice versa. The application to NIDDM, a particularly complex disease, was achieved through the input of approximately 2 person years at senior research fellow level plus 1.5 persons years of research fellow/research assistant. (A relatively modest resource commitment relative to

available health planning budgets, or to the \$700 million allocated to the management of NIDDM annually and the substantial excess mortality and morbidity attributable to NIDDM.)

Over time and assuming appropriate resources can be allocated to the research task, the Disease Based Model provides for the analysis of the full range of health interventions using a consistent approach. It can thus contribute to the redistribution of resources across the health system, between disease stages/health problem development and disease categories, in such a way that community wellbeing is enhanced.

5.4 Other Comments

Classification into disease groups

The simple description of the Disease Based Model presumes a unique classification of health interventions into a single disease category or health problem. However the reality is more complex, with many interventions, particularly in the field of public health and health promotion, contributing to a reduction in burden across several diseases/health problems.

Three possible approaches to dealing with this situation have been considered:

- i Use of simplified allocation rules* - One approach is to apportion the cost of the intervention across the diseases and health problems for which burden may be reduced, according to a simple allocation rule, such as relative benefit.
- ii All costs are allocated to a primary disease category* - An alternative is to adopt the perspective of an authority with a designated disease focus, such as cancer or cardiovascular disease and to ignore other benefits. The intervention would then need to be justified on its capacity to yield sufficient benefits in relation to the subject disease, with all costs assigned to that disease. Other benefits would constitute a 'free gift'. From a societal perspective this approach is too narrow.
- iii Measure of benefit adjusted to incorporate all impacts* - A third alternative is to expand the assessment of benefit, to incorporate the beneficial impact on all diseases and health problems, not just that which forms the primary focus of the analysis. This is the preferred approach.

Classification into population subgroup

Both costs and benefits tend to vary with participant group, so that desirable resource shifts may differ by community. Thus, classification of health problem and intervention options by patient/population subgroup is central from an efficiency perspective. It also enables the impact of possible resource shifts for each sub-population to be determined, thus contributing to analysis of equity and access objectives. The cost (in say life years forgone) in pursuit of a nominated equity objective (say of greater health equality between designated sub-populations) could then be calculated. The most appropriate way of defining the sub-population will depend on the context, but may include disease severity, region, socio-economic class and ethnicity.

In sum, it may be appropriate from both an equity/access perspective, as well as an efficiency perspective to conduct separate analyses for sub-populations. This represents a genuine marginal analysis in which each narrowly defined patient subgroup (or at the extreme individual) defines another

program type. It also means that in identifying programs for expansion and others for contraction, precise description of the patient as well as program characteristics is desirable. The allocative efficiency question is recast thus: for each population subgroup, how can resources be allocated to maximise health and wellbeing.

The importance of the margin in the priority setting concept

While the expected outcome of a priority setting process is a ranking of health interventions from more to less cost-effective, this does not imply a simple hierarchical solution, in which selected programs are 'fully funded', while others 'miss out'. The ranking is (should be) based on marginal benefit-cost ratios, meaning it is specific to a nominated 'base-line' situation and the characteristics of the marginal potential/actual user.

Further, the relative performance of programs can be expected to change depending on circumstances - program size and patient characteristics, which is why a priority setting exercise is concerned to identify incremental changes from the status quo. The expectation is that many (if not most) program types will retain some funding, but where the level of funding/size of program will reflect marginal cost-effectiveness, and with access constrained if possible to those most likely to benefit.

A related issue is the possibility of interdependence rather than substitutability of intervention options. Joint implementation of a set of interventions may be more cost-effective than any single initiative, and make a greater contribution to net present value. This may need to be handled as an additional set of intervention options.

In Chapter 10, the performance of the Disease Based Model is compared with the other models covered in this Paper. This is followed by a description of the application of the Disease Based Model to NIDDM in Chapter 11.

Chapter 6 Health Benefit Groups/Health Resource Groups

6.1 UK Health Resource Groups (HRGs)/Health Benefit Groups (HBGs)

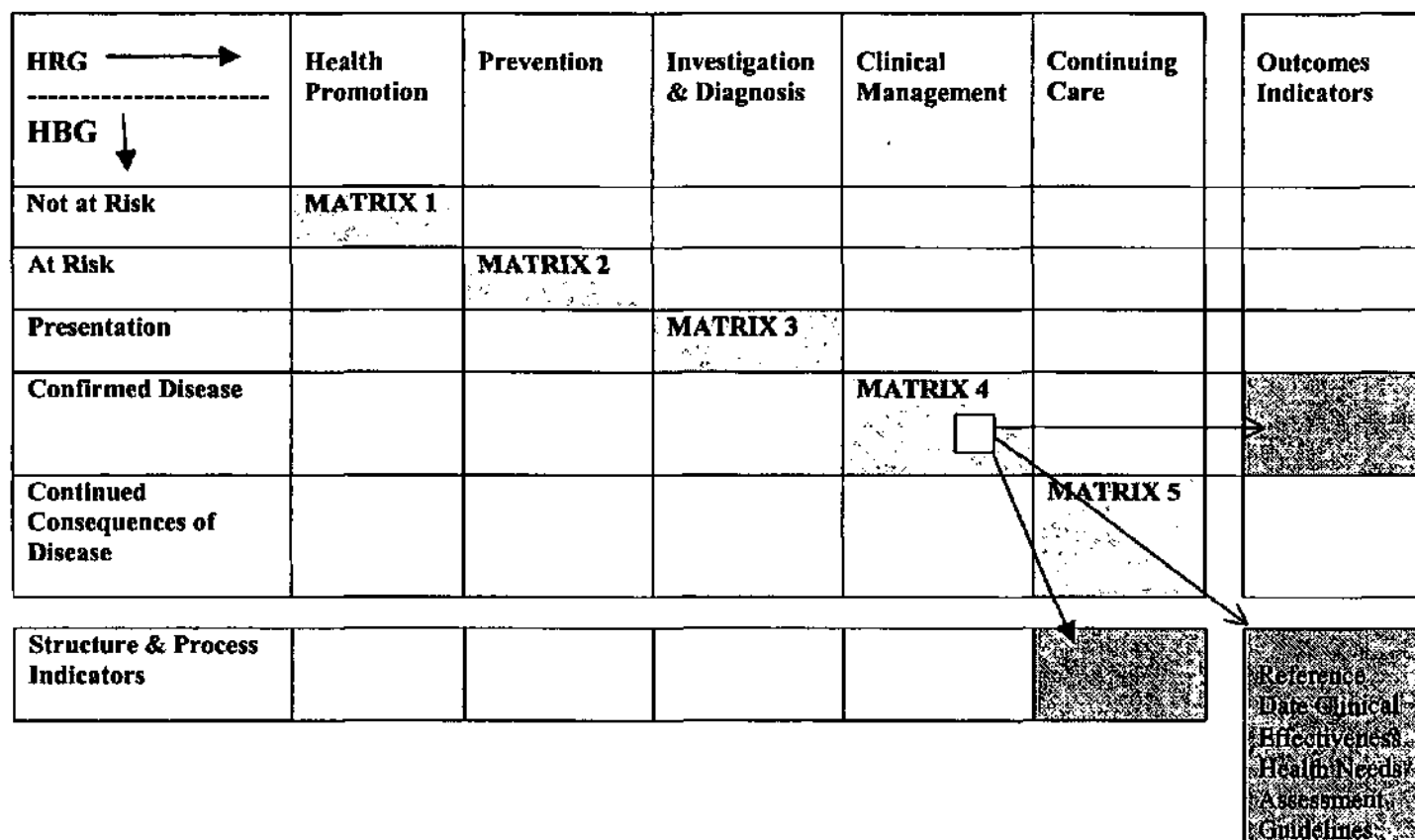
The UK government introduced the internal market with the purchaser-provider split in the early 1990s. The Health Benefit Groups and Healthcare Resource Groups was one of the tools established to inform health resource allocation decisions for the contracting of purchasing of health care (Sanderson 1996; NTHS 1999).

According to Mountney (1999), the health benefits groups (HBGs) are designed to categorise the population on the basis for their need for healthcare. Broad categories used are persons at risk, those with symptoms; those with confirmed disease; and those with ongoing consequences. The HRGs (similar to DRGs) are groups of treatments that use similar amounts of resources and that are clinically similar.

While initially focused on acute care, the UK NHS has recently developed the HBGs/HRGs to be applied across the whole health care continuum, (see new Healthcare Framework, NHS 2000). The two matrices of HBGs/HRGs are important components in this new Framework. The approach is to map HBGs onto HRGs and by incorporating appropriate process and outcome indicators, determine the health needs of the population and the implication for healthcare interventions required and their cost and benefits. The framework is aimed at identifying conditions that need to be addressed and to be used as a comprehensive planning tool.

The UK NHS has conducted pilot studies, in which multi-disciplinary working groups are set up to work through the major health conditions to define HBGs (for cancers, CHD, stroke, head injury, and female sexual health), and to define HRGs, in terms of acute inpatient days, outpatients, primary care, mental health and palliative care Mountney 1999). Figure 6.1 provides a representation of the proposed approach. But there is limited explanation as to exactly how the approach is to be implemented. The experience of the Northern Territory Health Service, which has made an attempt to implement the model, is interesting (See Section 6.2).

Figure 6.1 UK HBG/HRG healthcare framework



Source: Healthcare Framework 2000, NHS 2000

6.2 Northern Territory Health Service (NTHS) Computer-Based Model of HBGs/HRGs

Drawing upon the concept of HBGs/HRGs from UK and the Health-Sector-Wide Disease-Based Model (HSW-DBM) (Segal and Richardson 1994) described in the previous chapter, the Northern Territory Health Service (NTHS) has developed a Computer-Based Model as a health planning exercise to assist in the setting of health service priorities within the Territory (Beaver et al 1999; NTHS 1999).

The NT HBGs/HRGs model predicts, from the existing health status of the population and current management patterns, the future call on health care resources (Beaver et al 1999; NTHS 1999). This is compared with expected downstream health service use and health status of nominated changes to the current health policy involving a redirection of health care resources. The nominated tasks inferred from documentation are:

- selection of disease for analysis;
- allocation of population into HBGs - which are presumed to experience similar health problems and similar use of services. These groups are defined as i) population not at risk, ii) population at risk, iii) presentation, iv) acute disease, v) chronic disease;
- allocation of the services into HRGs;
- determination of current resource allocation to each of the health benefit groups across all modalities of care;
- identify broad strategies to reduce disease burden - defined in broad terms, of prevention, investigation, health promotion, acute care, or continuing care;
- estimate the impact of the alternative strategies on disease burden, defined in terms of net health service cost and DALYs.

The aim is to establish where health resources should be invested for greatest return in terms of health gain and cost/DALY or other pertinent objectives). The model has been applied in what is best termed, an illustrative fashion to diabetes, hypertension, renal disease and ischaemic heart disease.

For each of these diseases the population is allocated to HBGs and the average cost of care for each group determined by interrogating health data bases. The likely impact on disease progression of additional resourcing targeted at alternative HRGs is determined, based essentially on clinician judgement. This component of the work seems to be little more than illustrative. For instance, in relation to diabetes, investment in 'prevention' of an extra 10% each year for 5 years, is 'expected' to decrease new presentations, the number of acute care patients, and the number of persons with chronic disease patients by 10% after 5 years. The change in HBGs drives a change in use of health care resources, presuming no change in average per patient cost in each HBG. Evidence to support the nominated impact is not provided.

Each disease example has been fully worked through, and results are reported in terms of the implication for total health service cost and DALYs of alternative investment strategies. The desirable investment strategy is determined from this analysis, to reflect alternative possible criteria - such as maximising DALY gain, minimising cost per DALY gain or maximising cost savings.

The diabetes example is presented in Table 6.1, showing the allocation of the subject population (rural Darwin) to the HBGs, average cost of care and 'expected' impact of alternative investment strategies.

This shows, based on the assumptions of the exercise, greatest DALY gain (5.5) is achieved through an investment in health promotion, which is also estimated to reduce net costs by \$22,762. Greatest cost saving, of \$59,374, would be achieved by the prevention strategy, which would achieve a gain of 4.7 DALYs. Relative to the initial investment, the continuing care strategy offers the greatest return in terms of cost saving, i.e. with an initial investment of \$1,241 (lowest among all investment strategies while achieving DALY gains of 3.2).

Table 6.1 Economic analysis, chronic disease strategy rural Darwin: diabetes

| Popn group persons | 1996/7 popn | 2001/2 no change in policy | Broad investment strategy : Outcome in five years (2001/2) | | | | |
|--|-------------|----------------------------|--|---------------|-----------------|------------|------------------|
| | | | acute care | investigation | continuing care | prevention | health promotion |
| Not at risk | 10,677 | 12,222 | 12,222 | 12,222 | 12,222 | 12,314 | 12,555 |
| At risk | 1,988 | 2,291 | 2,291 | 2,358 | 2,291 | 2,291 | 2,005 |
| Presentation | 38 | 48 | 48 | 67 | 48 | 43 | 45 |
| Acute disease | 7 | 9 | 11 | 9 | 7 | 8 | 8 |
| Chronic disease | 680 | 863 | 863 | 777 | 865 | 777 | 820 |
| Health care cost ^{a)} \$ | | | | | | | |
| Health promotion | 39,612 | 45,344 | 45,344 | 45,344 | 45,344 | 45,685 | 58,222 |
| Prevention | 13,378 | 15,420 | 15,420 | 15,872 | 15,420 | 23,130 | 13,492 |
| Investigation | 64,299 | 81,572 | 81,572 | 114,201 | 81,572 | 73,415 | 77,494 |
| Acute care | 86,984 | 110,351 | 132,421 | 110,351 | 82,763 | 99,318 | 104,833 |
| Maintenance | 380,191 | 482,324 | 472,678 | 434,092 | 483,568 | 434,092 | 458,208 |
| Total cost \$ | 584,464 | 735,011 | 747,435 | 719,860 | 708,664 | 675,638 | 712,249 |
| Outcomes | | | | | | | |
| Investment ^{b)} \$ | | | 22,070 | 32,629 | 1,241 | 7,710 | 12,878 |
| Net cost ^{c)} \$ | | | +12,424 | - 15,151 | - 26,347 | - 59,374 | - 22,762 |
| DALY gain | | | 3.2 | 2.8 | 3.2 | 4.7 | 5.5 |

Source: NTHS 1999, Table 20

Note

- Baseline average cost of care per head per year: Not at risk, \$4; At risk, \$7; Presentation \$1,707; Acute \$12,426; Chronic \$559.
- Outcomes of alternative strategies, based on hypothetical scenarios, eg increase funding for health promotion by 5% each year etc.
- Total cost estimate compared with no change policy; + increase in net cost, net cost saving.

In theory, it is possible to establish the best strategy, depending on the objectives of the health agency. Use of the model for priority setting however relies on the validity of the assumptions underpinning the analysis. The process of moving from an illustrative exercise to one more firmly based on evidence is not a trivial step.

6.3 Performance of the NTHS HBG/HRG Model

The HGB/HRGs model covers the whole continuum of disease progression and matches health need with service delivery and resource use. It is community-based, disease specific and multi-dimensional. With a developed computerised system, it may be able to serve as a decision support system for health planners, especially in identifying the implied future resource requirements of addressing current health problems.

Reviewed in terms of the criteria outlined in Section 2.4, the model performs well in some respects and poorly in others

i *The decision rule and process for setting priorities are specified:*

The HBGs/HRGs framework allows various criteria for determining performance and describes in broad terms a process for setting priorities. However the actual application of that process is not entirely clear.

ii *The research question and analysis perspective is that of society:*

The model is set up in a way that various perspectives can be taken - that of the funder, of the community, or by modality of care. The modelling approach enables the net impact on alternative funders and broad program areas to be established. The research question is described broadly. The model could potentially be applied to priority setting across the entire health sector to encompass all modalities of care and disease stages.

iii *The selection of program/service options is comprehensive and precisely defined:*

The model does not refer to specific interventions, but rather to broad areas for health service investment. This is probably the weakest aspect of the model. It is difficult to understand how impact on health status and resources use can be determined without reference to specific interventions. The identification and analysis of intervention options that could form part of the broad investment strategies, is necessary for the results of model application to be credible.

iv *Objectives are well defined:*

The Model is not explicit about the objectives of the health sector, although the current applications, as illustrated in Table 6.1, uses the DALY as the primary measure of health benefit. Financial impact overall and by year is also highlighted as a possible subsidiary objective or constraint. The capacity to consider distributional outcomes while not explicitly mentioned, could be accommodated, but would require an appropriate segmentation of the population at all stages of the analysis.

v *A marginal perspective is adopted:*

The Model adopts a marginal perspective in the sense that costs and health impacts are measured relative to the status quo which is defined as the 'no policy change' scenario. The population is also divided into subgroups, in terms of disease stage, which are said to be relatively homogenous in terms of health need and resource utilisation. Whether this is a reasonable assumption is not demonstrated. However, the model uses average costs based on current expenditure on each HBG, which are presumed to be unaltered over time. Also because specific interventions are not identified there is nonsense in which the model can identify marginal interventions.

vi *There is rigour in measurement of costs and benefits:*

The Model recommends the use of existing health data-bases for the attribution of the population into the HBGs, but the authors note some difficulty with this process (NTHS 1999).

In relation to the specification of the alternative 'investment strategies' and the impact of these on disease progression and expected health service use and health outcomes, the requirement for and use of evidence seems minimal.

In sum, the Northern Territory Health Service Model may provide a structure within which a health agency could explore alternative health strategies across an entire health sector. The capacity to develop the model to encompass data inputs of sufficient quality is yet to be established.

vii *There is capacity of implementation:*

Both the UK and the NT HBGs/HRGs have been implemented to a degree. While the UK has operated largely in the acute sector as casemix groupings (Mountney 1999), the Northern Territory Health Service has applied it across the entire health sector. The application in the NT is on-going. Whether implementation can be carried to the point of achieving confidence the assumptions and data inputs and thus the results of the model is yet to be seen. The use of the DALY as the primary health outcome measure, as discussed in Section 4.4, has problems. Full implementation of the model would be extremely resource intensive and data intensive.

Chapter 7 Program Budgeting and Marginal Analysis

7.1 Introduction

Program Budgeting and Marginal Analysis (PBMA) approach added the marginal analysis component to the US Plan-Programming-Budgeting-Systems (PPBS) model of the 1960s. The recent application of PBMA to the Australian national cancer programs have refined the original PBMA methodology to move towards an approach which is evidence-based and has dropped the program budget element. (It might more accurately be referred to as EBMA - Evidenced Based Marginal Analysis). This Chapter describes and reviews both the original PBMA and the revised model. A more detailed description of EBMA in its application to cancer is provided in Chapter 12.

7.2 The Original PBMA Model

Development of PBMA

In 1961, the US Department of Defense was trying to relate planning to the budget process. Programming was used to bridge the gap between the planners and budget makers (Hilleboe 1972). This experiment was known as Plan-Programming-Budgeting-Systems (PPBS). Based on the principles of allocative efficiency, it aimed to determine the cost/benefit ratios of all possible alternative approaches to all possible goals, to determine priorities accordingly, and then to follow through with action. Its principal purpose was to improve the basis for making major program decisions. Data have to be organized on the basis of programs and reflect future as well as current implications of decisions. Ambitious as it was, its use was extended to all Federal US Government Departments (Hilleboe 1972). It failed on technical grounds due to insufficiency of information on each program related to each goal. UK governments have used program budgeting to examine expenditures across programs and to set priorities for resource allocation in 1970s (Hollinghurst, Bevan and Bowie 1999). However, the approach encountered unfavourable comments. It was criticised for 'its lack of principles for defining programs, difficulty in linking inputs to outputs in public services, lack of a single rationality which could be used for decision making, omission of politics and decision making is incremental' (Lockett, Raftery and Richards 1995, p90).

