

**Disease Based Allocative Efficiency
Framework: Implementation**

Volume II: Full Report

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Reprinted November 1998

March, 1997
ISSN 1325 0671
ISBN 1 875677 69 0

ACKNOWLEDGMENTS

The research reported here has been supported by funding from the Public Health Division of the Department of Human Services Victoria, together with core funding from Monash University, Victorian Health Promotion Foundation and NH&MRC Public Health Research and Development Grant.

The contribution to the broad allocative efficiency research program by officers from the Department of Human Services, through the Steering Committee (initial membership, Dr Rob Simpson, Mr William Hart, current membership Dr Heather Buchan) and direct research input (from Ms Joy Easton and Mr Paul Gyslink) is also acknowledged, as well as research input from the Health Economics Unit, Monash University (Mr Andrew Dalton, Mr George Verikios).

The Allocative Efficiency Research Program

In response to concerns about inefficiencies that can be caused by a distorted health service mix, the Health Economics Unit has a major research stream on allocative efficiency. This paper reports on that research, with a brief description of the Framework for priority setting and its application to diabetes. The Framework has been developed based on economic principles which require that all options be treated equivalently, whether they be for primary prevention, management or end stage care. The Framework ensures the consideration of options outside narrowly defined areas of program responsibility of a single agency. The structure developed is that of a disease based model, which provides a mechanism within which to establish resource priorities to minimise disease burden. In application of the model to diabetes, the overwhelming conclusion is that too few resources are allocated to primary and secondary prevention and health promotional approaches to management, with a consequent higher complication rate than could otherwise be achieved. This is consistent with the distortions expected from a medically focused funding system.

We found the broad structure of the Framework to be workable, and the priority setting task tractable with a modest resource commitment (of perhaps 3 to 6 equivalent full time research staff at senior and junior research fellow level, per disease). Suggested modifications to the Framework largely reflect the extreme paucity of cost-effectiveness and health outcome data. The role of this type of research in contributing to research agendas and priorities for clinical and health services research is perhaps one of the more important conclusions.

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THE DISEASE BASED ALLOCATIVE EFFICIENCY FRAMEWORK

1 The Disease Based Allocative Efficiency Framework

1.1 The Allocative Efficiency Research Program

To date the dominant focus of health economics research has been technical efficiency - the achievement of minimum cost service provision. Relatively little attention has been accorded to allocative efficiency - the achievement of the optimal health service mix. The observed health service mix is the result of a myriad of program based funding decisions, and the supply of individual services funded through Medicare and private payments. There is a pervasive view that the health service mix is highly inefficient and that resource shifts between program areas - program types, health delivery settings, target groups etc., could add substantially to health outcomes within existing health and welfare budgets (Machlin 1991; Harvey 1991; Renwick & Sadkowsky 1991).

The reform of this ad hoc and historically driven system requires a comprehensive approach to priority setting based upon economic principles which is capable of consistent application across the entire health and welfare sector. The objective of the present research program was to develop such a comprehensive approach and to pilot it to determine its practicality. A two stage research plan was developed with i) a theoretical phase, and ii) a practical implementation phase. The primary objectives of the two study phases were:

(i) Theory:

- to document the theoretical principles for allocative efficiency;
- to describe an economic framework or model for priority setting based on the established criteria for allocative efficiency;
- to provide a tool for policy makers to improve decisions about health service priorities - by documenting how the theoretical principles for allocative efficiency could be used to generate a work plan which could be applied in stages to inform decisions about health service priorities.

(ii) Application of the Framework through a case study:

- to demonstrate the practical implementation of the Framework, and techniques for implementation, through its application to a selected disease;
- to fine tune or, as necessary, to make substantial adjustments to the theoretical model;
- to contribute to evidence concerning desirable resource shifts in the disease selected as the case study disease;
- if appropriate, to identify types of resource shifts likely to be more generally applicable.

The purpose of this paper is largely to report on Phase II of the research program, the lessons gained from application of the Framework to the case study of non-insulin dependent diabetes mellitus (NIDDM). Other reports arising from the allocative efficiency work program cover:

- development and documentation of the allocative efficiency framework: a research report published through the Department of Human Services Victoria and CHPE issues paper and journal article (Segal & Richardson 1994a, 1994b, 1994c);
- the role for primary prevention of NIDDM (Segal, Dalton & Richardson 1996);
- the cost of screening for NIDDM and implications for an efficient screening strategy (Easton & Segal (forthcoming));
- the cost of managing diabetes (Dalton & Segal 1996; McCarty, Zimmet, Dalton et al 1996);
- evaluation of diabetes education (Segal 1994; Pirkis & Segal 1996);
- health service funding and delivery arrangements for allocative efficiency (Segal 1996).

1.2 Overview of the 'Disease Based' Allocative Efficiency Framework

The fundamental economic principle for achieving allocative efficiency is that the ratio of marginal benefit to marginal cost should be equalised across all possible interventions. If this condition is not fulfilled then it follows, as a matter of logic, that health gain could be achieved, at no additional cost, by reallocating resources from where the marginal benefit cost ratio is low to where it is high. The

practical application of this principle is daunting: there are an immense number of possible interventions and potential comparisons across the health sector.

A primary objective of the Disease Based Framework was to group potential interventions in a way that permits a staged comparison of marginal benefit cost ratios, and to provide a structured research program which could, over time, cover the entire health and welfare sector. The aim was to develop a Framework that would also maximise effectiveness of research effort. A brief description of the proposed Framework is provided below. More detail can be found in Segal and Richardson (1994a, 1994b, 1994c). We note that the framework, being based on economic principles has elements in common with Program Budgeting with Marginal Analysis (PBMA) (see Cohen 1994, Donaldson & Farrar 1993) and League Tables (Mason et al 1993). It is in the method of implementation, the process for making what is an immense task tractable, that the differences between the approaches emerge. Most importantly, the unit of analysis tends to be different. PBMA is generally focussed on the health agency – with service options restricted to those funded by that agency. While the disease based frameworks takes a societal view, and is not restricted by current health service funding and delivery arrangements. This ensures a wider range of options is considered, and encourages comparisons of interventions across disease stages.

The Framework is described by reference to Figures 1.1 and 1.2 which represent resource allocation across the entire health sector. In Figure 1.1 all possible interventions, actual and potential are grouped by a two way classification: (i) disease category, (and subclass) along the horizontal axis; and (ii) stage in the disease process, from primary prevention through to end-stage or palliative care down the vertical axis. The Framework proposes an initial focus on within cell comparisons, of possible interventions at a single disease stage for the disease under study. This is followed by comparisons between stages within the disease class (that is down a column in Figure 1.1).

Figure 1.1 Health Planning Approach to Allocative Efficiency

Disease Stage	Disease Class and Subclass					Total Resource Use	
	Endocrine Disorders		Cancers	Neuro-logical	Cardio-vascular		Other
	NIDDM	IDDM					
Primary prevention							
Early identification							
Disease management Prevent complications							
Treatment of end stage conditions/Palliative care							
Total resource utilisation							

The analysis within each disease category is illustrated in Figure 2.2. Each of the possible interventions at a disease stage is identified and then ranked using cost effectiveness analysis, to identify the most and least cost effective options at each disease stage. The results of such analyses are represented in Figure 1.2 by $X_{b/w}$ (b=best, w=worst). The initial policy recommendation would be for a shift of resources from least cost-effective (X_w) to more cost-effective programs (X_b), with no change to intra-marginal programs until, with iterative resource shifts, they become the marginal programs.

Comparisons between stages, which are more likely to require the use of more complex cost-utility analysis, would be limited, in the first instance to the marginal interventions. This will be valid provided there are not important differences in utility between programs not captured in the measure of effectiveness. If there is reason to believe otherwise, cost-utility analysis may need to be undertaken at an earlier stage.