In the 1990s, based on the experiences of PPBS, Mooney and colleagues added the marginal analysis component to the approach and developed Program Budgeting and Marginal Analysis (PBMA). A model developed to assist the purchasing role of regional health authorities which had become more urgent with the split in purchaser and provider roles in Britain (Mooney et al 1992; Donaldson and Mooney 1991; Shiell et al 1993).

The PBMA approach has been applied in various contexts (Cohen 1994; Cohen 1995; Peacock et al 1997a; Peacock et al 1997b; Craig et al 1995; Jones and Wright 1995; Twaddle and Walker 1995; Street et al 1995; Ratcliffe et al 1996). The model is described below by reference to two applications.

The specific activities of the PBMA approach are:

1. Description of the broad programs/program areas for which the priority setting exercise is to be undertaken;
2. The establishment of working parties or expert panels to undertake budget allocation and priority setting tasks, for each program area;

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3. The allocation of current budgets across all programs and services/interventions,
 4. Definition of the objectives of each program/sub-program;
 5. Development, by the working party, of a preliminary list of services for potential expansion - expected to generate most benefits for additional resources allocated, and another list of services for possible contraction - expected to involve the least loss of benefits, for a given reduction in resources;
 6. Estimation, for a nominated budget transfer, of the level of additional services in the expansion list and level of service reduction for the contraction list;
 7. Calculation of additional benefits obtainable from services in the expansion list and loss of benefit from services identified for potential contraction;
 8. Development of recommended resource shifts – from those services, which would result in least loss of benefit, to services, which will generate most additional health benefit, to maximise net benefit.

Application of PBMA to health promotion programs in Wales

Following a recommendation of the Welsh Health Planning Forum that each district produce a resource neutral local strategy for health gain the PBMA approach was applied to the Mid Glamorgan Maternal and Early Child Health Services (Cohen 1994). In a prior planning task a provisional budget had been established for each 'health gain area', and a Maternal and Early Child Health Working Party set up. This consisted of 18 persons (including clinicians, health promotion officers, members of the community health council and national Childbirth Trust representatives).

A one-day seminar was conducted for the Working Party to identify, with the aid of a facilitator, ten programs for potential expansion and ten for potential contraction. A large number of potential services were identified for expansion. The top ten were selected through a vote. Difficulties were encountered in identifying programs for dis-investment.

The group was then asked to estimate the impact on health and resource use of a £100,000 expansion in each of the ten services in the expansion list and the loss of benefit of a similar contraction in the ten services in the dis-investment list. A set of criteria was developed by a planning team to score the benefit of the programs.

The criteria included number of patients treated, evidence of effectiveness, distance from national target, whether the intervention was people centred, severity of condition and whether it fell within the jurisdiction of the Health Authority. A consensus on the weights to be attached to the criteria could not be achieved. Eventually, five superior projects were identified for expansion and five projects that most warranted contraction. The services included on the dis-investment list were generally considered to be of little or no benefit. In the final recommendations, only four projects were identified for dis-investment.

Comments on the performance of the traditional PBMA approach are provided after a brief description of another application.

Application to Community Mental Health in South Australia

An application of PBMA to community based mental health services that incorporated a unique approach to the specification of objectives is reported by Peacock and colleagues (Peacock et al 1997a, b). The study was undertaken for the Health Department South Australia, for three separate regions. It was not expected that resources would be reallocated on the basis of priorities that were identified (Peacock et al 1997b, P16). The purpose of this pilot study was to contribute to 'the

development of a long term strategic planning approach' to health services planning. The process followed the standard PBMA steps. Three working groups, one for each region, were established, drawn exclusively from agency staff. The program budgets were developed jointly by agency staff and the research team.

The definition of service objectives was a major focus of the PBMA exercise. Three classes of benefit were identified by the working groups: individual health gain, community health gain and equity. For each of the three domains, detailed descriptions of the nature of benefit, incorporating differing levels, were developed by each of the working parties. Total benefit was defined by individual health gain adjusted for contribution to the two other dimensions, using weights elicited from the working parties by the research team. Agreement about the appropriate weights was sought employing a trade-off exercise, which reportedly struck some difficulty, with one working party rejecting entirely the trade-off method.

The marginal analysis proceeded through the standard options appraisal format, with the working parties identifying between three and five programs within each region for possible expansion, and a similar number for possible contraction. In common with the Welsh example, development of the dis-investment list was problematic.

The research team then derived cost-benefit ratios for each of the listed programs, using estimates of benefit (gained or lost) developed by the working group. These estimates reflected a consensus reached by the working group on the expected impact of a hypothetical \$50,000 contraction or expansion of each listed service.

This was done by considering a 'typical recipient' of the program and determining the expected level of individual health gain or loss, by reference to the descriptive system that each working party had developed. Total benefit was then derived, by adjusting individual health gain for the contribution to the community health and equity objectives using the weights previously elicited. In this way the benefit from each service was expressed in the same units, being a combination of individual health, adjusted for the impact on equity and community health, all assessed against a common descriptive system.

The projects selected for the contraction and expansion lists, and the cost-benefit ratios calculated by the research team are reproduced in Table 7.1. The data demonstrate a lack of consistency in allocations to the expansion and contraction lists by the working groups and performance as indicated by the cost-benefit ratios. A consistent result would show lower cost-benefit ratios (greater benefit per unit cost) for projects in the expansion list than in the contraction list.

Table 7.1 Allocation to expansion and contraction lists and cost-benefit ratios

| Region | Initial Expansion List | | Initial Contraction List | |
|------------------|-----------------------------------|------|--|------|
| | Project | C/B | Project | C/B |
| Northern Region | Saxon street | 1.1 | Parenting skills | 15.3 |
| | Youth suicide | 2.1 | Stress management | 6.3 |
| | Aboriginal mental health | 5.7 | One on one counselling | 5.8 |
| | Kids and you | 9.3 | Post Natal Distress group | 5.9 |
| | | | Cancer support group | 0.4 |
| Central Region | Mental health awareness | 4.8 | Long term counseling | 24.7 |
| | Early intervention child | 9.3 | Elderly social isolation | 11.3 |
| | Aboriginal family health | 14.2 | Promoting mentally healthy communities | 8.1 |
| | Young men risk taking | 50.8 | Women well-being project | 5.3 |
| | | | COPE (assertiveness/confidence) | 5.4 |
| Noarlunga region | Integrated mental health approach | 0.2 | One on one counseling registered | 13.5 |
| | Aboriginal health | 11.0 | Food with friends | 2.8 |
| | Men-life changes | 21.3 | One on one counselling unregistered | 1.7 |
| | | | | |

Source: Derived from Tables 2, 4, 5, 7, 8, 10 in Peacock et al 1997 b.

Notes: C/B - Cost-benefit ratio, developed by research team from working party estimates of benefits

Projects marked for expansion do not consistently perform better, measured by cost/benefit ratio, than projects nominated for contraction. For instance, in the Northern Region, 'cancer support', a project with an estimated cost-benefit ratio of 0.4, a strong performance, is on the contraction list, whilst the 'kids and you' project, with an estimated cost-benefit ratio of 9.3 suggesting poorer performance is on the expansion list.

Or in the Noarlunga Region, two of the three programs on the expansion list performed far worse at 11.0 and 21.3 cost/unit benefit than two of the programs on the contraction list at, 1.7 and 2.8 cost/unit benefit.

This lack of congruence was not explored in the study. However, as a rigorous application of PBMA approach, it does raise concerns about the capacity of the PBMA approach to identify the most marginal programs. In the absence of empirical evidence from a large number of PBMA application, it is not possible to establish whether this is a general problem with the PBMA approach or only related to this specific application.

7.3 Performance of the Original PBMA Model

The PBMA approach is reviewed against the nominated criteria.

i The decision rule and process for setting priorities are specified:

PBMA has a clearly defined process for establishing priorities and recommending resource shifts.

ii *The research question and analysis perspective is that of society:*

Based on the model description and reported applications, the perspective of PBMA is normally the agency - a provider or perhaps a regional health service region. The agency perspective may, or may not be, consistent with a community wide perspective. This will depend on the constraints imposed on choice of projects and how resource use (costs) and benefits are defined. While it may be reasonable for an agency to establish priorities from the agency perspective, this may result in different decisions to the society perspective, involving a loss of net benefit to society. The agency may focus on the services it already provides, or on those consistent with the skills and experience of current staff, or on services relevant to a particular part of their constituency. Issues of financial viability may also dominate.

Craig and colleagues (1995) are concerned about the issue of scope and focus of priority setting. They talk about micro level priority setting, referring to the within program context, as distinct from macro priority setting, referring to the across program context. They note that the mechanism for the application of PMBA, is more readily applied to the within program context, and taking agency and program boundaries as givens. The PBMA model as traditionally applied is a partial model and does not encompass a framework for priority setting across the entire health sector.

iii *The selection of program/service options is comprehensive and precisely defined:*

The initial nomination of services on the expansion list and on the contraction list by the expert panel is a critical part of the PBMA process. Only those services that appear on either list are subject to any further analysis. So the initial selection process must ensure, with reasonable certainty, the inclusion of the most marginal services (those that yield greatest or least contribution to program objectives for a change in service level). Otherwise the entire process is flawed.

The model proposes the initial expansion and contraction lists be drawn up through a consensus process by a 'working party' established for the priority setting exercise. Little guidance is provided concerning the membership of these working parties, or the type of information with which they should be provided.

This introduces an element of discretion into a PBMA exercise. It might be presumed that working party membership, the mix of providers (management staff, health workers, professional groups), interest groups, consumers (as individuals or consumer bodies), and government officers, will influence the services selected for the expansion and contraction lists. Further, it introduces a presumption of bias because working parties are to be made up of experts and tend to include only those people who make an effort to be heard.

It may be possible to determine the preferred composition of working parties by empirical study of the choices made by alternative panel membership and the consistency of these choices across panels and with cost-benefit estimates. This work has not yet been undertaken. As noted by others, a strong reliance on 'expert group' processes runs the risk of reinforcing the status quo and reflecting the views of the most articulate, or those with the greatest status eg Coast at al (1996, Ch 5).

The process whereby the working party arrives at the selected lists, the evidence and information available to working party members, and time frame for the priority setting exercise, may influence the expansion and contraction lists produced. None of these elements is proscribed, nor is there a body of evidence that demonstrates the robustness of the method, regardless of how it is implemented. On the

contrary, the study by Peacock et al (1997a,b) highlights the problem. Despite the support by the research team to the working groups to explain the PBMA process, the focus on a single program area and the effort applied to definition of program objectives, the services nominated for expansion and contraction do not appear to represent the most marginal.

The services nominated for expansion do not consistently perform better in terms of cost/unit of benefit than projects listed for contraction, so there can be no confidence that the most marginal programs have been identified. There might be services, not included in either list, that may be more appropriate for expansion or contraction than any of the identified projects. The issue concerns the subset of service option selected for consideration. If the working party cannot perform the function of selecting the most marginal programs, the value of the PBMA approach for priority setting is compromised.

In a number of reported PBMA applications, the contraction list is limited to projects that were entirely ineffective or of very limited effectiveness, or where an (at least) equivalent but cheaper service option was known to exist (eg Twaddle 1995).

An argument to contract such services does not require the application of a formal priority setting model. Services that are ineffective or for which there are equally effective but cheaper options available should not be funded. The primary purpose of PBMA may be as a political process to gain consensus for decisions which must be taken, rather than a vehicle for technical decision making.

iv Objectives are well defined:

The PBMA approach incorporates, as one of the specific tasks, the definition of program objectives, and is an important contribution of the PBMA approach. This task may be completed by the expert panel and/or involve wider community input. In published PBMA studies a number of objectives are identified, which typically cover efficiency, equity and access dimensions, but also objectives to reflect the mandate of the agency undertaking the priority setting exercise. There is however little guidance about how objectives are to be defined, by whom, and how different dimensions are to be combined.

In the study by Peacock and colleagues (1997a), considerable attention was devoted to the description of program objectives. The development of a comprehensive descriptive system for each of the three nominated dimensions of benefit - individual benefit, community health and equity, enabled project benefits to be described in a consistent way. In combining the three dimensions of benefit, individual health was presumed to constitute the pre-eminent objective, with the dimensions of community health and equity introduced only via a weighting on individual health benefit - using relative weights established by the expert panels. While this method for defining objective represents an interesting development, its robustness or even acceptability has not been demonstrated. The lack of consistency between initial project rankings and performance based on estimated cost-benefit ratios suggests that the technique may not have been successful in embodying the objectives held by the participants.

An outstanding research issue is that different groups within society will almost certainly have different views about the purpose of the health sector and the objectives of particular health programs. Whether an expert group made of interested parties is able, or willing to take a 'community perspective' in defining objectives is not known.

v *A marginal perspective is adopted:*

PBMA is concerned with the margin, primarily defined in terms of a hypothetical reduction or increase in the budget allocated to services within the program area under review. The means for achieving service expansion or contraction - whether via more (less) services to the same group, or by extending (removing) the service to (from) a different group, or by modification of program features- may not be specified. Thus it is not clear whether all pertinent aspects of the margin are incorporated in the decision making process.

Further, while the explicit aim of PBMA is to identify the most 'marginal' (best and worst performing) services for expansion and contraction, as discussed above, whether the PBMA approach will in practice support identification of the most marginal programs has not been demonstrated.

The PBMA method also has a program budget component, involving the estimation of total resources allocated to the program and to individual services. The purpose of this task in the priority setting exercise is not explained, nor is it self-evident. As frequently argued by Mooney et al (Mooney and Creese 1994), priority setting should be focused on the margin. If research effort is to be applied to the program budget task, a clearer explanation of its role is desirable, particularly as it is reported by some researchers to generate considerable difficulties.

vi *There is rigour in measurement of costs and benefits:*

The PBMA model presumes that estimates of benefits will be based on the judgements of working parties. PBMA exercises are often completed within short time frames, making use of available evidence. There is no minimum requirement about quality of evidence.

While some argue it is better to adopt an explicit approach to priority setting, making use of whatever evidence is available, an alternative view is that such an approach gives undeserved credibility to consensus decision making. Where evidence regarding the size of benefits is largely based on 'expert opinion', it is reasonable to question whether recommended resource shifts will make a positive net contribution to community objectives. On the basis of reported applications it is difficult to form a judgement. The problem is similar to that historically facing clinical management. Medical care based on 'expert opinion' resulted in widely disparate management practices and frequent changes to 'agreed best practice'. The adoption of evidence based medicine, drawing on randomised clinical trials, is now the accepted standard. 'Expert opinion' rates very poorly, in terms of quality of evidence.

vii *There is capacity of implementation:*

Applications demonstrate that the program budgeting component is difficult to implement, as is drawing up contraction lists. However, a major attraction of the PBMA approach is the promise of setting priorities on the basis of relatively little resource input. (Although often the time allocated by the working party members, which can be considerable is not fully costed).

The strength and weakness of the PBMA approach lie in its focus on decision making in the agency setting. The involvement of agency staff and key stakeholders in the priority setting task can facilitate a shift in the culture of an agency to a focus on services, options for change, program objectives, costs and outcomes. It can contribute to an acceptance of the reality of resource scarcity, in the face of unlimited wants/needs and bring service providers and others together in a potentially productive health planning exercise.

On the other hand, the PBMA approach with its reliance on expert panels, may compromise more rigorous approaches, by suggesting that the complex task of priority setting can be completed satisfactorily in short time frames and with little or no objective evidence. Current applications of PBMA fail to report whether the process does result in the identification of marginal programs (most and least cost-effective). In the absence of such reassurance it is possible that PBMA as a priority setting process will fail to enhance community wellbeing. Similar concerns have been raised by others (Posnett and Street 1996, Coast 1996). Coast in reflecting on PBMA notes that; *'There is a question, however, as to how much the scheme is one of technical rationing based on an efficiency principle and how much it is one of pluralistic bargaining'* (Coast 1996, P132).

A final comment on the PBMA approach relates to the scope of a PBMA exercise. Essentially PBMA represents a partial approach to priority setting. It does not propose a framework for priority setting across the entire health sector.

7.4 Refined PBMA Model: A Move towards an Evidence-Based Approach

Background

In 1999, a research team, led by the Health Economics Unit, Monash University was commissioned to trial the use of the PBMA approach as part of the Australian Cancer Strategies Group (CSG) review of priorities determined in the Cancer Control Towards 2002 Report.

The model of PBMA was substantially refined for use in this trial to address the weaknesses in the original application. Specifically, the program budgeting component was excluded, to focus entirely on the marginal analysis; the reliance on expert opinion was replaced by the use of objective evidence to determine effectiveness and costs of the selected interventions, and a societal rather than agency perspective was adopted. The PBMA elements retained relate essentially to the use of an expert panel to identify the options for consideration and to define the concept of benefit.

The description of the model is taken from the unpublished research report 'Trial of Program Budgeting and Marginal Analysis (PBMA) to Assist Cancer Control Planning in Australia' by the research team (Carter et al 2000). The subsequent assessment of the refined PBMA models performance is based on this application.

Research Tasks

The activities followed in the refined PBMA approach were:

1. Establish working Party and define research question and scope of analysis,
2. Identify possible options for change (both increments and decrements);
3. Undertake marginal analysis of the options;
 - 3.1 establish objectives of the organisation and/or program and develop the approach to measurement of benefits,
 - 3.2 assess benefit of options with the instrument and/or approach developed in 3.1,
 - 3.3 assess net cost of the options (cost of implementation adjusted for possible down-stream impacts),
 - 3.4 estimate the PBMA cost-effectiveness ratios using 3.2 and 3.3 (and undertake sensitivity analysis),

4. Assess and discuss the PBMA results, including comparison with any existing appraisals and/or broader dimensions of benefit included as second stage filters; and
5. Develop recommendations, design implementation strategy (if appropriate to research question).

Establishment of a Working Party

A nine-member working party, the 'Cancer Strategies Working Group' was established, with representation from the Cancer Control Information Centre of the Cancer Council of NSW, the Asthma and Cancer Control Section of the Commonwealth Department of Health and Aged Care, the Anti-Cancer Council of Victoria, the Australian Cancer Society, the National Cancer Control Initiative of the Victorian Department of Human Services, and a consumer participant. The chief investigator of the research project was also designated a member of the Cancer Strategies Working Group. The Working Party was established to both manage and participate in the PBMA pilot. The Working Party played a key role in major tasks of the project, including the selection of intervention options for consideration, determination of the criteria for assessing benefit, and input to the cost-effectiveness calculations. The research team briefed the Working Party with the available evidence on a regular basis and prepared nine briefing papers to support their contribution.

Identifying intervention options for 'change'

Options were selected for 'change', reflecting an expectation that they would be either highly cost-effective and suitable for expansion, or cost-ineffective and appropriate for contraction. The selected options would then be subject to cost-effectiveness analyses incorporating objective evidence. The options for change were identified through a three-step process:

- i. Starting with the 'top 20' priority actions from the National Cancer Control Initiative (NCCI) report 'Cancer Control Towards 2002' (NCCI 1998);
- ii. A National Cancer Strategy Development Workshop (Commonwealth Department of Health and Aged Care 1999) which re-visited the strategy areas and added options to the NCCI 'top 20'.
- iii. The Working Party assessed the resulting list of 21 action areas (involving over 40 individual interventions and/or activities) and classified them into one of five groups according to the following six criteria:
 - the clarity, detail and precision with which the intervention was specified,
 - access to evidence needed to assess effectiveness,
 - the need to include both options likely to be highly cost-effective as potential increments and options likely to perform poorly as potential decrements,
 - the inclusion of options from across the complete disease pathway (i.e. from prevention to palliation);
 - the inclusion of options that test the assessment of both mortality and/or morbidity impacts on health status; and
 - prior assessments as reflected in the NCCI rankings (NCCI 1998), a survey of CSG members (DHAC 1999a) and the National Cancer Strategy Development Workshop (DHAC 1999b).

The five categories into which the 21 interventions were classified were:

- i. *Options for change* – likely to represent the most marginal programs to include both; interventions where evidence exists that additional expenditure would be result in substantial health gain (per unit

-
- cost); and other intervention options for which a decrease in expenditure would be associated with little or no reduction in health gain;
- ii. *Possible options for change* – as above but where quality of evidence is poorer;
 - iii. *Monitor developments/liaison* – interventions which might be in place but there is insufficient evidence to perform an economic evaluation at present;
 - iv. *Research strategies* - defined as possible interventions that need more research before they can be evaluated i.e. evidence does not yet exist concerning effectiveness and a clear intervention cannot be specified.
 - v. *Motherhood strategies* – defined as those ideas for action that were considered to have merit but were too broad and abstract to evaluate.

The intention was to conduct cost-effectiveness estimates for all interventions in the *Options for Change* and some of the *Possible Options for Change*.

Establishing objectives

The goals and objectives were taken from 'Cancer Control 2002' (NCCI 1998) and the 'National Cancer Strategy Report' (CSG 1999)' and were to;

- reduce the incidence of cancer,
- increase survival,
- improve quality of life,
- meet community expectations,
- identify and reduce inequities in the system,
- increase research capacity and the knowledge base for cancer control, and
- optimise the use of resources.

These objectives were to be achieved through a range of health sector wide activities, including primary prevention, screening and early diagnosis, and optimal treatment and management of cancer. This would require a system that was responsive to the needs and wishes of consumers, offered attention to groups within the population, facilitated timely research, and was able to promote cancer control programs that represent value for money and discourage ineffective and/or inefficient activities. The CSG draft report also argued for underpinning principles of being evidence-base', consumer focused' and 'integrated and efficient'. These were seen to support effectiveness, equity, consumer empowerment, integration of agencies and jurisdictions, and efficiency in the use of resources.

Description of health benefit

In considering the performance of an intervention seven criteria were adopted as relevant:

- size of the problem;
- efficacy/effectiveness of the intervention;
- capacity of the intervention to reduce inequity in health status and the health care system;
- efficiency (cost/effectiveness) of the cancer control intervention;
- cost of the cancer control intervention;
- acceptance by stakeholders, particularly the general community; and
- likelihood of successful implementation.

These criteria essentially collapse into cost-effectiveness, equity and acceptability.

The Working Party decided to utilise these seven criteria in a two-stage approach to ranking the options in the marginal analysis. In the first stage, options would be ranked by those criteria directly related to resource use and the size and distribution of the anticipated health gain measured by DALYs. In the second stage the ranking of options would include the more pragmatic acceptability/feasibility issues. The first stage is characterised by aspects that lend themselves to decision-rules drawn from the disciplines of health economics and epidemiology. The second stage incorporates aspects that are more subjective.

The DALY was chosen as the measure of health gain because it is a combined single measure of mortality and morbidity, and Australian and Victorian values are available across a wide range of diseases and intervention types. Further an explicit objective of the application of an evidence-based approach to PBMA, was to assess the suitability of the DALY for the purpose of measuring benefit.

Measurement of first stage health benefit

The principle dimension of health benefit was the estimated health gain of each intervention, measured in DALYs, based on the scientific literature supported as required by expert opinion. The method used to derive DALYs in this application is described in some detail in Chapter 12. The reference study year (1996) was selected because of the availability of the key data sets, especially the results from the Australian BOD studies.

The Working Party's intention was to provide weighting to the DALY score attributed to each intervention for equity based on the health status implications for four target groups – socio-economic status, Aboriginal and Torres Strait Islander, rurality, and ethnicity. While some of the issues associated with using equity weights were examined, the concept was not able to be applied and was included through the second stage filter.

Assessment of net costs of options

Health service costs were considered from a societal perspective, and based on the estimated use of health services associated with each intervention, adjusted for estimated downstream impacts. The approach to measurement of cost was typical of any cost-effectiveness analysis. The 'steady-state operation' for interventions was used in the evaluation, assuming that the intervention was fully implemented and operating in accordance with its potential efficacy as established by the available evidence. Evidence used to estimate costs was based on the literature, 1996 Victorian Hospital Inpatient Data, and consultation with experts. Any changes in health service utilisation patterns were predicted and unit costs were assigned to each of the services involved.

Costs, reported in both gross (without estimated cost offsets) and net (with the estimated cost offsets) terms, were adjusted to the reference year using AIHW health sector deflators. A 3% discount rate was applied to both costs and benefits, a figure consistent with the Australian BOD studies.

Sensitivity Analysis

Point estimates for cost utility ratios for the various interventions were derived in the primary analyses. However, as there is always a level of uncertainty associated with cost and outcome estimates, a sensitivity analysis was performed to develop a plausible range for cost-utility values. @Risk software was used for this purpose, and enabled the simulation of 2000 iterations (with associated probabilities), reflecting the range of parameter values identified in the literature and from expert opinion. Thus using the @RISK software it was possible to define confidence intervals around the point estimates.

Two-Stage approach to setting priorities

A two-stage approach was adopted to the setting of priorities. The first stage filter reflected the ranking on the basis of the cost-per DALY. The second stage involved the more pragmatic issues that may impact on the implementation of an option, issues of equity and access, together with those factors that influence the degree of confidence that can be placed in the cost-effectiveness ratio were considered. In this application the second-stage filter did not change any of the rankings but did highlight other issues, for instance the need to strengthen the evidence base, and to consider how a proposal might be implemented. The approach adopted to assessing the robustness of likely cost-effectiveness ratios is summarised in Table 7.2.

Table 7.2 Classifying the strength of the evidence

| Strength category | Strength of the evidence |
|---|--|
| Sufficient evidence of effectiveness, or ineffectiveness | <p>The effect is unlikely to be due to chance (eg., P is <0.05) and</p> <p>The effect is unlikely to be due to bias: evidence from</p> <ul style="list-style-type: none">➤ a level I study design and/or;➤ several good quality level II studies; and/or➤ several high quality level III-1/2 studies from which effects of bias and confounding can be reasonably excluded on the basis of the design and analysis. |
| Limited evidence of effectiveness, or ineffectiveness | <p>The effect is probably not due to chance (eg., P is <0.05) but</p> <p>Bias, cannot be excluded as a possible explanation; eg evidence from:</p> <ul style="list-style-type: none">➤ one level II study of uncertain or indifferent quality;➤ evidence from one level III-1 or III-2 study of high quality;➤ evidence from several level III-1 or III-2 studies of insufficient quality to rule out bias as a possible explanation; or➤ evidence from a sizeable number of level III-3 studies which are of good quality and consistent in suggesting an effect. |
| Inconclusive evidence of effectiveness or ineffectiveness | <p>No position could be reached on the presence or absence of an effect of the intervention (eg., no evidence from level I or level II studies and level III studies are available, but they are few and of poor quality, or only level IV studies are available.)</p> |

Source: Carter et al 2000, Table A

7.5 Performance of the Evidence-Based PBMA Approach

Key Characteristics of the Evidence-Based PBMA Approach

The key characteristics of the refined PBMA approach which differ from the original model are:

- the focus on marginal analysis – that is the exclusion of the program budget task,

- the adoption of an evidence-based approach in relation to cost and effectiveness of interventions,
- the choice of the Disability Adjusted Life Year (DALY) as the measure of health gain,
- the adoption of a two-stage approach to the assessment of benefit – the primary criteria being efficiency defined as cost per DALY (incorporating equity weights if possible), with other issues particularly concerned with acceptability to stakeholders and feasibility of implementation introduced as a second stage filter, and
- the adoption of a societal perspective.

Assessed against the criteria for priority setting models, the revised PBMA model performs far better than the original model.

The refinements were incorporated to strengthen its capacity to guide the setting of priorities in a societal context, rather than the original agency context. The refined model is now reviewed against the seven criteria outlined in section 2.4 of this report.

i The decision rule and process for setting priorities are specified:

The model provides for priorities to be set either on the basis of cost/DALY, with equity incorporated through equity weights, or as a second stage filter. Exactly how the equity weights are to be determined, or the 'second stage' filters are to apply requires further development and explication.

ii The research question and analysis perspective is that of society:

The refined evidence-based PBMA approach adopts a community perspective, moving away from the agency perspective. However the model does not specify how the priority setting task is to be extended across the entire health sector, or if that is even the intention.

iii The selection of program/service options is comprehensive and precisely defined:

The basis for selection of intervention options is similar to that proposed under the original PBMA model. It constitutes the primary task of an expert working group. As with the original model it is uncertain how effective such a process will be in identifying the potentially marginal projects. There is nothing in the approach that ensures comprehensiveness of coverage

iv Objectives are well defined:

The refined model as with the original PBMA approach is concerned with the specification of objectives and engages the working party in this activity. In this particular application, the selection of the DALY as the primary measure of outcome has however not been well justified.

v A marginal perspective is adopted:

A marginal perspective is adopted with care taken to define intervention options, relative to a nominated base case. Sufficient detail of each option is also required to enable costs and outcomes to be defined for a particular patient/population group. The model meets the requirement for a marginal perspective.

vi There is rigour in measurement of costs and benefits:

It is in relation to the rigour in measurement of costs and benefits of intervention options, and specifically the requirement for objective evidence, that the refined PBMA approach represents a substantial advance on the original model.

vii *There is capacity of implemetation:*

The refined model has been recently applied and in a way that is relatively comprehensive to explore several options to reduce disease burden from cancer, to arrive at clear recommendations for projects to be expanded and others to be contracted, supported by cost-utility analyses. That is the model is capable of implementation with the modest application of resources - of approximately 2 person years of input (0.5 at junior and 1.5 at senior research fellow level).

The refined PBMA model which is evidence based and focused entirely on the marginal analysis performs well against the nominated criteria. As described in Chapter 13, when the performance of all the models considered are brought together, it is clear that this model and the health sector wide disease based model perform best. These two models are thus explored further to guide recommendation for the adoption of a particular model by the Department of Health and Aged Care for Priority setting.

The application of the evidence-based PBMA approach to the Australian national cancer programs and its performance is also described in more detail in Chapter 12.

Chapter 8 The QALY League Table Approach

8.1 Introduction

The QALY League Table is an approach to priority setting in which health services are ranked on the basis of their marginal cost per gain in quality adjusted life years (QALYs). Methods for the development of League Tables and major problems in their application have been extensively discussed in the literature (Drummond et al 1993; Mason et al 1993; Gerard and Mooney 1993).

The priority setting principle is that those services or interventions with a lower cost per QALY (marginal benefit cost ratio) receive priority over services with a higher cost per QALY. The theoretical ideal is to use an iterative approach. An initial ranking of all health services in terms of cost/QALY is determined and health resources redistributed from the service with the highest cost/QALY to the service ranked lowest. Revised estimates are then prepared and reallocation occurs to what are now the most preferred services with the process repeated until cost/QALY is equalised across all health services within a given budget.

8.2 The Oregon Plan

The Oregon Plan is the most typical example of the use of the QALY League Table. The purpose was to establish a set of core health services to be publicly funded in Oregon through Medicaid (for low-income beneficiaries). The services to be funded were to be based on a list ordered by cost/QALY, moving down the QALY League Table until funds were exhausted (Coast 1996; Dixon and Welch 1991; Eddy 1991; Street and Richardson 1992; Hall and Hass 1993). A number of approaches were applied (Models 1-3) before a final set of core services was adopted.

Oregon 'Model 1'

The original method involved a standard application of the QALY League Table approach. Cost/QALY estimates were derived for 1600 condition/treatment pairs.

Costs of treatment were obtained from Oregon's Medicaid Program. Treatment effectiveness was determined from a literature review and clinician judgement and defined in terms of impact on quality of life and life expectancy. Utility weights to be applied to health states were established through direct community participation. Public participation was invited, through public hearings, community meetings and a telephone survey, to establish views about nominated states of functional impairment. Results were used to derive values for the Kaplan Quality of Wellbeing Scale for use as a quality of life weight.

A resultant ranking in order of cost/QALY was prepared and results released in May 1990. Concern was expressed with the rankings, with some treatments for life threatening and serious illness lower than treatments to improve quality of life for relatively trivial problems. These 'anomalies' may reflect the poor quality of data on costs and effectiveness, but might also reflect the nature of cost-effectiveness as the basis for priority setting.

Oregon 'Model 2'

A revised approach was used in which the cost/QALY became a secondary basis for ranking. Informed by community views, seventeen broad condition/outcome categories were developed and ranked by the Health Service Commissioners. All condition/treatment pairs were allocated to one of these categories according to whether the condition was acute or chronic, the likelihood of fatality, and expected improvement in quality of life with treatment. Condition/treatment pairs were ranked within each category according to benefit of treatment, estimated as per the original exercise. Costs of treatment were derived from provider agencies.

A final ranking was developed, firstly according to the seventeen broad categories of benefit, then within each of the seventeen groupings based on QALYs. Costs were only incorporated into the ranking if services were ranked equally on benefit, or where Commissioners questioned the ranking. Finally the Oregon Health Services Commissioners adjusted the rankings, based on their judgement. The available Medicaid budget was applied, moving down from the highest ranked condition/treatment pair, to establish the 'core set' of services to be funded. The ranking was still not accepted, due to a perceived discrimination against disabled persons in the use of QALYs. Thus a third model was proposed.

Oregon 'Model 3'

In this approach, benefit was restricted entirely to prevention of death, and quality of life was excluded from the analysis. Costs were again only introduced where two condition treatment pairs were ranked equally on benefit. Commissioner judgement was again applied to adjust ranking where this was thought warranted. The services to be funded reflected the available budget applied to the final ranking. The final Oregon Plan was approved early in 1994, with 565 out of a list of 696 condition/treatment pairs approved for funding. Provision was made for items not approved for general funding to be approved in particular cases, through appeal.

8.3 Experiences of New South Wales Illawarra Health Region

Based on the Oregon experiment, the QALY League Table approach was trialed at the Illawarra Health Region in New South Wales, but restricted to the acute sector only (Cromwell et al 1995; Cromwell et al 1998). It used the Oregon quality of life weightings developed under Model 1. Acute services provided by the Illawarra Area Health Service (IAHS) were grouped into classes, for which costs of provision and outcomes were expected to be similar.

AN-DRG categories were used for this purpose, but modified to allow for a sequence of admissions to form a single course of treatment. Average costs were calculated based on National cost weights (KPMG Peat Marwick 1993) with some adjustment to reflect the IAHS public private mix. Average benefits were determined by mapping 709 Oregon condition/treatment classes onto the AN-DRG classes, to which Oregon QALY estimates were applied. A total of 470 classes were identified for which cost-utility ratios could be developed representing 56% of acute in-patient activity. A set of constraints was developed to reflect demand and supply conditions. An integer program was run to determine service mix that would maximise QALYs given the nominated constraints. (For description of the technique, see Cromwell et al 1995). Alternative scenarios were explored for their impact on level of activity and loss or gain in QALYs including a change in global budget, priority to waiting list reduction, change in demand, and change in effectiveness of treatment.

The main contribution of the QALY League Table application by the IAHS is as a planning tool to demonstrate for instance the loss of QALYs implied by particular demand and supply constraints. An alternative to the QALY League Table Approach to identify core services is presented in Box 8.1.

Box 8.1 The New Zealand Core Service Program

In terms of the identification of the core services, the New Zealand Core Services Program is a contrast to the Oregon Plan. Instead of employing the QALY League Tables, it relies substantially on community input and negotiation. Its role was to identify the core set of services to be supported through public funding (See National Advisory Committee on Core Health and Disability Services 1992; the Bridgeport Group 1992; Coast 1996 Ch.3). Public input was sought through public meetings and a series of consensus development conferences on key health problems and disease areas. The reliance on consensus through public input has resulted in some paralysis in decision making, and a lack of concrete recommendations (Coast 1996). Difficulty has been experienced in identifying areas not suitable for funding or for contraction, other than those services agreed to be deleterious. So while a process for decision making has been specified because of the requirement for consensus and with the explicit rejection of cost-effectiveness ratios and failure to agree on alternative objective criteria, the process has only been able to develop broad recommendations not translatable into resource shifts.

8.4 Performance of the QALY League Table Approach

The QALY League Table approach, as illustrated by the Oregon and Illawarra experiences, is reviewed against the priority setting criteria outlined in section 2.4 of this report.

i. The decision rule and process for setting priorities are specified:

The QALY League Table approach has a defined decision rule and process for ranking interventions and recommending resource shifts, however, it only tells you that an intervention with a lower cost/QALY is more desirable than one with a higher cost/QALY. A subjective decision as to whether that cost per QALY is acceptable still needs to be made.

ii. The research question and analysis perspective is that of society:

The QALY League Table approach adopts a community perspective, with costs and benefits to be established from the viewpoint of the society. The scope of the priority setting exercise depends on the research question, eg. in the Oregon Plan it covered all health services for Medicaid beneficiaries. In terms of the scope of the research question and the community perspective, the approach is consistent with economic principles for priority setting. Theoretically, it provides a structure for priority setting across the entire health sector.

iii. The selection of program/service options is comprehensive and precisely defined:

The QALY league Table approach should result in the ranking of every existing and potential service option. However, the final priority listing in the Oregon Plan covered 696 condition/ treatment pairs while the Illawarra study covered 470 classes of in-patient services. In the Oregon model, a prior selection process has to have occurred. Service options/client groups have also been described in general rather than precise terms.

The authors of the Illawarra study note the restriction of their study to in-patient services (the main responsibility of the Illawarra health Service) and to 56% of in-patient activity (due to data deficiencies). This is identified as a weakness of their application, but also a reflection of the enormous data demands of a full application of the model.

iv. Objectives are well defined:

In Oregon the main change with model development was the definition of benefit. In the original model, cost/QALY was the sole basis for ranking alternatives, implying that quality of life and time in alternative health states, fully comprehend the objectives of the health sector. In the second model, the two-level ranking process effectively introduced other components into the objective function, notably severity/importance of condition, capacity for recovery, and client group. The QALY was used only to rank condition treatment options within each of the seventeen condition/outcome classes. The ranking process ignored cost (except where QALY values were equal), meaning that health benefit was specified relative to the individual, abandoning marginal cost-effectiveness as the decision rule. In the final ranking quality of life was ignored altogether. The application of QALY League Table approach in Oregon involved the community explicitly through public meetings and a telephone survey; and implicitly, as illustrated by the changes to the models in response to the community views. The provision for ad hoc adjustment of the final ranking by the Commissioners might also be thought of as a subjective response to perceived community views.

v. A marginal perspective is adopted:

Both the Oregon and the Illawarra experiments adopt average, rather than marginal costs and benefits.

As the authors of the Illawarra study note, as a result of the use of average costs and benefits, a small change in QALY score for services either just above or below the funding cut-off would change the funded set, reflecting the small difference in average cost/QALY between funded and unfunded programs. This would be avoided if marginal benefit cost ratios were used.

Selecting a core set of services to be fully funded, moving in descending rank order until the budget is exhausted does not recognise that some services lower on the ranking may yield far greater benefit (per unit cost) for some patients than services higher on the ranking. Decisions based on averages, especially where condition treatment pairs include disparate patient groups are unlikely to maximise community benefit.

An option is to pursue a genuine marginal analysis by developing several cost/QALY estimates for each service, as a function of program size and patient type. However, access to reliable data on effectiveness would be problematic. The extent of the data requirements reduces the likelihood that the QALY League Table approach will give adequate attention to the margin.

vi. There is rigour in measurement of costs and benefits:

The QALY League Table approach presumes that cost/QALY estimates will be based on the best available evidence. If these estimates are to be based on objective data, a substantial information requirement emerges, which can only be met through an intensive and on-going clinical research program. The rejection of the initial Oregon listing was due partially to concerns about the quality of the data. Reverting to life years for ranking within the seventeen broad categories suggests the technique used in the final model to incorporate quality of life to yield QALY scores was not acceptable. There is no consensus about the best way to calculate QALYs. Results from application of the available

instruments show substantial divergence, and all of the available instruments and approaches are subject to criticism (Hawthorn et al 1999; Schwartz et al 1993; Richardson and Cook 1992; Richardson 1991). Debates around using QALYs to reflect aspects of health benefits are on-going.

vii. *There is capacity of implementation:*

The initial Oregon Plan demonstrates that a QALY league table can be completed and rankings established across the entire health sector. However, implementation of such an exercise is built upon certain compromises in determining benefits - through substantial reliance on expert opinion and restriction in the scope of interventions/services to be ranked (through nomination of a typical patient and a typical intervention).