Policy recommendations can then be made in relation to resource shifts between disease stages, to reduce resources to the least efficient interventions across all disease stages (D_w in Figure 2.2), and to correspondingly increase resources to the most efficient intervention A_w in Figure 2.2); followed by iterative analysis to identify the next most desirable resource shifts. Finally the analysis is directed across disease classes (and subclasses) at a single disease stage (along a row in Figure 2.1) and ultimately across the entire health sector.

Figure 1.2 Ranking of Interventions

Disease Stage	Less cost-effective				More cost-effective			
Primary prevention						*Aw	*	*
					**	*	*Ab	
Early diagnosis	*Bw	*	*	*				*Bb
Disease management						*Cw	*	*
					*	*Cb		
End stage care	*Dw	*	*					*Db

Notes X_b most cost-effective intervention at nominated disease stage.
 X_w least cost-effective intervention at nominated disease stage.

The focus on a single disease class is proposed for two main reasons:

- (1) It minimises the research effort into the disease process. Economic analysis of interventions targeting early disease stages (including prevention of complications) must normally consider downstream consequences of the disease. The comparison of interventions targeted at different diseases requires information on the epidemiology of each disease. The present model achieves economies of scale, as information gained on epidemiology and disease processes will be pertinent to each of the interventions being studied.
- (2) The Framework overcomes one of the chief defects in current policy, which is the lack of attention to the allocation of resources between stages of disease and in particular the relative resourcing of disease prevention and disease management.

Commencement of research at a single disease stage maximises the likelihood that decisions can be based upon the simpler economic evaluation technique of cost-effectiveness analyses. For cost-effectiveness analysis benefits are measured by a common intermediate health outcome, most likely to be applicable at a particular disease stage.

Implementation of the Framework therefore requires the following steps:

- (i) selection of disease group(s) and subgroup(s) for analysis;
- (ii) description of the disease process and options for interventions, across the full spectrum of the disease progression with primary prevention in healthy populations (and those at high risk), through to palliative care for persons with end stage disease;
- (iii) at each disease stage:
 - identification of intervention options;
 - development of program descriptions;
 - collection of evidence on costs and effectiveness (the latter based on a suitable outcome indicator);
 - derivation of cost-effectiveness estimates for each intervention option;
 - identification of the most marginal programs (least and most cost-effective);
- (iv) comparison of the most marginal programs between disease stages, using epidemiological relationships to translate intermediate outcomes into the same health unit, which may be life years gained or quality adjusted life years;
- (v) development of recommendations concerning desirable resource shifts. Initial recommendations would be based upon comparisons between the most marginal (best and

worst) interventions at each disease stage. Subsequent recommendations would be based upon the next most marginal interventions at each disease stage. This may involve further analysis as these interventions may not have been subject to sufficiently detailed economic evaluation for comparison between disease stages;

- (vi) undertaking of progressive disease management reviews: Stages (i) through (vi) above are repeated until all disease categories have been covered;
- (vii) development of conclusions about desirable resource shifts between disease categories, initially at a single stage in the disease process.

The analysis would ideally be continually updated to reflect new information from health program research and to reflect changes in the cost and effectiveness of interventions associated with resource shifts and changes in health technology, disease patterns and population attributes.

Issues of access and inequality in health outcomes must be simultaneously addressed. The model proposed that in step (iv) above, the economic analysis of marginal programs, the likely implication for equity would be incorporated into the analysis. Where no conflict arises between equity and allocative efficiency, recommended resource shifts would be unequivocal; where they do arise, some consideration of the acceptability of a trade-off between equity and allocative efficiency would need to be made.

In sum, the central features of the Framework are:

- a method for applying the correct economic principles to resource allocation across the entire health sector;
- a method for staging the analysis of all health sector programs;
- the opportunity to apply the relatively efficient (with respect to research effort) technique of cost-effectiveness analyses;
- an opportunity to bring together the range of evidence relating to a particular disease - epidemiology, options for prevention and management, disease progression.

The Framework is based on the premise that all possible health interventions should be judged by consistent criteria. The evaluation of interventions at only one stage of a disease, or delivered through one agency, or component of the health delivery system, or provided through a single funding source, can result in the endorsement of strategies that are 'locally' effective but less cost-effective than alternatives. The inevitable consequence of this is poorer health outcomes for the community from the resources allocated to the health sector.