The Oregon Plan demonstrates that while the development of a health sector wide QALY League Table is possible, the scope of intervention options must be restricted and standards of evidence downgraded due to massive data requirements.

Chapter 9 Program-Based Approaches

9.1 Introduction

There is a vast literature reporting on the comparative cost-effectiveness of a limited number of health service options addressed to a particular health problem (eg see Sculpher et al 1991; Hall et al 1988; Robertson and Segal 1999; Smith and Wideatmoko 1998). Such studies may be used to guide resource allocation decisions at a local or agency level.

A comprehensive example of the use of comparative cost-effectiveness analysis as the central element of a priority setting model is the requirement by the Pharmaceutical Benefits Advisory Committee (PBAC) for an economic analysis to support the listing of drugs on the Pharmaceutical Benefits Schedule (PBS). The approach is based explicitly on economic principles. The approach is described and reviewed in terms of its suitability as a framework for priority setting for pharmaceuticals and for the wider health sector. It also provides a means to explore the role for large scale but restricted comparative cost-effectiveness analyses, which are used elsewhere, such as the application by the World Bank in calculating cost/DALY for various interventions (World Bank 1993) and the use of comparative cost-effectiveness analyses within the in-patient setting (Olsen et al 1996).

9.2 Priority setting model of the Pharmaceutical Benefits Advisory Committee (PBAC)

The compulsory health economic framework adopted in 1993 (optional in 1991 and 1992) by the Commonwealth Government for the listing of drugs on the Pharmaceutical Benefit Scheme (PBS) is an Australian example of the systematic use of comparative economic analyses to inform resource allocation decisions. Drugs listed on the PBS receive a substantial government subsidy, reducing the cost to the consumer, (to either a maximum of \$20 or \$2.50 per script, depending on patient health care card status). It has been a requirement since 1993 that for a drug to be listed in the PBS, a request for listing must be submitted to the PBAC supported by an economic analysis prepared according to published Guidelines (Commonwealth Dept. Health & Family Services 1995) which demonstrates to the satisfaction of the PBAC and the Government the cost-effectiveness of the drug.⁹ Drugs may be refused, or approved for listing at the proposed price or subject to a price reduction. Drugs that were listed on the Schedule before 1993 do not require a cost-effectiveness analysis in support of continued listing.

The Guidelines require an incremental cost-effectiveness or cost-utility analysis of the drug proposed for listing, against a suitable comparator, preferably another drug of the same class, already listed on the PBS. The measure of effectiveness adopted is to reflect the clinical role for which the listing is sought. It will commonly relate to a clinical parameter, (such as proportion of patients who achieve adequate control say of blood pressure, blood glucose etc., or the mean value of a clinical parameter, such as serum cholesterol). It may also be expressed in terms of time free of illness or symptoms (such as average time in remission for cancer patients). Final health outcome measures such as life years or quality adjusted life years QALYs are also commonly used.

⁹ A formal economic evaluation is only required for a drug to be subsidised. Drugs can still be sold on the Australian market provided they have been registered and declared safe and efficacious with ADEC (the Australian Drug Evaluation Committee)

Where an intermediate health outcome measure is used, the economic evaluation must demonstrate the relationship between the clinical parameter and final health outcome.

The Guidelines are detailed. They define how costs are to be measured, the quality of evidence that is required and the nature of the comparator. A comprehensive literature search is essential and compulsory. Evidence of effectiveness must be relevant to an Australian population and is ideally derived from randomised control trials. Expert clinical opinion has low credibility as a form of evidence of effectiveness. The decision rule for the listing of a new drug is not defined. But if the new drug absolutely dominates a drug on the PBS (additional or equal benefits at lower cost), listing is normally granted. Where additional benefit is achieved, but at additional cost, no formal cut-off, in terms of incremental cost per increment of benefit (QALY, life year etc.) has been specified. The final decision about listing on the PBS is made by the Commonwealth Health Minister, informed by the PBAC and the Pharmaceutical Pricing Authority. A recent empirical study shows drugs are likely to be listed at the requested price where cost per life year (or QALY) is less than \$40,000, with reducing likelihood as cost/QALY increases, (George et al 1999). However cost effectiveness is not the only consideration when considering whether a drug should receive a government subsidy.

The Guidelines have been in operation for seven years and have been instrumental in determining the drugs listed on the PBS and in receipt of government subsidy, and has undoubtedly had a major influence on the use of various drugs.

9.3 Performance of PBAC Approach

The PBAC Model has supported a formal process for determining which pharmaceuticals are to receive public funding and at what price. Model performance is now reviewed in terms of the nominated criteria for priority setting.

i The decision rule and process for setting priorities are specified

The PBAC approach has a clearly defined process for establishing priorities and recommending resource shifts.

ii Scope of research question and perspective taken

The perspective of the PBAC is that of society - in the sense that costs and benefits are defined from a societal, but not necessarily in a way that is comprehensive. As the primary responsibility of the PBAC is the pharmaceutical budget and within that the government contribution, this represents an important focus of the analysis.

As dictated by the Guidelines, the scope of the research question is precisely but narrowly framed. The preferred comparator is another drug, of the same class, (and preferably one already listed on the PBS). The research question is; how does the new drug proposed for listing, perform against similar drugs (usually those already listed on the PBS) in relation to management of the nominated indication. It is different from the question of how best to manage the nominated health problem - regardless of modality of care.

iii *Basis for selecting interventions to be included in the analysis*

Because of the narrow mandate of the PBAC, the selection of interventions for analysis is, as noted above constrained, to alternative drug(s) for the same indication where these are available and ideally within the same class. While the Guidelines allow for comparison across drug classes or with other modalities of care, this is discouraged, unless there are no drugs of the same class already listed that can be used as a comparator. This means, for example, in evaluating a new ACE inhibitor for the management of hypertension, the comparison is usually an ACE inhibitor on the PBS. Comparison with other drug classes for the management of hypertension or to non-drug therapies is considered less relevant.

This restriction in scope of the research question, which some argue, strengthens technical efficiency, but weakens the PBAC process as a means for addressing broader allocative efficiency. Because of the partial framework adopted, it is uncertain whether the resulting decisions will promote overall efficiency, unless the PBAC takes the opportunity to conduct broader reviews.¹⁰

iv *Definition of objectives*

The PBAC Guidelines provide for definition of benefit to reflect the indication for the particular drug, typically a relevant clinical parameter or health status indicator. Each drug is analysed against the nominated comparator using the selected measure of benefit. Decisions about listing are made separately for each drug, with the final decision about listing that of the Commonwealth Health Minister.

Matters of equity and access cannot really be incorporated into individual submissions. Although the decision about listing can take matters other than cost-effectiveness into account, and provide a means (albeit adhoc) of bringing broader community views into the decision process.

In a general sense, the government subsidy for drugs listed on the PBS reflects a view that access to prescription drugs, that are efficacious and cost-effective, should be based on need not capacity to pay.

v *Adoption of a marginal perspective*

The Guidelines are explicit that the analysis is to be at the margin, relative to the nominated comparator drug. The primary measure of performance is the 'incremental' cost/effectiveness ratio - reflecting the additional benefit provided by the new drug relative to the additional cost. Precision about the target population, the indication for the drug, and the manner and context of delivery is required. Segmentation of the potential target, to define that subgroup for whom the drug will be most cost-effective, is encouraged. The relevance of the clinical literature to the setting into which the drug is to be applied is also to be addressed. The Model thus fully meets the requirement for a marginal analysis.

vi *Level of rigour in the measurement of costs and benefits*

The cost-effectiveness analyses in PBS submissions are prepared to a high level of rigour, in terms of methodology and source of evidence on costs and outcomes. The need to follow published guidelines

¹⁰ Taking hypertension as an example - during the 1990's there has been a shift away from diuretics and other lower cost proven approaches to blood pressure control, to ACE inhibitors and little public support for lifestyle management. Between 1993-4 and 1995-6 there has been a 64% increase in the cost of anti-hypertensive agents, from \$240 to \$397 million, (Henry et al 1994, Segal et al 1998), while the number of dietitians in the community health sector has fallen (Selby-Smith 1996). This is despite evidence that the adoption of a healthy life style can be cost-effective in the control of high blood pressure, either alone or in combination with drug therapy (Robertson and Segal 1998).

means that all analyses are prepared according to the same format, using consistent definitions of costs and nature of comparator. Explicit direction is given concerning the quality of evidence and comprehensiveness required in the search for published evidence. Standards of evidence follow NH&MRC Guidelines, with the double blind randomised control trial designated as the gold standard, observational studies considered generally unreliable and expert opinion the weakest standard of evidence. Unless the clinical trial evidence is sound and relevant to the Australian population for whom the drug is intended, a submission for listing will have little chance of success.

In relation to level of rigour, the PBAC Model is highly demanding. This is desirable and recognises that setting priorities in the absence of data on clinical effectiveness and cost is totally unsatisfactory. It does, however, create a bias in favour of drugs/conditions for which the gathering of evidence is easier. Modelling should theoretically overcome this.

vii Capacity of implementation

The PBAC approach is being implemented with undoubted success, demonstrating the capacity for application. It is also a model being considered or utilised by overseas agencies.

General comments on PBAC approach

The PBAC model provides a clear and well-defined approach for the prioritisation of drugs and has influenced the pattern of drug use in Australia. The Guidelines provide for consistency and rigour in analyses and the use of evidence.

The narrow framing of the research question, combined with a pre-existing set of drugs on the PBS¹¹ and exacerbated by an open-ended drug budget (with capped budgets elsewhere) undermines the capacity of the model to contribute to allocative efficiency. The PBAC model has supported a continued increase in the share of the recurrent health budget allocated to drugs by identifying and accepting health gains as a justification.¹²

9.4 World Bank Report: Cost/DALY

As mentioned in Chapter 4, in the early stages of the GBD study the World Bank, in its report *Investing in Health*, supports the adoption of comparative cost-effectiveness as the basis for decisions about health service priorities, defined in terms of '*net gain in health (compared with doing nothing) divided by cost*' (World Bank 1993, p59). The DALY is proposed as the unit of outcome.

The authors note that while cost-effectiveness analyses have been prepared for relatively few interventions, shifting resources away from poorly performing interventions (high cost per DALY), to those identified as more cost-effective, could make a substantial contribution to health gain at little cost.

While the approach is broadly consistent with economic principles, it does not provide a strategic model for priority setting within the health sector. Rather it implies an ad hoc approach, whereby interventions found to be highly cost-effective would attract additional funding, and those found to be cost-ineffective should be contracted. In the context of limited health planning resources and an

¹¹ This means that while on an incremental cost-effectiveness basis listing of a new drug is justified, it may not be the case if it were judged against other modalities of care, or relative to a do nothing scenario.

¹² The proportion of the health budget allocated to pharmaceuticals increased from 10.4% in 1992-3 to 12.1% in 1996-7, while pharmaceuticals on the PBS increased as a share of the recurrent health budget from 6.0% to 7.9%.

expectation of gross differences in cost-effectiveness ratios, an ad hoc approach may well be appropriate, and make an important contribution to health gain. The approach does not however, constitute a complete approach to priority setting in health and fails to emphasise the need to focus on the margin.

Chapter 10 Overview of Performance of Priority Setting Models

This chapter provides an overview of the performance of the various types of priority setting models against the nominated performance criteria. The aim is to select two models worthy of further scrutiny, for possible adoption by the Department of Health and Aged Care in the pursuit of allocative efficiency, to be subject to a more thorough assessment through a pertinent application.

10.1 Health Planning Models

Needs based models/studies

These include community surveys, burden of disease, cost of illness, avoidable mortality/ morbidity and are all essentially descriptive in nature. They provide valuable insights into the size and distribution of health problems, measured in various ways: in terms of community concern, impact on health status, and health resources applied. Such studies can contribute to the prioritisation of health problems.

What they do not do, is define decision criteria for translating problem identification into desirable resource shifts. This limitation is acknowledged by those engaged in such studies. For instance Mathers (1997) notes that *'while health impact data may suggest areas that would be fruitful for further work to identify opportunities for cost-effective health interventions, it does not, by itself, provide a method for selecting national health priority areas'* (P6). Similarly, Nutbeam and colleagues (1993a) reporting on the setting of Goals and targets across a range of health problems, recognise that it will not be possible to address all the goals and targets and suggest health agencies establish priorities based on *'a careful appraisal of the costs and effectiveness of different strategies...'* (P19).

Cost of illness and other needs-based studies can provide input into the development of research priorities and contribute to the debate about the objectives of the health sector. Knowledge of health status and its distribution is central to the development of potential programs to reduce health inequalities and for monitoring achievement of access and equity objectives. But, to move from a description of 'the size of the problem' to recommended resource shifts, requires the support of a formal priority setting process, which is not contained in the protocol of the needs based models. Translating 'size of problem' into resource shifts is far from trivial.

Best Practice Guidelines

Best Practice Guidelines represent an important influence on the pattern of patient care and management. They are, developed on the basis of clinical effectiveness, with little, if any, regard to the capacity of the health system to deliver best practice care.

Decision rules for making choices when resources are limited is implicit rather than explicit. There is no widely accepted process to establish priorities if resources are not sufficient to offer best practice care to all those who meet relevant clinical criteria. Knowledge of what constitutes best practice care is an important input to priority setting notably in defining intervention options for consideration.

In sum, the non-economic approaches while they represent a dominant thrust of health services planning, without exception fail to incorporate decision rules for priority setting of services in a situation of resource scarcity. Thus, they cannot provide a mechanism for adjusting the health service mix towards optimal. They can however, provide a valuable input to a priority setting exercise, but where the decision rules for making choices are introduced from elsewhere.

10.2 Economic Approaches

All the approaches to priority setting, based on economic principles on the other hand recognise resource scarcity, but involve a range of compromises in application. The Health-Sector-Wide Disease-Based Model (HSW-DBM), the QALY League Table approach and possibly the NTHS HBGs/HRGs approach are the only models to provide a structure for priority setting across the entire health sector. All the other models represent partial applications.

There are valuable insights to be gained from all the models studied, such as the process within PBMA for eliciting objectives, and the consistency in approach and high quality of evidence demanded by the PBAC model. The extent of compromise with key principles must also be acknowledged. For instance the standard PBMA approach involves an unacceptable sacrifice to the scope of analysis, comprehensiveness of coverage of interventions and levels of evidence concerning costs and benefits in an attempt to develop priorities with limited research effort. The NTHS model maintains a breadth of scope, but at the sacrifice of confidence in the quality of data and lack of specification of interventions. The PBAC model maintains a consistency in approach and high quality of evidence, but at the cost of a restricted scope and narrowly defined objectives.

The QALY League Table approach promises a breadth of scope and consistency of approach, but again applications highlight major challenges. These relate particularly to the excessive demands of data collection, and a fundamental confusion about the purpose of the QALY League Table approach. The description of a core set of services to be funded based on average cost-effectiveness ratios, (a common but not necessary trait of the application of the QALY league table approach), is inconsistent with the importance of the margin. It ignores the variation of cost-effectiveness ratios with population subgroup, program size and health service setting. An efficient solution is unlikely to involve the allocation of resources into the service with the greatest average benefit-cost ratio, until all opportunities for care are exhausted and only then moving to the next service.

Only if intervention options were defined in minute detail, to cover all relevant sub-populations, and take account of regional variations and differential program characteristics, could this conceptualisation of priority setting be valid. (As then average cost-effectiveness might approximate marginal cost-effectiveness.)

The Oregon experience suggests some disquiet within the community with cost-effectiveness and cost/QALY as decision criteria for the allocation of health care resources. While definition of benefit is acknowledged as an important issue for economics and a focus of several models, more research into the community's views about the objectives of the health sector and of the criteria for allocating health care resources is required.

The performance of nine models against the seven performance criteria developed in chapter 2 is summarised in Table 10.1 and generally documents mixed performance. Most models perform well with respect to perhaps two or even three criteria, but fail badly on others. The only two models to meet most criteria are the Health-Sector-Wide Disease-Based Model (HSW-DBM) and the refined PBMA (or EBMA – Evidenced Based Marginal Analysis). This is not surprising, as both of these models were developed in an attempt to address the formal requirements of a model for priority setting in view of the apparent weaknesses of other models.

The major flaw with the original PBMA – the reliance on expert opinion in the selection of projects on the expansion and contraction lists – has been addressed with the refined PBMA model. Cost-effectiveness ratios have been developed based on objective evidence and these estimates have been used to determine projects that warrant expansion and which should be contracted. However there is still a reliance on expert opinion in developing options for consideration and the lack of a structure to guide priority setting across the entire health sector.

The health sector wide disease based model on the other hand commences with the entire health (and community services) sector, and also incorporates the use of objective evidence and a focus on the margin. As reported in Chapter 5 this model performs well in relation to all the pertinent criteria.

The HSW-DBM and EBMA models come closest to achieving implementability without undue compromise to the theoretical principles. They best address the challenge of retaining breadth of scope in specification of the research question, whilst also demanding high levels of evidence and the adoption of a genuine marginal analysis, within realistic health planning budgets. Recent applications of these two models, for HSW-DBM to non-insulin dependant diabetes and of EBMA to selected interventions for cancer are explored in the next two chapters to confirm the suitability of one or both of these models to guide priority setting for the health sector.

Table 10.1 Overview of performance: Major economic approaches to priority setting

| Model | Decision criteria for resource shifts | Scope: health sector wide, society perspective | Intervention: comprehensive and precise | Approach to objectives | Marginal analysis | Rigour in measurement | Ease of application |
|--------------------------------------|---------------------------------------|--|---|------------------------|-------------------|-----------------------|---------------------|
| Historic | ✓ | ✓✓ | | | | | ✓✓ |
| Burden of disease | | ✓✓ | | ✓ | | ✓ | ✓ |
| Avoidable morbidity/mortality | | ✓ | | | | | |
| Health sector wide disease based DBM | ✓✓ | ✓✓ | ✓✓ | ✓ | ✓✓ | ✓✓ | ✓✓ |
| PBMA | ✓✓ | | ✓ | ✓ | ✓ | | ✓✓ |
| Refined PBMA evidenced based EBMA | ✓✓ | ✓ | ✓ | ✓✓ | ✓ | ✓✓ | ✓✓ |
| League Table: Oregon | ✓✓ | ✓ | ✓ | ✓✓ | ✓ | | |
| Limited C-E PBAC | ✓✓ | | ✓✓ | ✓ | ✓ | ✓✓ | ✓ |
| HBG/HRG NTHS | ✓✓ | ✓✓ | | ✓ | | | ✓ |

Notes:

- ✓ partially meets criteria
- ✓✓ fully meets criteria
- Blank cells: performs poorly with respect to the criteria

Section III APPLICATION

Chapter 11 Application of Health-Sector-Wide Disease-Based Model to NIDDM

11.1 Research Activities

The Health Sector wide Disease Based Model has been applied to establish desirable resource shifts in relation to interventions for the prevention or management of non-insulin dependent diabetes Mellitus (NIDDM). The reason for selection of NIDDM is described in detail in Segal 2000, but largely reflects the high disease burden, wide range and variety of potential intervention options to reduce disease burden, and concerns that current resource allocation was inefficient.

The priority setting exercise proceeded according to the following established activities for the disease Based Model:

- i. **Obtaining of a thorough understanding of NIDDM:** Consideration of disease etiology and epidemiology, risk factors for onset of NIDDM and for the development and severity of complications, approaches to management and their impact on disease severity and rate of complications.
- ii. **Establishment of a disease staging structure:** Definition of key points of intervention based on opportunities to reduce disease burden for definable sub-populations with similar health problem and exploration of possibilities along the disease continuum, from the general population and high-risk subgroups and the possibilities for primary prevention and/or early diagnosis, to persons with early stage NIDDM, and persons with established NIDDM and advanced complications; definition and completion of the rest of the tasks relies on this structure, which is illustrated in Figures 11.1 and 11.2.
- iii. **Ranking of intervention options at each disease stage:** Conducting of a series of comparative cost-effectiveness analyses at each disease stage/point of intervention. This involved three sub studies on primary prevention, interventions for early case finding, and options for management of those with established disease. The set of tasks for each sub-study (the comparative cost-effectiveness analyses) is similar and described in Figure 11.A. (Annex to this Chapter)
- iv. **Development of recommendations for desirable resource shifts at the disease stage:** This presumes resourcing at the disease stage is to be retained and the aim is to determine which prevention, screening or management programs should be expanded and which contracted. Prior to the development of recommendations, the likely distributional implications should be considered in the light of community objectives in relation to equity and access. Where resource shifts implied by allocative efficiency objectives are consistent with community values, initial recommendations would be supported; otherwise trade-offs between equity and efficiency need to be considered.
- v. **Recommendation of resource shifts across disease stages:** Comparison of program options across disease stages, using a suitable outcome measure applicable to all interventions, and establishment of desirable resource shifts between disease stages.

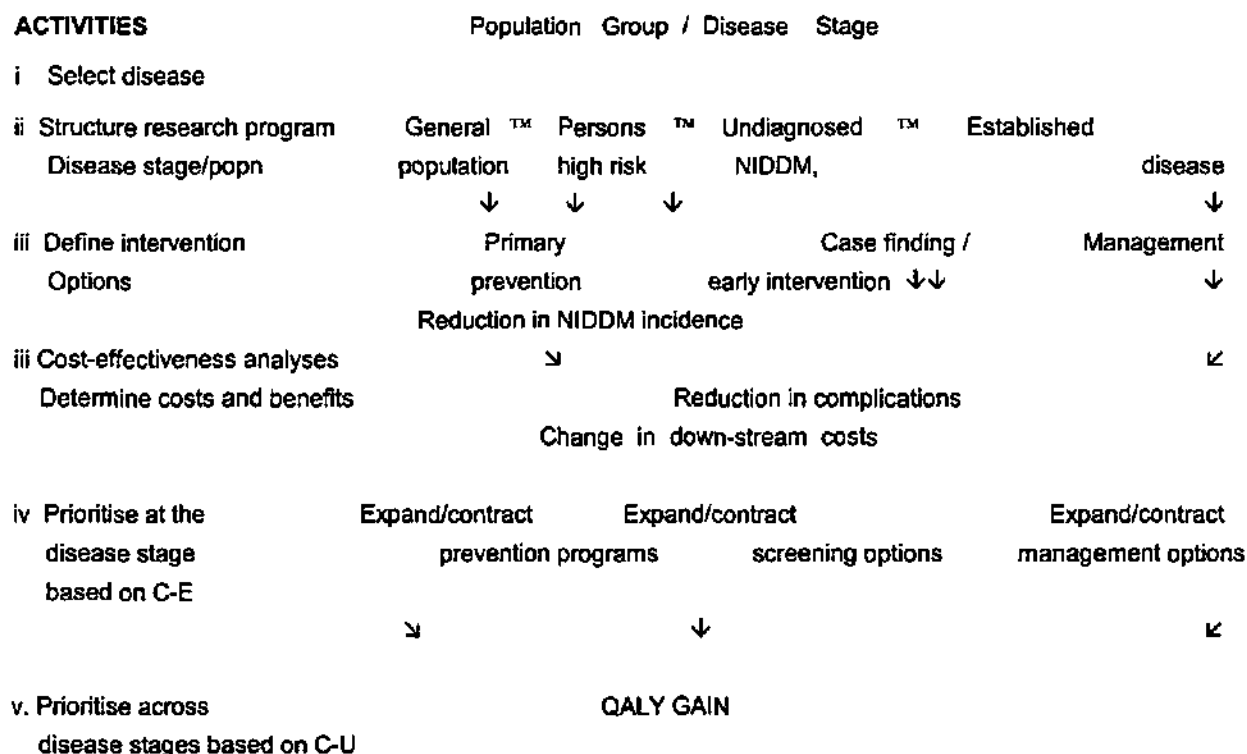
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- vi. **Consideration of the distributional implications.** This research task involves the comparison of the marginal (best and worst) programs at each disease stage. The life year was adopted as the outcome measure for this purpose. While the quality adjusted life year is a more comprehensive measure, as it incorporates both quality of life and life expectancy, suitable quality of life data were not available to support its use when the research was being conducted. There is also considerable on-going debate about the validity of any of the quality of life utility instruments.

Figure 11.1 Disease staging structure

Three main points of intervention and thus three sub-studies were identified.

- i. **primary prevention** - for the general population and for those at high risk. The single program objective, for all interventions addressed at this stage, is the prevention or delay of NIDDM - expressed as diabetes years avoided, or reduction in the rate of incidence of NIDDM.
 - ii. **screening and early case finding** - for those at high risk and with established but undiagnosed NIDDM. The immediate objective of case finding could be expressed as number of new cases of NIDDM identified, or reduction in time between disease onset, diagnosis and management.
 - iii. **management** - for persons with established disease (newly diagnosed and advanced), but restricted to consideration of broad approaches to management, relevant both to persons who are recently diagnosed or with more advanced disease. Management of advanced complications, for instance management of renal failure, or stroke would be excluded.
-

Figure 11.2 Application of Economic framework for allocative efficiency: NIDDM



11.2 Structure of Research Program - Points of Intervention

It was established that primary prevention, screening and management all represent potential points of intervention. In relation to prevention potential intervention points were essentially based on disease etiology, observational studies, and a handful of intervention trials rather than an established program of services. The documented delay between disease onset and diagnosis, observed morbidity on diagnosis, and the efficacy of best practice care in reducing the rate of complications, suggested the possible role for early case finding. This meant that the priority setting research program needed to address primary prevention, early case finding, and management of those with established disease.

However, selecting a suitable structure for the analysis of interventions addressed at those with established disease, that would define population groups with a common health problem, proved challenging due to particular features of NIDDM. Firstly, the main complications of diabetes such as renal failure, heart disease, stroke, neuropathy (leading to foot ulcers etc.,) are not unique to diabetes. Secondly is the extreme diversity of the complications of NIDDM, such that there is little in common in the objectives of management across the various complications. The solution was to focus only on broad approaches to management for those with established disease. This prevented additional complications and excluded consideration of specific approaches to the treatment of advanced complications. The proposed disease staging structure is described in Figure 11.1.

The structure of the Model as applied to NIDDM is illustrated in Figure 11.2 which shows the way interventions at each stage can contribute to the enhancement of health and wellbeing, as well as the relationship between primary prevention, screening and patient management.

Three separate priority setting research programs were conducted to establish desirable resource shifts in relation to NIDDM; primary prevention, early diagnosis and management of those with established disease. These are now reported.

11.3 Primary Prevention¹³

Background

As NIDDM is essentially a life style disease primary prevention is a possible means of reducing disease burden. Stomach surgery has been found to reduce the incidence of NIDDM by over 90% in obese persons with impaired glucose tolerance² (Long et al 1992). Diet and behavioural programs are reported to reduce the incidence of NIDDM by around 50 per cent within 5 years in persons with IGT (Eriksson et al 1994, Pan et al 1997).

Description of intervention options

While there are few services specifically for the prevention of NIDDM, there are numerous possible options to address obesity and sedentary life-style, the primary risk factors for NIDDM. Program options were selected for analysis to cover a wide range of health delivery settings, distinct target groups and different program philosophies. It was found that by defining 11 options, reasonable comprehensiveness of coverage could be achieved. The program types reviewed were:

- an activity enhancement program for overweight men for a general and all IGT group,
- an intensive diet/behavioural program for seriously obese persons, for a general and all IGT group,
- an intensive diet and behavioural program for weight loss and increased activity for women with previous gestational diabetes, for a general and all IGT group,
- bariatric surgery (stomach stapling, stomach banding etc) for seriously obese persons, for a general and all IGT group,
- general practitioner life style advice, for weight loss for overweight persons in general or with IGT,
- a media based life style campaign with community based support.

Benefit

Program effectiveness was defined in terms of diabetes free years and life years gained. A model was developed, consisting of a series of linked Markov sub-models, which followed an intervention and control cohort through time to establish projected diabetic status and survival at five yearly intervals. Transition matrices were derived for each program type to reflect incidence of NIDDM either based on no intervention, or an adjusted rate reflecting published evidence on the effectiveness of the particular intervention. Diabetes years avoided was estimated from the difference in rate of development of NIDDM between the control and intervention cohort.

Survivors at each 5-year interval were estimated by applying a mortality transition matrix, to the cohorts. Transition values were based on annual all-cause mortality at each age group, adjusted for

¹³ For a full description see Segal L., *Allocative efficiency: Development of a model for priority setting and application to NIDDM*. Monash University Ph.D. Dissertation, and Segal et al 1997.

² Impaired glucose tolerance or IGT is a state of elevated blood glucose, above normal but below that which defines diabetes.

diabetic status and whether weight loss was achieved. The difference between the number of survivors in the intervention and control cohorts provided the estimate of life years gained through the intervention. Model values were based primarily on the literature.

Costs

Program costs were developed from a description of service inputs, to which standard unit costs were applied. Potential downstream savings reflected estimated mean annual patient cost of managing NIDDM, adjusted for NIDDM years avoided.

Cost-effectiveness

The primary measure of performance was cost/NIDDM years prevented and gross and net cost per life year gained¹⁴. Key results, in terms of cost per life year gain are reproduced in Table 11.1. It is estimated that all the behavioural approaches to the prevention of NIDDM are highly cost-effective at less than \$3,200 per life year saved (\$1996/7). Three types of interventions were found to be cost saving,

- the media based approach to weight loss/activity enhancement,
- the workplace group program for overweight men, and
- the workplace group program for overweight men, and
- the intensive diet and behavioural program for seriously obese persons with IGT.

With projected savings in downstream health care costs greater than the cost of the intervention these interventions are dominant in that they generate benefits at the same time as generating resource savings. Any program which is cost saving, unequivocally represents a valued use of the communities health resources. Such programs warrant expansion, without the need for comparison with programs, or any need to identify other programs for contraction.

Surgery while by far the most effective intervention is also by far the most expensive, which explains a higher cost/life year saved. If targeted at obese persons with IGT this program is also highly cost-effective at a cost/life year saved of \$4,200. (See discussion below for further interpretation of performance). In general targeting interventions at people with IGT will improve performance, due to their far higher risk of NIDDM and higher expected mortality.

¹⁴ Costs and benefits discounted at 5% p.a. Net cost is based on gross cost adjusted for estimated savings in downstream costs through avoiding management of diabetes.

Table 11.1 Estimated cost-effectiveness of Programs for the Primary Prevention of NIDDM (\$A 1996-1997)

| Program type/target | Program cost per participant | Participant group ^(a) | Cost per life year gained ^(b) | |
|--|---------------------------------|---|--|-------------|
| | | | gross cost \$ | net cost \$ |
| Group behavioural for overweight men | \$ 195 | IGT only IGT only ^(a) 10%IGT 90%NGT | 500 | net saving |
| | | | 1,600 | net saving |
| | | | 700 | net saving |
| | | | | |
| Intensive diet/behavioural seriously obese persons | \$ 2,500 | IGT only 10%IGT 90%NGT | 4,200 | net saving |
| | | | 5,900 | 2,600 |
| II Diet/behavioural women previous GDM | \$ 2,500 | IGT only 25%IGT 75%NGT | 4,400 | 1,200 |
| | | | 4,600 | 2,400 |
| IV Surgery for serious obesity | \$13,300 | IGT only 10%IGT 90%NGT | 12,100 | 4,600 |
| | | | 19,100 | 12,300 |
| GP advice to patients with CVD risk, BMI>27 | \$ 420 | IGT only 10%IGT 90%NGT | 3,000 | 1,000 |
| | | | 3,200 | 2,600 |
| V Media with community support | \$2m for a popn of 4mil persons | mixed population | 500 | net saving |

Source: Segal 2000, Table 7.31.

Notes:

- a) Testing for IGT/diabetes was assumed to be part of standard management and thus identifying an all IGT group was not costed except for the group behavioural program for overweight men for which the cost of screening is included at \$382 per new case of diabetes found (Easton et al 1997),
- b) Program costs and life year saved discounted at 5% p.a. rounded to nearest \$100,
'net cost saving' : Expected saving in downstream health cost (disc @ 5%) > program cost.

Other Performance criteria

All programs should be acceptable in terms of equity, although care would need to be taken in program development to ensure they were particularly relevant to disadvantaged groups who are most at risk of NIDDM. Quality of the evidence is a problem with most programs due to the very limited experience with primary prevention initiatives. Thus program introduction would ideally proceed via pilots which incorporated a formal evaluation component.

11.4 Screening for early diagnosis

Background

There is evidence of significant delay, of at least four years on average, between onset of NIDDM and diagnosis (Harris 1992). Screening for earlier diagnosis and the instigation of more timely management is thus proposed as a possible means to reduce disease burden from NIDDM. Also based on the research on primary prevention, if people with IGT can be identified they would make a suitable target for NIDDM prevention.

Method

In the absence of a formal screening program for NIDDM, possible screening options were identified based on the theoretical possibilities. Program options were devised to cover various target groups, whether screening was opportunistic or not, and whether case finding would focus on NIDDM alone or NIDDM plus IGT. A one off screening campaign was assumed.

In the initial analysis new cases of NIDDM and IGT found were the outcome measures. Estimates of cost per new case found were derived using a model combining the cost of screening tests (based on recommended screening protocols WHO 1995), unit test costs (based on the Medicare Benefits Schedule), and expected case finding. Case finding reflected prevalence rates for undiagnosed NIDDM and IGT in various population subgroups (ABS Health Survey 1995) and the accuracy of the screening test.

An attempt was also made to estimate cost/life year gained, for alternative screening strategies, but due to lack of data, particularly on the likely impact of a screening program on disease progression, this represented little more than scenario development.

Results

Key results are reproduced in Table 11.2. Cost per new case of NIDDM diagnosed is estimated to lie between \$1,880 and \$3,295 on a full costing basis, or between \$212 and \$770 on a marginal cost basis (costs are as defined in notes to Table 11.2). If identification of IGT is also an objective of screening, which would be appropriate in the context of a strategy for the prevention of NIDDM, then cost per case identified of NIDDM or IGT is lower, due to the higher case finding rate. It is estimated at between \$460 and \$802 on a full costing basis or \$73 to \$200 on a marginal cost basis.

The analysis highlights the advantage of opportunistic screening - testing for diabetes at a GP visit made for another reason, and especially when a blood test is in any case to be conducted. A screening program targeted at communities with a higher rate of undiagnosed NIDDM and IGT may or may not be more cost-effective than a general program, depending on the differential publicity cost of a targeted compared with general program. Some conclusions about the type of screening program that should be implemented if one is to proceed were developed.

However conclusions could not be drawn about whether screening represents an efficient use of scarce health resources, compared with other approaches to reduction of disease burden (the comparison across disease stage) without evidence on the benefits from screening. But there is no published evidence on the impact of early case finding on health outcomes.

In the absence of such evidence the issue has been explored through scenario development. Cost per life year gained was calculated reflecting plausible values for key parameters as described in Table 11.3. Performance of screening is found to vary widely, depending on the scenario, from \$350 per life year gained to \$72,450 per life year gained. (See Table 11.A in the Annex to this Chapter). The result is highly dependent on the presumed impact of early diagnosis on life expectancy, the impact on costs of management (extra costs of management less offsetting savings in downstream care) and whether screening is for NIDDM alone or for NIDDM plus IGT. The analysis suggests that provided a gain of at least 6 months in life expectancy is achieved, screening will involve a cost per life year gain of less than \$12,500, under most plausible sets of assumptions.

Table 11.2 Screening cost ^{(a),(c)} per case NIDDM and/or IGT identified (\$1996)

| Target Group ^b | | full cost ^d | partial cost ^e | Marginal ^f cost | weighted cost ^g |
|-------------------------------------|--------------------------|------------------------|---------------------------|-------------------------------|-------------------------------|
| All adults 45+ | undiagnosed NIDDM (2.1%) | 3,295 | 1,864 | 212 | 2,128 |
| | + IGT (6.6%) | 802 | 464 | 73 | 526 |
| Adults 45+ and BMI >30 | undiagnosed NIDDM (3.6%) | 2,693 | 1,300 | 334 | 1,621 |
| | + IGT (11.5) | 522 | 327 | 101 | 363 |
| Adults 45+ and Italian born | undiagnosed NIDDM (3.5%) | 2,175 | 1,290 | 335 | 1,460 |
| | + IGT (11.3%) | 530 | 330 | 100 | 367 |
| Italian born adults 45+ and BMI >30 | undiagnosed NIDDM (5.7%) | 1,880 | 1,370 | 770 | 1,463 |
| | + IGT (18.4%) | 460 | 340 | 200 | 362 |

Source: Segal L., 2000, Chapter 8, Table 8.5

Notes

- a) covers test cost, GP visit (full cost), publicity for region of 4.5 million people, \$800,000 for population based screening campaign, or \$400,000 if addressed at ethnic sub-group.
- b) assumed prevalence of NIDDM and IGT of target group shown in parenthesis.
- c) initial screening test fasting blood glucose, OGTT performed as confirmatory test, pathology test conducted by pathology centre, cost ~ 10% higher if undertaken by GP.
- d) full cost - assumes patient attends GP specifically for screening test.
- e) partial cost - assumes patient attends GP for some other reason.
- f) marginal cost - assumes patient attends GP for other reason and blood test ordered primarily for other reason.
- g) weighted cost 30% full costing, 60% partial costing and 10% marginal cost.

Other performance criteria

As noted access to suitable data proved a major problem. While advice can be provided about the preferred structure of a screening program should one be introduced, (a pertinent priority setting question at the disease stage), no conclusions can be drawn about the quantity of resources that should be allocated for screening.

This reflects the lack of information about the accuracy of screening tests, the prevalence of NIDDM and IGT (known and undiagnosed) in the population and by subgroup and the effect of screening on disease progression. In particular objective evidence is required on the impact of screening on health outcomes and downstream costs of management.

11.5 Diabetes Management

Background/selection of intervention options

Specification of intervention options for diabetes management proved complex. The management of NIDDM is individualised, with each patient accessing a unique set of health services. A decision was made to focus on four distinct philosophies of care:

- **Comprehensive Care** – involving intensive medical management and patient education reflecting a patient empowerment model,
- **A patient Education/empowerment model** - involving the patient empowerment component only of the comprehensive care model,
- **A pro-active medical model for intensive management**, of both blood glucose but also blood pressure, cholesterol and other risk factors,
- **Standard care**, typified by the traditional medical model.

Measurement of Impacts

Benefits were measured in terms of life years gained. The few reported longer-term clinical trials of alternative models of patient care which reported outcomes in terms of survival, formed the basis of estimates of effectiveness.

Performance

Program costs were based on program descriptions multiplied by published unit costs. Potential downstream cost savings were based on evidence of reduction in complication rate, for example for renal failure and cardio-vascular disease.

The results of the cost-effectiveness analysis are summarised in Table 11.3, taken from the manuscript by Segal 2000, Chapter 9. The incremental cost per life year gained is calculated at less than \$1,000 for Comprehensive Care, based on 14 years of follow-up, (the time frame of the clinical trial from which effectiveness was drawn). While for intensive management, cost per life year gained is estimated at \$2,200, based on reported outcomes to 8.4 years follow-up (the time frame of the relevant clinical trial) or less than \$1,000 per life year gain, based on modeled outcomes taken to full life expectancy. Under certain plausible sets of assumptions both of these alternatives would be cost saving. The patient education/empowerment approach is also shown to be highly cost-effective at an incremental cost of \$5,900/life year gained relative to standard care, (based on 8.4 years follow-up). However, it is probably less cost-effective than the other models.

Best practice management defined by Comprehensive Care, incorporating diabetes education plus intensive clinical support or intensive pro-active medical care are both highly cost-effective relative to the traditional (reactive) medical model. Based on this analysis, a shift in management from standard medical care to best practice care, as described under either of these two models, is desirable.

11.6 Implication for Desirable Resource Shifts

Measure of Benefit

For the comparison across disease stages, outcomes need to be defined using a consistent outcome measure. As life years gained has been adopted as the primary outcome at each disease stage (together with an intermediate health outcome for prevention and screening), estimated performance for each of the three stages could simply be brought together and compared¹⁵. This has been done and the key results taken from Segal 2000 are presented in Table 11.4.

Cost-effectiveness results

All results are expressed in terms of net cost per life year gained, with expected downstream cost savings set against program costs. Estimates have in most cases been taken to full life expectancy (unless noted). The results represent marginal cost-effectiveness ratios, calculated against a status quo comparator. In relation to primary prevention and screening this is against no program, while for management of those with established disease the comparator is traditional medical care.

Some programs for the reduction of disease burden for NIDDM are cost saving – notably a number of primary prevention programs. The performance of screening could not be established with any certainty reflecting the lack of evidence on which estimates could be based. Estimated cost per life year gained varies between \$400 and \$72,450. Improving management of patients with established disease is seen to involve a cost varying from \$675 to \$5,900 per life year gained. While comparability between programs is somewhat compromised by differences in period of follow-up and time frame over which benefits are presumed to accrue, some conclusions can still be drawn about desirable resource shifts.

Based on the available evidence, expanding health resources allocated to the primary prevention of diabetes, (particularly to selected behavioural programs), is likely to yield substantial net benefits to the community. Such a resource shift could be supported in large part through savings in the use and cost of downstream services. For those with established NIDDM, transferring resources from standard care to comprehensive care or the intensive medical model is indicated to be highly cost-effective, or potentially cost saving. The benefits for supporting an education/empowerment approach to care unless associated with an intensive medical approach may not be quite as great, but still more cost-effective than many other health services (see below).

In relation to screening, given the uncertainty concerning the potential benefits, there is little justification for a major screening campaign for NIDDM. This is consistent with comments by others. For instance de Courten and Zimmet (1997) note in a recent editorial on screening for NIDDM that as screening is costly, and may have negative as well as positive outcomes, its value is not certain. They suggest, in sympathy with these study results, that primary prevention is more readily justified, both in terms of documented benefits and less potential for harm. This would not preclude the introduction of screening for research purposes, to collect data on outcome and cost which could then be used to refine the assessment of the performance.

¹⁵ The use of an ultimate health outcome in assessment of performance at each stage may well be preferred, both for the integrity of the analysis at that stage and to facilitate analysis across disease stage, (and diseases).

Table 11.3 Comparative cost-effectiveness by disease stage

| Disease Stage | Program type | Estimated cost per life years gained (a) \$ 1997 |
|----------------------------------|---|--|
| Primary prevention | Group behavioural weight loss for overweight men | Cost saving |
| | Intensive diet/behavioural for seriously obese persons | Cost saving to \$2,600 |
| | Intensive diet/behavioural for women with previous gestational diabetes | \$1,200 to \$2,400 |
| | Surgery for seriously obese persons | \$ 4,600 to \$12,300 |
| | GP advice to high risk overweight persons | \$ 1,000 to \$2,400 |
| | Media/community based campaign to improve eating habits and target sedentary living | Cost saving |
| Screening for early case finding | <i>Optimistic scenario:</i> screening extends life expectancy by 12 months, all obese adults 45+, extra cost of management offset by downstream cost savings. | \$400 to \$1,700 |
| | <i>Conservative scenario:</i> weighted screening cost, screening extends life expectancy by 1 month, screen all adults 45+, net additional costs of management \$1000/year for 4 years, screening for NIDDM only. | \$66,150 to \$72,450 |
| Patient management | Comprehensive care | \$685 (to 14 years) |
| | Intensive pro-active medical care | \$2,206 (to 8.4 years) \$675 to life expectancy |
| | Education/empowerment approach to care | \$5,900 (to 8.4 years) |

Source : Segal 2000, Chapters 7, 8 and 9.

Notes a) Cost and life years relate to full life expectancy, except as noted for patient management.

Other performance criteria

Equity

A limited assessment of the implications for equity and access is reported. The resource shifts consistent with efficiency are also likely to be consistent with equity and access objectives. Expanding access to programs for the primary prevention of NIDDM and access to best practice care for diabetes management would support those in poor health and at high risk of morbidity and mortality. Obesity and NIDDM are considerably more prevalent in those on low incomes (McNeill et al 1999) with limited capacity to access privately funded weight loss services.

It is also documented that low socio-economic status is associated with less timely initiation of medical care, such that under standard care, typified by the reactive medical model, lower income groups will tend to receive worse quality care. Publicly funded programs for NIDDM prevention or comprehensive care are currently inadequate to meet current need. There are long waiting times to access services of public sector dietitians, diabetes nurse educators, podiatrists and service options limited due to demand in excess of supply. Similarly public sector multi-disciplinary weight loss clinics offer only a small number of places.

It is thus likely that expansion of group weight loss programs for overweight men, intensive weight loss for people with serious obesity and women with previous gestational diabetes, and more intensive and comprehensive care for persons with diabetes, should contribute most to the health of persons from lower socio-economic background, who are more likely to be obese and at greater risk of or already to have diabetes. Gestational diabetes is considerably more prevalent in women from non-English speaking backgrounds (notably ethnic Chinese and Indian, etc.), further supporting the likelihood that recommended resource shifts could contribute to a reduction in health inequalities.

In short it seems likely that equity and access objectives will be consistent with efficiency objectives, in supporting greater access to publicly funded primary prevention services, and best practice care for diabetes management (to replace standard care). A reduced focus on screening may also be consistent with equity objectives, in that screening programs tend to be accessed by the well informed, who are also more likely to access indicated treatment if diagnosed. In selecting particular services for expansion, there is a further opportunity to target them at particular populations, chosen on the basis of equity and access considerations.

11.7 Broader resource allocation implications

The staging of the priority setting task envisaged the comparison of performance of interventions offered at a single disease stage, then across disease stages and then between diseases. Comparison of programs for reduction of disease burden for NIDDM with other programs addressed at other diseases represents the next broad stage of the priority setting model. While there was no intention within the application to NIDDM, to explore in a complete sense the resource allocation across diseases, preliminary consideration of this matter can place the recommended resource shifts in a wider perspective.

A report of the results of applications to the Pharmaceutical Benefits Advisory Committee, for the listing of drugs on the Pharmaceutical Benefits Schedule (for public subsidy), is informative (George et al 1997). The study covers all drugs submitted for listing, between 1991 and 1996 for which life years gained is the primary outcome measure and about which a decision for listing was made (26 drugs in total). Of eleven drugs for which incremental cost per life year saved was below \$36,500, 91% were approved at the nominated price. In relation to nine drugs submitted for listing at a cost/life year saved of between \$36,500 and \$69,000, 44% were approved at price, while no drugs (of six), which cost more than \$69,000 per life year gained were approved at price.

Based on the literature interventions appear to be justified at a cost of up to \$40,000/life year gained for this group of health policy makers (George et al 1997). Laupacis and colleagues (1992) argue, based on a review of available economic evaluations and suggested guidelines that *'technologies that cost less than US\$20,000 per QALY [-A\$40,000 1996/7 dollars] are almost universally acceptable as being appropriate ways of using society's and the health care system's resources'* (p475). While for the purpose of evaluating road safety initiatives in Australia, a value of life of \$631,000 has been adopted, suggesting a value per life year of between \$30,000 and \$40,000 (\$1996/7) depending on mean age of fatality (Bureau of Transport and Communication Economics 1992). There is a surprising consistency in these figures, suggesting an incremental cost per life year gained in the vicinity of \$40,000 might approximate current community values.¹⁶

¹⁶ The literature on valuation of life is extensive, especially within transport economics and the environmental health literature. Values are derived from approaches such as wage risk adjustment, revealed preference through the purchase of safety equipment, contingent valuation approach or the human capital approach. A review of this literature is outside the scope of this Paper, but in the context of a serious on-going priority setting program for the health sector wide, it would be relevant to explore and contribute to this literature.

If the performance of programs for reduction in disease burden for NIDDM, is compared with programs elsewhere in the health sector and related to decisions of policy makers, NIDDM as a disease appears to be relatively under-resourced. Even the least cost-effective primary prevention program, surgery for seriously obese persons at an estimated \$4,600 for an all IGT group or \$12,300 otherwise, would warrant continued funding or possibly expansion.

The role of screening is confirmed as equivocal. Its primary justification would be as a research program, to gather evidence concerning the costs and impact of screening. Additional resourcing to support for the wide adoption of comprehensive or intensive care for those with established disease is also confirmed as desirable.

Annex to Chapter 11

Table 11.A1 Ranking of intervention options at each disease stage: research activities

Rank Options for Primary Prevention

Select intervention options for review:

- locate and analyse evidence on preventability of NIDDM,
- list and classify all possible primary prevention intervention options,
- search literature for reports of interventions for prevention of NIDDM,
- select intervention options for comparison.

Undertake cost-effectiveness analyses:

- collect descriptions of intervention options, their costs and effectiveness,
- select a suitable outcome measure,
- establish the cost of disease management and possible resource savings from prevention,
- estimate performance - gross and net cost per life year gained and per diabetes year deferred.

Rank intervention options:

- establish the relative cost-effectiveness of interventions for the prevention of NIDDM
-

Screening/Early diagnosis

Preliminary analysis and data gathering:

- consider the possible role for screening, evidence of delay between disease onset and diagnosis, effectiveness of early management,
- obtain data on screening tests, costs and accuracy,
- obtain data on prevalence of undiagnosed NIDDM and IGT, total and by population groups.

Calculate cost per new case identified:

- select assumptions to incorporate in calculations, re screening protocol, cost concept (full or marginal costing to reflect stand-alone or opportunistic screening), publicity campaign,
- calculate cost per case found under alternative assumed.

Calculate cost per final outcome:

- estimate benefits of early diagnosis and relate to cost per new case of NIDDM diagnosed.

Rank alternatives

- identify the most marginal screening program (or research required to determine this),
 - consider the effect of targeting and other program attributes on cost-effectiveness.
-

Management of persons with established disease

Review the literature, describe alternative care models:

- confirm the basis for sub-classification of management of NIDDM,
- confirm management of complications to be excluded,
- describe alternative models of diabetes management.

Estimate cost-effectiveness of alternative options for diabetes management:

- collect material on diabetes management, costs and outcomes,
- undertake cost-effectiveness analyses of alternative approaches to diabetes management.

Rank alternatives:

- rank alternatives on the basis of cost-effectiveness ratios to highlight the most marginal
 - identify attributes that contribute to cost-effectiveness in management of diabetes.
-

Table 11.A2 Exploration of the role for screening

Evidence

1. NIDDM is the cause of a reduction in life expectancy of up to 10 years, depending on age at diagnosis and gender, but typically of 4 to 5 years. Differential annual all-cause mortality is observed to be 100% for persons with NIDDM.
2. Time between disease onset and diagnosis is estimated to be at least 4 years.
3. Comprehensive care, relative to standard care, results in a reduction in all-cause mortality, estimated at 19%. Where comprehensive care is commenced earlier, before comorbidities are established, the potential gain is greater, *especially for women*.
4. NIDDM imposes additional health care costs, mean \$2,040 per diabetic per year (\$1996-7).
5. The average time with NIDDM from diagnosis (till death) is 12.1 years, or just over 16 years from disease onset. This means that typically 25% of the time that a person has NIDDM is undiagnosed and untreated.

Scenario

1. Case finding results in earlier diagnosis and more timely management, extending life expectancy by somewhere between 1 month and 18 months. Relative to a typical loss in life expectancy of 4 to 5 years, this represents a reduction in this loss of between 2% and 35%.
2. Cost per life year gained can be calculated by relating estimated gain in life expectancy to cost of case finding (see Table 11.2) adjusting for an assumed impact on cost of management - immediate and downstream.
3. In relation to costs of management of NIDDM it is presumed either i) there will be a net cost increase of \$1,000/diabetic year over four additional years of treatment or ii) there will be a zero net cost impact with offsetting downstream cost savings balancing additional costs of management.

Table 11.A3 Performance of screening - cost/life year gained ^(a) \$1997

| Target | Assumed gain in life expectancy per new case of NIDDM | | | |
|--|---|----------|-----------|-----------|
| | 1 month | 6 months | 12 months | 18 months |
| Net management cost zero | | | | |
| NIDDM only | | | | |
| all adults 45+ | \$26,400 | \$4,400 | \$2,200 | \$1,450 |
| obese adults 45+ | \$20,100 | \$3,350 | \$1,700 | \$1,100 |
| NIDDM+IGT ^(b) | | | | |
| - all adults 45+ | \$6,550 | \$1,100 | \$ 550 | \$ 350 |
| - obese adults 45+ | \$4,500 | \$ 750 | \$ 400 | \$ 500 |
| Net management cost \$1,000/year for an extra four years (disc @ 5% pa) | | | | |
| NIDDM only | | | | |
| -all 45+ | \$72,450 | \$12,100 | \$6,050 | \$3,000 |
| -obese 45+ | \$66,150 | \$11,000 | \$5,500 | \$2,750 |
| NIDDM+IGT ^(b) | | | | |
| - all 45+ | \$52,550 | \$8,750 | \$4,400 | \$2,200 |
| - obese 45+ | \$50,550 | \$8,400 | \$4,200 | \$2,100 |

Source: Segal 2000, Chapter 8

Notes: a) Based on weighted screening cost: 30% full cost, 60% partial cost, 10% marginal cost.

b) Zero discounting of life years. Joint NIDDM prevention/screening program, screening for IGT costed to NIDDM prevention. Life year gain relates only to new cases of NIDDM.

Chapter 12 PBMA Application to Cancer

12.1 Introduction

Section 7.4 of this paper outlines the research methods of the evidence-based PBMA approach. This Chapter summarises its application and the major findings and recommendations, in the application of the approach to Cancer. This is based on Carter et al report entitled *Trial of Program Budgeting and Marginal Analysis (PBMA) to Assist Cancer Control Planning in Australia*. The purpose of the application was to directly contribute to the National Cancer Strategy, but also trial the use of an evidenced based PBMA approach for priority setting where the DALY was used as the primary outcome measure.

12.2 Identifying the Options for Change

The Working Party assessed a list of 21 action areas, which encompassed over 40 individual interventions/activities, taken from the top 20 action areas in the 'Cancer Control Towards 2002' report (NCCI 1998) and a National Strategy Development Workshop. The 21 action areas were classified into five groups with two identified as suitable for further consideration; options for change and possible options for change. The action areas included in these two categories, which were candidates for cost-utility analysis were:

Options for change

- Reduce Smoking Prevalence,
- Reduce the risk of skin cancer,
- Improve skills in diagnosing skin cancer,
- Improve efficiency of cervical screening,
- Improve detection of colorectal cancer,
- Rationalise prostate specific antigen testing,
- Develop guidelines in areas of need,
- Improve palliative care – specifically guidelines for pain management,
- Improve access to psychosocial care.

Possible Options for Change

- Increase consumption of fruit and vegetables through health promotion,
- Organise education and resources for those with familial cancers,
- Meet urgent national needs in data collection.

Eight options which might involve increments (additional expenditure) and decrements (reduced expenditure) were selected for analysis. Only eight options were considered due to the time constraint on the study, (which was completed in less than 9 months), relative to the resource requirements of the evidence-based approach and the involvement of experts. The selection of options for detailed consideration was made by the working party and the research team and reflected in part the previous ranking of the options by National Cancer Control Initiative (NCCI) and the Cancer Strategies Group (CSG). The eight options selected for evaluation were:

- Colorectal cancer screening,

- Cervical cancer screening (2 options),
- Skin cancer prevention,
- Psychosocial care (2 options),
- Tobacco control,
- Encourage consumption of fruit and vegetables.

The analyses and results for each of these options is now described, including the ultimate recommendation, for increment or decrement.

12.3 Option 1: Colorectal Cancer (CRC) Screening

Background

The intervention selected for evaluation was colorectal cancer screening targeted at an average-risk population aged 55 to 69 years, using Haemoccult II to detect faecal occult blood. The 'average-risk population' was defined as those who are asymptomatic and have no family history or a first degree relative diagnosed later than 55 years.

The research assumed a steady-state operation¹⁷ had been achieved and estimated the net costs and benefits of one year of screening. A biennial screening for the 55-69 age group was analysed as 'the minimum screening program' which was compared to the current practice of 'ad hoc' screening in the absence of an official screening program. The health benefit of a screening program was calculated as the difference between the DALYs with and without a screening program.

Method

The Australian Burden of Disease (BOD) study Disability-adjusted Life Year (DALY) estimates attributable to colorectal cancer were remodelled to assess the loss associated with four identifiable disease stages. This adjustment was determined from the published literature. The effectiveness of Faecal Occult Blood testing (FOBT) for population screening in terms of impact on disease progression was based on four randomised control trials.

Benefit

The introduction of a biennial screening program directed to the 55-69 age group was estimated to result in 251 fewer deaths per annum and a gain of 3,194 life years (YLLs). A decrease in overall burden of disease by 3,187 DALYS per cohort screened was estimated after taking account of a small increase in years lived with disability (YLD).

Costs

The direct health service cost included costs for recruitment, screening, diagnosis, treatment, palliation, follow-up/surveillance and associated infrastructure. Costs of a screened population were compared with the estimated costs of the population accessing screening in the existing ad hoc fashion and reflecting current rates of diagnosis, treatment and follow-up, for 1996. The current health service utilisation pattern was identified and the change in this pattern with a national screening program was predicted. Unit costs were assigned to each service category. The data was derived from the

¹⁷ For an explanation of 'steady-state operation', see the Glossary at the end of this report.

literature, the Victorian Hospital Inpatient Data set and base program costs from the cervical cancer program costs for Victoria scaled up for the national level. The cost streams were used to derive a Net Present Value with and without screening, with the difference between the two representing the incremental cost of a screening program for CRC.

Cost effectiveness

The cost effectiveness results show that a total of 3187 DALYs would be recovered under a base program at a cost of \$12,000 to \$16,700 each. The best buys were 'adding biennial screening of older age groups; and going to annual screening for 55-69 and annual or biennial for 50+'; and the worst buys were 'adding the 45-49 age group to annual screening.

Sensitivity analysis

Confidence limits were determined by applying a plausible range to the relevant values, and recalculating the estimated benefits. The base program of biennial screening of the 55-69 age group was estimated to result in 110 – 390 fewer deaths per annum associated with a gain of between 1,360 and 4,920 YLLs and a decrease in the overall burden of disease of between 1,360 to 4,910 DALYs.

Second stage filters

The equity filter showed that the incidence and/or the mortality rate from CRC were higher in the four specified equity target groups, (low socio-economic status, Aboriginal or Torres Strait Islander, rural, other ethnic). It was suggested that differences may be due, in part, to barriers in accessing health care services which could also impact on the effectiveness of any screening program.

In this case, the introduction of a national CRC screening program could increase the existing inequalities. Equity weighting of outcomes should therefore be considered in implementing a national program.

In terms of 'size of health problem' CRC is large whether considered in terms of cases, deaths, life years lost or resources allocated for treatment. These criteria would thus support the inclusion of screening for CRC in the Cancer Strategy. The level of evidence for the efficacy of CRC screening was rated as Level 1, being based on a number of RCTs.

In terms of implementation, it was anticipated that a national CRC screening program would be slow to build-up and if implemented, would be hard to wind down. The study team recommended trialing *implementation of a national colorectal screening program directed at the over-55 age group.*

12.4 Options 2 and 3: Improve Efficiency of Cervical Cancer screening

Background

In relation to cervical cancer screening, there were two intervention options assessed in this PBMA trial:

- Option One: Women commence having pap smears once they are sexually active and aged 18 to 20 years, and then routinely every three years, presuming no symptoms or history suggestive of cervical pathology.

-
- Option Two: Women who have ever been sexually active should have pap smears from age 25 years, with routine screening every two years, presuming no symptoms or history suggestive of cervical pathology.

Method

This study used the 1996 Australian incidence rates to calculate the burden of disease associated with cervical cancer by DALYs and compared with the estimated burden of disease if the proposed options for change in the screening program were introduced. Like in other options, the DALY methodology used in the Australian Burden of Diseases studies (Mathers 1999, DHS 1999a, b). The incidence rates were derived from the Victorian Cervical Cytology Registry (VCCR) from 1995 to 1997 and for the number of women having a pap smear based on 1996.

The research compared DALY results from the following alternatives of cervical screening:

- 2 year screening interval commencing at age 18 to 20 years (current practice),
- 3 year screening interval commencing at 18 to 20 years of age (modified),
- 2 year screening interval and commencing screening at 25 years of age (modified).

Benefit

It was estimated that a change in the screening interval from 2 to 3 years (commencing at age 18 to 20 years) would be associated with an additional 18 cases of cervical cancer diagnosed and an additional 6 deaths cervical cancer each year, resulting in an additional 98 DALYs per year.

While retaining the 2-year screening interval but commencing screening at 25 years of age would result in an estimated increased detection of cervical cancer amongst women aged 25-29 years, and a shift towards more advanced disease at time of diagnosis. This was estimated to incur an additional 30 DALYs.

Costs

The health service costs included the recruitment of women, the costs of conducting the smear test, diagnosis, treatment of cervical abnormalities, the cost of registries and the training of medical and scientific staff. Costs were measured by combining estimates of health service utilisation with unit cost of the various health services. Costs were estimated for Victoria and then pro-rated up to the national level. It was estimated that with the recommended options, there would be a potential saving of \$50.7 million per annum in the case of triennial screening and \$23.7 million per annum in the case of a delayed age of commencement.

Cost effectiveness

Cost effectiveness analysis was conducted to compare the screening options with the current recommendation (assuming steady-state operation). The marginal cost effectiveness ratio of moving to triennial screening (staying with 2-yearly screening) was estimated at \$517,000 per DALY saved. The marginal cost effectiveness ratio of delaying commencement age from 18 years to 25 years of age was estimated at a saving of \$790,996 per DALY.

Sensitivity analysis

Based on the sensitivity analysis the bounds for the cost effectiveness ratios were calculated to be \$156,172 to \$955,407 per DALY for 3-yearly screening and \$624,242 to \$959,259 per DALY to delaying commencement age from 18 to 25 years.

Second-stage filters

In relation to equity and access it was postulated that the proposed changes would not further any existing inequities and that the potential savings could be used to address inequities. The adverse health status impacts of the proposed changes would be minor. While the quality of evidence for cervical cancer screening was considered good, the impact of varying age of commencement was more limited.

The recommendation was to adopt an alternative screening strategy for cervical cancer involving both a delay in screening to age 25 and an extension of the screening interval to 3-yearly.

12.5 Option 4: Skin Cancer Prevention

Background

The intervention option was the adoption of a nationally coordinated skin cancer prevention program based on the Victorian SunSmart Program. The Option comprised three elements: a comprehensive education strategy, structural change and sponsorship.

Method

The estimated benefits of a proposed national skin cancer program were compared with a hypothetical 'current practice' comparator, the extension of the current practice in Victoria to a national level. Previously published cost effectiveness results were used in the analysis (Carter et al 1999).

Benefit

Benefits were measured using the DALYs reported in the Australian Burden of Disease study (Mathers 1999). The BOD study estimated that in 1996 there were 20,010 DALYs due to melanoma and 4,560 DALYs due to non-melanocytic skin cancer in Australia. Burden of disease for skin cancer in 2006 was projected using Australian BOD worksheets. Assuming no change in policy, the worksheets estimated a total of 26,936 DALYs from melanoma and 6,195 DALYs from non-melanocytic skin cancer in 2006. If a national SunSmart Program were introduced, it was estimated that there would be 699 fewer deaths and a gain of 5,757 life years, leading to a reduction of 8,135 DALYs. This estimate assumes a 30.2% reduction in cancer incidence after the campaign, as reported by Carter et al 1999.

Costs

The net cost of implementing a national skin cancer prevention campaign was estimated at \$2.53 million. This cost was estimated by subtracting the reduction in management costs due to a lower incidence rate, from the difference between the average costs of the Victorian SunSmart Campaign (28 cents per person) and average expenditure on skin cancer prevention across Australia (14 cents per person). Expected cost savings were based on the current management costs of skin cancer which

covered hospital admissions, outpatient services, medical consultations, prescriptions, use of allied health professionals, and nursing home admissions. The costs for skin cancers due to exposure in 1996 were assumed to have a lag of 10 years.

Cost effectiveness

The research report concluded that an extension of the Sunsmart campaign was highly cost-effective from a societal perspective as projected downstream cost savings were greater than program costs and it would save money and reduce the health burden.

Sensitivity analysis

Sensitivity analysis and comparison with previous studies confirmed that this option should be recommended for adoption nationally.

Second-stage filters

The equity impact of introducing a national campaign was likely to be neutral thus supporting program adoption. In terms of size of problem, the large burden of disease and costs associated with skin cancer further justified the recommendation for adoption. The level of evidence was considered acceptable although not of the highest standard desirable.

12.6 Option 5: Introduce Breast Care Nurses for Patients with Breast Cancer

Background

The introduction of breast care nurses to support women diagnosed with breast cancer was included for consideration due to evidence that psychosocial problems were present in a significant proportion of these women, and breast care nurses were found to be effective in reducing mild to moderate levels of associated morbidity. The aim of the program was reduction in years lived with disability. It was not expected to reduce mortality.

The intervention involved access to breast care nurses for all women diagnosed with breast cancer at eight key points of time during their illness. This was compared to the current practice in which breast care nurses are generally not available.

Benefit

The impact on disease severity as reported in clinical trials was translated into the health state descriptors of the EuroQol 5D+ (the European Community utility instrument but with one extra dimension). The utility results were translated into DALYs using the regression model of the Dutch disability weights used in the Australian BOD study. Using this method, the introduction of breast care nurses was estimated to reduce disability by 5,186 YLDs. Given it was assumed that the introduction of Breast Care Nurses would not affect mortality, the introduction also resulted in a reduction of 5,186 DALYs.

Costs

It was estimated that 67 breast care nurses would be required, based on 10,000 new cases of breast cancer diagnosed each year. This was costed at \$3.6 million/year, the primary component of which was salaries including wage on-costs. Based on an assumption that salaries constitute 60% of the total cost of introducing BCNs, the total cost of the 67 BCNs amounted to approximately \$5 million.

Cost effectiveness

Based on the above estimates, the study concluded that the cost-effectiveness ratio for the introduction of breast care nurses would be approximately \$965 per DALY saved, suggesting a potentially well performing intervention. However, these results were based on limited evidence.

Sensitivity analysis

A sensitivity analysis using @RISK computer software estimated a mean benefit of 3,659 YLDs (between 2,089 and 5,228) and a mean cost of approximately \$4.0 million (between \$1.3 and \$6.6 million). These calculations produced a mean cost effectiveness ratio of approximately \$1,100 per DALY (between \$208 and \$2,070 per DALY).

Second-stage filters

To ensure equity of access additional resources may be required to meet special needs groups, such as persons living in rural and remote areas. In terms of size of problem the psychological morbidity was considered substantial. The primary impediment to recommending this option was the quality of the evidence.

12.7 Option 6: Introduce Psychologists for Cancer Patients

Background

Providing access to psychologists for cancer patients may enhance quality of life, based on evidence in the literature of the effectiveness of cognitive behavioural therapy in reducing affective disorders such as depression and anxiety, particularly in the acute phases of illness. Longer-term supportive psychotherapies were also found to be effective in disseminated and terminal cases of cancer. The short-term intervention included 12 sessions of cognitive behavioural therapy, either individually or in a group, while supportive psychotherapy entailed individual weekly contacts for patients with terminal cancer, until they died. The PBMA trial assumed that a psychologist would assess all patients at initial therapy, recurrence and disseminated/terminal phases and provide further therapy to patients with moderate to severe levels of morbidity.

Benefit

It was assumed that the introduction of psychologists for cancer patients would only have an impact on the level of disability (YLDs), not longevity (YLLs). Two methods were used to measure the impact. The first method was similar to the method used in the breast cancer nurse intervention, i.e. by a regression model of the Dutch disability weights and EQ5d+ descriptions, and translation of the utility results into DALYs. By this method, 28,913 YLDs related to anxiety/depression could be averted in the top 5 cancers i.e. colorectal, prostate, breast, melanoma and lung cancers.

Using a second disability weighting method, a much smaller benefit of 4,839 YLDs in the fore-mentioned top 5 cancers is identified, (see Carter et al 2000).

Costs

From the perspective of the government as the funder and provider of the services, the overall cost of the intervention was estimated to be approximately \$25.66 million. This included mostly the salary and associated on-costs for 286 full time equivalent level 3 psychologists based on the assumption that each psychologist would have 5 patient contacts per day lasting 45 minutes to an hour. The remainder of the working day was used for preparation, administration and professional development).

Cost effectiveness

When the first disability weighting method was used, the cost-effectiveness ratio was \$887 per DALY based on a total of \$25.66 million for 28,913 DALYs averted. When the second method was used, the cost-effectiveness ratio was \$5,300 per DALY based on a total of \$25.66 million for 4,839 DALYs averted. The cost-effectiveness ranking for the cancers would be melanoma, breast, colorectal, prostate and lung cancer, which indicated that cancers with low early mortality would have a greater proportion of YLDs than cancers with a high early mortality. This implied a greater scope to save potential YLDs in cancers with low mortality compared with cancers with high mortality.

Sensitivity analysis

A sensitivity analysis by the threshold analysis method showed that on the benefit side, 855 YLDs needed to be averted to achieve a cost effectiveness ratio of \$30,000 per DALY, while the cost of psychologists would be \$146.7 million for a cost effectiveness ratio of \$30,000 per annum, equivalent to the provision of approximately 1,635 psychologists.

A sensitivity analysis using @Risk computer software showed that the mean benefit was 4,769 YLDs (uncertainty interval, 2,453 – 7,084 YLDs), and the mean cost was about \$16 million (uncertainty interval, \$8.8 million - \$23.5 million), Thus the mean cost effectiveness ratio was \$3,533 per DALY (uncertainty interval, \$1,1612 - \$5,453).

Second-stage filters

In terms of other benefit criteria the introduction of psychologists was somewhat mixed:

- Equity: unlikely to have an impact on any existing inequalities for cancer patients;
- Size of the Problem: significant;
- Level of Evidence: a number of randomised control studies for effectiveness but translation to DALY relies on judgement;
- Acceptability and Feasibility: difficult to judge the acceptability of this intervention to key stakeholders.

The recommendation of the research team was to introduce Breast Care Nurses to improve the psychosocial care for cancer.

12.8 Option 7: Tobacco Control

Background

The National Cancer Control Initiative (NCCI), the Cancer Strategy Development Workshop Initiative, and expert opinion from the National Expert Advisory Committee on Tobacco (NEACT) all identified the National Tobacco Campaign as an option to reduce the burden from cancer. It was thus selected for evaluation in this study.

Method

The results of two previously published studies were drawn on; *'Australia's National Tobacco Campaign: Evaluation Report No One'* (Hassard 1999), and an economic appraisal of a National Tobacco Campaign in terms of potential years of life saved (Carter and Scollo 2000). The key differences of the current evaluation from the Carter and Scollo study was the use of a 3% discount rate, an increase in the identified number of smoking-related diseases (from 7 to 25), and incorporation of the impact of the recent downward trend in smoking prevalence.

Benefit

Data from the two published studies were used with minor variations in the methods used to estimate the health benefit of tobacco control. It was calculated that there were a total of 3,280 Years of Life Saved (to age 75), 5,562 DALYs (to age 75), and 10,599 DALYs including all age groups.

Costs

The cost estimate of a National Campaign, but not the health care offsets, were taken directly from the Carter and Scollo study (2000). The costs included the expenditure on advertising, public relation activities; and community based program elements. Cost offsets were calculated, based on the reduction in disease incidence predicted from the fall in smoking prevalence. The direct health care costs attributed to the selected diseases were taken from the Australian Institute of Health and Welfare's Disease Costs and Impact Study 1989/90 (Mathers et al 1998), and inflated to the 1996 reference year by using the health care deflator (AIHW 1996), and at a 3% discount rate.

The cost of a Commonwealth government campaign was taken to be \$7.1 million between the period of 1 April and 30 November 1997, and the costs of additional State/Territory Quit campaigns were assumed to be \$1.85 million. Cost offsets were calculated to be 39.07 million.

Cost effectiveness

It was estimated that the first phase of the proposed National Tobacco Campaign should prevent 920 premature deaths to achieve over 3,000 additional years of life (to age 75 years) at a 3% discount rate. Excluding cost offsets, the cost per DALY (all age groups) was reported to be \$844.

Sensitivity analysis

Sensitivity analysis showed that the cost per DALY varied between \$544 and \$3,879. Including expected downstream cost savings, the intervention was found to be cost saving. The research results show that a National Tobacco Control Campaign is thus highly cost-effective.

Second-stage filters

Application of the second stage filters (equity, access and level of evidence) had no adverse impact on the ranking of the National Tobacco Campaign, but reinforced the importance of ensuring the Campaign was continued as a truly national effort in tobacco control. The program was recommended for increment.

12.9 Option 8: Encourage Consumption of Fruit and Vegetables

Background

From the literature it is clear that insufficiency in the fruit and vegetable intake in the diet is a high risk factor for a range of health problems including colorectal and other cancers. There have been fruit and vegetable interventions in Australia (the Western Australian and Victorian, '2 Fruit n 5 Veg' campaigns), and the New South Wales Campaign in 1999. The WA and Victorian campaigns used multiple strategies including mass media and community-based education. The NSW Campaign was not described in the Carter et al Report (2000).

Method

The evaluation was based on the Victorian campaign and pro-rated up for a national campaign. The Victorian campaign was divided into 4 phases and implemented between 1992 and 1995. The main feature of the campaign was short intensive television advertising over a 3 week period in the first 2 phases and for 1 week in the third phase. Other strategies included support to community-based health and education professionals, joint activities with food retailers and food service providers, and point-of-sale materials.

The data sources included the Australian Burden of Disease studies (Mathers, Vos and Stevenson 1999; DHS 1999a,b), the Anti-Cancer Council of Victoria, the New Zealand Ministry of Health review of epidemiological studies, and the 1995 National Nutrition survey.

Benefit

The proportion of disease directly attributed to an inadequate intake of fruit and vegetables was estimated, and the total BOD was multiplied by the attributable fraction associated with either the 'with intervention' and 'without intervention' scenarios. An inadequate intake of fruit and vegetables was estimated to be responsible for 3.1% of total deaths and 2.8% of total DALYs in Victoria for 1996. The health benefit to be achieved by a screening program was estimated at 222 deaths averted, 2,640 years of life gained and 3,626 DALYs averted. This estimate for Victoria was pro-rated up for Australia.

Costs

The data used to calculate costs was based on the Western Australian campaign, discussion with the Victorian and Western Australian campaign organisers, and estimates from 1999 NSW campaign. Based on these, the annual cost of a national campaign, including staff, was assumed to be between \$1.7 million and 3.2 million, depending on the kind of campaign undertaken. Downstream cost savings were also calculated.

Cost effectiveness

Using a program cost of \$2.46m and excluding downstream cost offsets, a national fruit and vegetable campaign was estimated to cost \$930 per YLL and \$677 per DALY. Once downstream cost offsets are included the intervention is estimated to both reduce health care costs and reduce health burden.

Sensitivity analysis

Sensitivity analysis shows that the uncertainty range of cost per DALY to age 75 is between \$1,032 and \$2,255 (cost offsets excluded), and cost per DALY for all ages range from \$544 to \$1,180.

Second-stage filters

The Victorian campaign results suggest a national campaign should have the impact of lessening existing inequities in the consumption of fruit and vegetables. The Australian BOD study also shows inadequate fruit and vegetable intake to create a substantial disease burden. While the causal links between an inadequate intake of fruit and vegetables and cancer, ischaemic heart disease, and stroke were rated as strong there was limited evidence of the effectiveness of a fruit and vegetable campaign in modifying behaviour. The authors, however, concluded that the available evidence was sufficient to sustain a national 'Fruit n Vegetable' campaign.

12.10 Summary of Recommendations

A summary of the increment/decrement recommendations is listed in Table 12.1. The Report recommended that all increment options be considered for inclusion in the National Cancer Strategy. As shown in Table 12.1 these are the National Tobacco Campaign, Primary Prevention of Skin Cancer (SunSmart on national Basis), a National Fruit and Vegetables Media Campaign, Psychosocial Care (introduction of Breast Care Nurses and psychologists for cancer) and a National Colorectal Cancer Screening Program (Biennial for 50-69, and 50-74 age groups). They also recommended that all decrement options be acted upon. The Report also stated that these options relate to the National Cervical Cancer Screening Program: to change screening interval from 2 to 3 years, and to increase age of commencement from 18 to 25.

Table 12.1 Ranking of the interventions on net cost per DALY

| Interventions | Cost (Savings) \$ Millions | DALYs Recovered (Lost) | Cost per DALY Point estimate \$ | Cost per DALY Lower bound \$ | Cost per DALY Upper bound \$ |
|---|----------------------------------|------------------------------|--|---------------------------------------|---------------------------------------|
| Proposed Increments: | | | | | |
| 1 National Tobacco Campaign | | | | | |
| Gross Costs * | 8.95 | 10,599 | 844 | 544 | 1,180 |
| Net Costs (or net saving)# | (39.07) | | Dominant | Dominant | Dominant |
| 2 Primary Prevention of Skin Cancer (SunSmart on National Basis) | | | | | |
| Gross Costs | 2.53 | 9,965 | 254 | 238 | 505 |
| Net Costs (or net saving) | (37.4) | | Dominant | Dominant | Dominant |
| 3 Fruit & Vegetables Campaign | | | | | |
| Gross Costs | 2.46 | 3,626 | 677 | 513 | 16,392 |
| Net Costs (or net saving) | (12.15) | | Dominant | Dominant | Dominant |
| 4 Psychosocial Care: Breast Care Nurses | | | | | |
| Gross Costs | 4.85 | 5,186 | 935 | 455 | 1,745 |
| Net Costs (or net savings) | | Offsets | not estimated | | |
| 5 Psychosocial Care: Psychologists for Cancer Treatment Centres | | | | | |
| Gross Costs | 25.7 | 4,849 | 5,292 | 1,612 | 5,453 |
| Net Costs (or net saving) | | Offsets | not estimated | | |
| 6 National Colorectal Cancer Screening Program (Biennial: Ages 50-69) | | | | | |
| Gross Costs | 53.3 | 3,187 | 16,718 | 12,500 | 44,800 |
| Net Costs (or net saving) | 38.1 | | 11,958 | 10,300 | 39,700 |
| (Biennial: Ages 50-74) | | | | | |
| Gross Costs (no offsets) | 65.6 | 4,260 | 15,399 | | |
| Net Costs (or net saving) | 43.8 | | 10,300 | | |
| Proposed Decrements: | | | | | |
| 1: Rationalise the National Cervical Cancer Screening Program: Change Screening Interval from 2 to 3 years (Net Saving) | (50.6) | (98) | 516,864 | 156,172 | 955,407 |
| 2: Rationalise the National Cervical Cancer Screening Program: Increase age of commencement from 18 to 25 years (Net Saving) | (23.7) | (30) | 790,996 | 624,242 | 959,259 |

Source: Carter et al 2000, Table B

Notes: * gross cost: program cost

net cost: program cost less downstream cost saving from reduced disease incidence or enhanced management. Where program cost is less than projected reduction in downstream costs, program is said to be dominant in that it yields benefits while reducing use of health care resources.

12.11 Comment on the application

The application of the modified PBMA to cancer has demonstrated that the revised model, despite the additional data requirements can be implemented successfully, to yield concrete recommendations for resource shifts that are based on objective evidence. It also provides a structure for engaging key interest groups in decisions, which should facilitate their adoption.

The outstanding concerns with the technique relate to the mechanism for choosing intervention options for consideration and the use of the DALY as the primary outcome measure. Whether it provides a model to be applied across the entire health sector is also not clear.

Some of these issues are taken up in the final chapter of the Paper.

Section IV RECOMMENDATION FOR ADOPTION OF PRIORITY SETTING MODEL

Chapter 13 Recommended Model for Priority Setting in Health

13.1 Confirmation of Misallocation of Resources

Application of the two preferred priority setting models to NIDDM and cancer, has provided further evidence that the health service mix is sub-optimal and that opportunities exist for substantial health gain through resource shifts between programs. Results of all the health programs reviewed in these options are brought together in Table 13.1. This shows marginal cost-effectiveness ratios vary from cost saving (for services not funded) to well over \$500,000/DALY, for services that are funded. By shifting resources from poorly performing programs, for example by reducing the screening interval for cervical cancer, to any of the programs which are cost saving or highly cost-effective, such as intensive diet/behavioural program for seriously obese persons with IGT, or by providing access to comprehensive care for persons with diabetes, or extending the quit campaign, there would be a substantial net health gain. Health gain of 1000 life years (or more) is available for each \$1million that is redirected away from wasteful programs, to any of those with a net cost per life year of \$1,000 or less. It confirms the need of a priority setting framework, within which relative program performance can be determined, so that resources can be reallocated on the basis of evidence.

Table 13.1 Marginal cost-effectiveness ratios of selected interventions for NIDDM and cancer

| Program | Net Cost/effectiveness ratio* \$/DALY or \$/life year |
|--|--|
| Behavioural approaches to the prevention of NIDDM; group program for overweight men, media and community based support, intensive intervention for seriously obese persons with IGT. | cost saving |
| Extension of the Victorian quit campaign | cost saving |
| Comprehensive care or intensive care for the management of NIDDM (compared with standard care) | <\$1,000/life year |
| psychosocial care for persons with breast cancer | \$935/DALY |
| GP advice for weight loss in overweight persons with other risk factors for NIDDM | \$1,000 to 2,400/life year |
| Surgery for the prevention of NIDDM | \$4,500 to \$12,000/life year |
| National colorectal cancer screening program: biennial ages 50-74 | \$10,300/DALY |
| Changing the screening interval for cervical cancer from 2 to 3 years | \$516,900/DALY |
| Changing the age at which screening for cervical cancer is commenced from 18 to 21 years | \$791,000/DALY |

Source: Carter et al 2000, Segal L 2000. Notes: Net of downstream cost saving

13.2 Differential Model Features

The applications of the Health-Sector-Wide Disease-Based Model (HSW-DBM) to NIDDM and of the refined PBMA model to cancer confirmed the expectation that both models are capable of implementation without undue compromise to the theoretical criteria. Both models were able to identify health services for expansion and contraction that could reasonably be expected to enhance the health and wellbeing of the community, within existing resourcing.

The applications do also confirm certain differences between these two models. Unique features of the HSW-DBM are explored, followed by a discussion of the unique features of the refined PBMA approach. The Chapter concludes with a recommendation for a preferred approach to priority setting for adoption by the Department of health and Aged Care and its Population Health Division.

Health-Sector-Wide Disease-Based Model (HSW-DBM)

The Health-Sector-Wide Disease-Based Model (HSW-DBM) provides a framework for priority setting across the entire health sector. It thus offers a structure for an on-going research program, which over time, and given the allocation of sufficient resources, could set priorities across the entire health sector. Particular features of the HSW-DBM (most of which are unique) which support this are:

i A disease/health problem focus

This provides a context for the collation of the available evidence (epidemiological, aetiology, management, resource use, outcomes) ensuring efficiency in research effort, and a means for the staging of the research task;

ii A health sector wide model that provides for the staging of the priority setting task

The Model provides a means for tackling priority setting across the entire health sector, and allows for the task to be subdivided and staged in a way that minimises the risk of sub-optimising, in part by using the health problem/client group as the focus of the research question;

iii Comprehensiveness in description of intervention options

The approach ensures a wide range of interventions is included in the set for analysis – covering possible as well as existing interventions, not restricted by health delivery setting or current funding arrangement. This will maximise the chance of including the most marginal programs in the set being analysed;

iv A reliance on published data on costs and effectiveness/contribution to research agendas

The requirement for objective evidence and restriction on the use of 'expert opinion', (common to both the DBM and the refined PBMA), will contribute to a greater confidence in recommended resource shifts. It will also ensure that major data deficiencies are highlighted. In this way the priority setting exercise can directly feed into research agendas and provide a stronger policy focus to research funding for health;

v *A focus on final health outcomes*

While there may be role for cost-effectiveness analyses based on intermediate health outcomes at the disease stage, the use of final health outcomes such as the quality adjusted life year (or life year) is the preferred outcome measure to be applied at both the disease stage and for comparison across disease stages. This will ensure comparability across the entire range of programs - across disease stages and across diseases. It will also give confidence that conclusions drawn will be consistent with allocative efficiency. Final outcomes typically encapsulate the effect of a number of intermediate impacts. The use of intermediate outcomes always represents a compromise, unless there is a well-established and invariant relationship between a single clinical parameter and final health outcomes. Even then, conclusions concerning desirable resource shifts ultimately require translation into final health outcomes to enable comparison across disparate program types. Unfortunately clinical trials more typically report intermediate outcome measures only (such as blood pressure, weight, new cases diagnosed), with follow-up often insufficient to develop conclusions about impact on final health outcomes.

vi *Recognition of the need for a modest research effort*

The promise of some priority setting approaches, that conclusions can be derived on the basis of superficial analysis, has colluded with a policy environment in which inadequate resources are allocated to this task. But, the 'short-cut' approaches have not delivered. They have either generated recommendations which are so general as to be incapable of implementation, or where precise give little confidence in the recommended resource shifts. An important conclusion from both the HSW-DBM and the refined PBMA application is that the magnitude of the priority setting task is tractable, even when conducted in a rigorous fashion. The application of the HSW-DBM to NIDDM involved the efforts of a small research team amounting to approximately 2 EFT senior research fellows, plus approximately 2 EFT research fellows or research assistants.

The application of the refined PBMA model to several cancer interventions was implemented with a similar research team input. This is a modest commitment to research, especially when contrasted with the potential improvement in efficiency achievable through application of the recommendations.

vii *Promotion of research into society objectives in relation to health*

The HSW-DBM, together with the refined PBMA highlight the need for further research into community values in relation to health, to ascertain what the community wants from the health sector, and from particular programs. What meaning should be placed on equity and access and how important are they relative to efficiency. That is how important is the distribution of health care and health compared with the sum total.

Refined PBMA model

The refined PBMA model performs well in relation to the nominated performance criteria, and has been successfully implemented in relation to cancer. It is useful to consider the major differences between this model and the Disease Based Model. Key areas of difference in addition to those noted above, are the use of the DALY as the primary outcome measure and the role of the expert panel in selecting interventions for review and participation in other ways in the priority setting exercise.

In the application of the refined PBMA to cancer, the adoption of the DALY as the primary outcome measure was a central feature of the application. Should this become the standard? The DALY has received prominence through its use by the World Bank as the primary measure of cost of illness in the Global Burden of Disease Study (World Bank 1993, Murray and Lopez 1996). Its use in both contexts, for measurement of cost of illness and in priority setting is highly contentious.

A recent article by Alan Williams enunciates various concerns. His article covers both the role of the Global Burden of Disease, which he argues is of limited if of any value for priority setting, and the nature of the DALY as a health outcome measure. His criticisms of the DALY relate to its use in the global Burden of Disease Study, some of which are peculiar to that context, such as the age weighting and the adoption of worlds longest life expectancy as the point of comparison. (These are not relevant to the Australian Burden of Disease study). But he also comments on problems of the use of expert panels in the derivation of DALY weights and the interpolation from only 22 marker health states.

The use of expert panels is problematic because of doubt about the capacity of expert panels to make the necessary judgements to assign valid quality weights to a range of health states. Thus even where health status is based on objective evidence its translation into DALYs is based on 'expert' opinion reintroducing subjectivity into the measure of performance.

Williams argues for the description of health states by clinical experts, but for the allocation of quality of life weights to health status descriptors by members of the public (or persons with experience of the pertinent conditions). This would involve a lesser burden on those participating and arguably constitute a better match between task and capacity. It is more typical of the approach taken in the measurement of QALYS, (quality adjusted life years), whether measured directly or in the development of multi-attribute utility instruments.

The DALYs used in the application by Carter et al are those developed for Australia by Mathers et al (1999) and Vos et al (1999). While these do not incorporate the age weighting of the World Bank model they rely on quality of life weights developed by a Dutch team, which in turn is based on the EuroQol a utility instrument which consists of only five fields and three levels in each field resulting in an instrument which is extremely insensitive.

The adoption of the DALY must be considered highly contentious. The argument that it introduces a consistency into the measurement of health outcome and thus comparability is only valid if the measure itself is robust.

There are other approaches to the inclusion of quality of life, using a suitable utility instrument to develop QALYS, preferably not the EuroQol, or better still to establish quality of life weights from first principles, using the time-trade-off technique. Then quality of life weights can be developed that reflect the health states pertinent to the interventions selected for analysis in the priority setting task. While this would be impossible if the aim is to develop weights for hundreds of health states at once, it may not be impossible in relation to a more modest number of interventions, particularly if there is already some relevant data.

The adoption of the life year, while limited due to its inability to incorporate quality of life impacts, may also be appropriate for some conditions/interventions, where the outcome is primarily related to mortality rather than morbidity.

An alternative is not to be prescriptive about the precise outcome measure to adopt, but as in the Disease Base Model allow this to be determined as part of the priority setting process.

ii *Use of committees/expert panels*

This represents a consistent feature of both the original PBMA model and the refined approach. It provides both a means to engage key parties in the priority setting process which can provide access to relevant expertise and data, but also support for the resulting recommendations. The challenge is to ensure the tasks allocated to the expert panels are those that are suitable, that is which should not be based on objective evidence but where opinion is relevant.

iii *Adhoc selection of interventions for review*

Perhaps the least satisfactory aspect of the PBMA approach is the adhoc approach to the selection of interventions for review. There is no process to ensure a wide range of options is identified. It is essentially presumed that an expert panel will be able to ensure marginal programs are identified for inclusions.

The application to cancer was somewhat different as there had been a number of previous exercises in which options for inclusion in a cancer strategy had been derived through various processes, the expert panel developed for this priority setting exercise was not starting from scratch. Certainly the options analysed did include both interventions of highly varying cost-effectiveness thus suggesting both decrement and increments.

iv *Translation into a health-sector wide model*

The refined PBMA approach is not explicit about how the model might be extended to cover the entire health sector. This represents a weakness in the context of a model to guide priority setting for the nation (or even a region), although not a problem in the context of a particular agency or a specified health problem.

13.3 Recommendation

It is clear that both models perform well, and have their relative strengths. The best approach to priority setting may well be an amalgam of both. In an attempt to highlight the key features of the two models and where relative strengths might lie, key elements of both models are shown in Table 13.1. This is used to develop a preferred priority setting framework which incorporates the best features of both models.

This shows both models performing well across the board but the disease based model better in terms of the overall framework in the context of the entire health sector, while PBMA is more developed in relation to processes for engaging interested parties. (The latter can of course be both a strength and an impediment).

Table 13.2 Key attributes of the DBM and refined PBMA highlighting differences

| Attribute | DBM | refined PBMA |
|---|-----|--------------|
| Criteria for recommending resource shifts based on maximisation of net benefit – able to develop explicit recommendations | √√ | √√ |
| Health sector wide planning framework | √√ | — |
| Use of objective evidence | √√ | √√ |
| Adoption of suitable primary outcome measure | √√ | √√ |
| Use of processes to gain support of interested parties | — | √ |
| Objective process for selecting intervention options for comparison | √√ | √ |
| Description of intervention in a way that is precise | √√ | √√ |
| Marginal analysis | √√ | √√ |
| Capable of implementation | √ | √ |
| Mechanism to explore other components of benefit | √ | √ |

The recommended framework for adoption by the Department of Health and Aged Care and the Population Health Division, largely follows the structure of the health sector wide disease based framework, but also incorporating some features of the refined PBMA model - to incorporate:

- i* the health sector wide structure of the disease based model – and following the broad tasks described;
- ii* the use of objective evidence – a central feature of both models;
- iii* the choice of outcome measure to be determined as part of the priority setting process, with no presumption that the DALY is the preferred measure;
- iv* the involvement of steering group – to include not just clinical experts but others who may assist possible implementation of resource allocation recommendations;
- v* selection of intervention options for comparison to be comprehensive, as recommended in the disease based model
- vi* further exploration of the possible adoption of equity weights, as commenced under the refined PBMA model.

A framework incorporating these features, if adopted, could potentially make a substantial contribution to the achievement of allocative efficiency in the health sector.

13.4 Context of Priority Setting within a Broader Health Planning Framework

None of the priority setting models addresses the question of how recommended resource shifts are to be achieved. Policy instruments and funding arrangements to facilitate desirable resource shifts need to be explored in a complementary research program.

In the application of both models major limitations in the evidence on costs and effectiveness of intervention options is highlighted. Also a lack of knowledge of the views of the community about the

objectives of the health sector. Identification of data gaps should be an important output of priority setting process both models, which can inform clinical research priorities. The proposed priority setting Framework because of its focus on the questions important to priority setting can provide clear guidance for the research agendas of clinical and scientific communities that are policy relevant.

Glossary

| | |
|---|--|
| Allocative Efficiency: | <i>Allocative efficiency refers to the maximisation of benefits through the optimal combination of outputs or products. The basic condition for allocative efficiency is the equalisation of marginal benefit/cost ratios for each product or service, at which point no additional benefits are attainable by shifting resources between services. In the health sector, it is concerned with the optimal mix of health services.</i> |
| AQoL: | The AQoL is a utility instrument developed in Australia to measure quality of life. In common with other utility instruments it provides a weight on a scale from 0 (death) to 1 (best possible health) to adjust time in a given health state for loss quality. The AQoL consists of 5 categories; reliance on treatment, independent living, social relationships, physical senses and psychological well-being. Each category consists of 3 questions with 4 ordinal levels in the item responses. |
| Attributable Fraction: | The attributable fraction is the attribution of that proportion of a selected outcome or cost variable, (such as premature deaths or health service costs), to the subject disease or health problem under study, possibly also classified by age-sex groupings. |
| Average Cost: | Total cost divided by the level of activity. For instance, for a screening program, this would be the total cost divided by the number of people screened. |
| Benefit-cost ratio | The benefit-cost ratio is the health benefit achieved per dollar incurred. Benefit might typically be measured in life years, quality adjusted life years (QALYs), Disability Adjusted Life Years (DALYs), or a composite measure incorporating a number of benefit dimensions. Some reserve the term benefit-cost ratio and benefit-cost analysis to the translation of all benefits, as well as costs into dollars. |
| Cost Offsets | Cost offsets are the downstream cost savings attributable to an intervention. For instance if a primary prevention program results in lower disease incidence the reduction in costs of disease management would be classed as a cost offset. |
| Cost-effectiveness ratio: | A measure of program performance - where cost refers to program cost, measured in dollars, (with cost offsets sometimes included as a negative cost) and effectiveness measured in a parameter relevant to the program, such as life years saved, or a clinical outcome. The cost-effectiveness ratio is the measure of effectiveness divided by program cost - for instance to calculate cost per life years saved. The marginal or incremental cost-effectiveness ratio refers to the cost per unit of outcome, for an increase (or decrement) in the program. |
| DALY: | DALY expresses the sum of years of life lost YLL due to premature death and equivalent life years lost due to disability YLD. One DALY is one lost year of 'healthy life'. The higher the DALY the poorer the health state - 0 represents no disability and 1 the highest level of disability, (the inverse of the QALY). |
| Direct Cost: (Cost of Illness Studies) | Health service costs for management (and prevention) of the disease under study, including complications. |
| Discounting: | The process of converting future costs or benefits to an equivalent value in the present. The interest rate used is called the discount rate. The Global and Australian Burden of Disease Studies have applied a 3% p.a. discount |

rate to years of life lost in the future. There is debate about whether future health benefits should be discounted or whether only future costs should be discounted.

- Efficiency:** Efficiency is the maximisation of the benefits obtained from the resources allocated. There are two aspects to efficiency: technical efficiency and allocative efficiency (see Glossary items).
- EQ5D or EuroQol:** EQ5D is also known as the EuroQol, a utility instrument developed in Europe to measure quality of life. In common with other utility instruments it provides a weight on a scale from 0 (death) to 1 (best possible health) to adjust time in a given health state for loss quality. The EQ5D consists of 5 categories; mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each with 3 ordinal levels in the item responses.
- Indication:** In the context of the discussion of the PBAC Guidelines, it is the health problem for which the drug is 'indicated' or approved.
- Indirect Cost:** The value of lost production (economic activity) through illness and premature death attributable to the subject disease.
- Markov Model:** A Markov model is a mathematical modeling technique, used in transition matrix health to describe the movement between possible health states over time. The transition matrix, illustrated, defines the probabilities of moving between nominated health states between time interval t and $t+y$.

at time $t+y$

| at time t | health state 1 | health state 2 | health state 3 |
|----------------|----------------|----------------|----------------|
| health state 1 | | | |
| health state 2 | | | |
| health state 3 | | | |

- Net Present Value Cost:** Whereby costs (expected to be) incurred over a future time stream are discounted back to the present (using a suitable discount rate) and summed.
- Optimality:** The concept of Optimality is also known as Pareto Efficiency. An economically efficient (optimal) distribution of resources, is one under which it is impossible to improve the benefits (say health) to any person without reducing benefits to someone else. An efficient economy would necessarily have exhausted all means for mutual gains. In the context of priority setting in health, it reflects the optimal mix of goods and services, with service provision at least cost, (for given level of quality).
- QALY:** The quality adjusted life year, is a measure of benefit commonly used to evaluate health programs, and when compared with cost is known as cost-utility analysis. It combines quality of life and time in each health state, and survival in one measure. Each life year is weighted (by utility weights, such as developed by the EuroQol or AQol) so that its quality can be compared with a year of healthy life. When alternative health programs are compared, the lowest cost per QALY is considered the most efficient intervention.
- Steady State:** This represents the state reached which is on-going. For instance after the introduction of a screening program, a large increase in cases detected is expected, reflecting in part a backlog of undiagnosed cases. After a period

of time, once the backlog of undetected cases are found, incidence should be lower reflecting new cases as they emerge. This is considered the steady state of a screening program.

| | |
|-----------------------|---|
| Technical Efficiency: | Technical efficiency refers to the production of output at minimum resource cost, for a given quality. |
| Marginal: | Marginal means incremental and is used in many ways in priority setting. The marginal program refers to that program which performs either best or performs least well. The marginal patient is the person who would gain most from obtaining the extra service, or lose least from having it withdrawn. Marginal analysis is concerned when the implication of change from the status quo. |
| Utility: | Utility is a term used by economics to represent the 'level of welfare or wellbeing' of an individual. What this might encompass and how it should be measured is variously interpreted. Cost-utility analysis is a more precisely defined concept and refers to the use of cost/QALY as the measure of performance in health program evaluation. |
| YLD : | Equivalent healthy Years Lost due to Disability, which is equivalent to the disability impact (estimated as a severity weight) associated with a nominated health state and time in that health state. When estimating the YLD attributable to a particular condition this is calculated as the incidence of the health condition (disease or injury) multiplied by the average duration of the condition (to remission or death), adjusted for a severity weight, which might be modified for each identifiable disease stage. |
| YLL : | Years of Life Lost, refers to premature death attributed to the subject health problem or risk factor. This might be calculated relative to mean life expectancy, (of the whole population or to the subgroup to which the person belongs – which could be variously defined) or to any nominated age. |

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