The Framework does not explicitly address the question of how to achieve the desired re-allocation of health resources. Policy instruments and funding arrangements to facilitate desirable resource shifts need to be explored as a complementary research program.

2 Application of the Framework to NIDDM

2.1 Choice of NIDDM as Case Study

Non-insulin dependent diabetes mellitus (NIDDM), or adult onset or type 2 diabetes, is an important chronic condition in the Australian community. It represents over 85% of all cases of diabetes, the other cases being juvenile onset/insulin-dependant diabetes (IDDM) and gestational diabetes (the temporary appearance of diabetes during pregnancy). NIDDM is characterised by increasing insulin insensitivity (a reduced capacity to efficiently utilise insulin produced by the body). By contrast IDDM is the result of an immune disorder whereby insulin is no longer produced by the body and regular insulin injections are required for survival. The diseases are quite different in aetiology, although many aspects of management are similar. Persons with NIDDM often have co-morbidities of high blood pressure, dyslipidemia (eg high triglycerides) and abdominal obesity. NIDDM develops gradually through a stage of raised blood glucose levels defined as impaired glucose tolerance (IGT). Incidence is highly correlated with abdominal obesity and sedentary lifestyle factors.

There are an estimated 200,000 to 250,000 diagnosed diabetics in Australia plus 80-200,000 undiagnosed cases, representing 3-5 percent of the adult population. Prevalence increases with age, rising from an estimated 2.6% in 35 to 45 year olds, 5.3% amongst 45-55 year olds, 14.2% in persons 65-75 years and 15.9% in those over 75, (McCarty et al 1996). Prevalence within some communities is far higher - for instance amongst aboriginals, persons from the Indian subcontinent, ethnic Chinese, Southern Europeans, persons from the former USSR. Prevalence is increasing, by an estimated 50 percent between 1966 and 1981, and another 50% between 1980 and 1990 (McCarty et al 1996), probably due to an ageing population, greater prevalence of obesity and the changing ethnic mix. This trend is expected to continue.

Diabetes is a major cause of morbidity and loss in quality of life (Simons et al 1996; Phillips et al 1995; American Diabetes Association 1993; Knuiman et al 1986). Diabetes is ranked as the seventh most common cause of death (Australian Bureau of Statistics 1995). It confers an estimated 100% excess annual mortality rate, (Simons et al 1996; Balkau et al 1993). It is an important risk factor for stroke and coronary heart disease, conferring 2 to 4 times greater risk. Retinopathy and associated vision loss is common, with 30% of diabetics showing signs of diabetic eye change which in 30% is vision threatening. Kidney (renal) failure is a further debilitating complication of diabetes. Diabetes is the major cause of renal failure in many communities. Neuropathy or nerve damage is also common and has a wide range of impacts including lower limb amputations (conferring a several times excess risk). Ongoing management of NIDDM and its complications is a substantial burden on both the individual patient and the health delivery system, imposing attributable costs of at least \$1,800 per diabetic per year (Dalton & Segal 1996).

There are a wide range of options for reducing the burden of NIDDM. These span all disease stages; primary prevention for the general population and high risk groups, to screening for early diagnosis, on-going management for prevention of complications, and delivery of end stage care. Programs are (or can be) offered through different health delivery settings, they may involve alternative models of care and a different mix of health professionals. Concern is expressed by

clinicians and others involved with diabetes management that current patterns of care are suboptimal, implying an opportunity to improve health outcomes through an adjustment to the health service mix.

2.2 Structure of Research Plan

Once NIDDM was selected as the case study for testing the applicability of the Disease Based Allocative Efficiency Framework, the general research tasks described in the Framework needed to be particularised for NIDDM. The result of this process is outlined below (Figure 2.1).

Figure 2.1 Application of Allocative Efficiency Model to NIDDM - Research Tasks

Broad Activity	Task
Epidemiology/disease progression NIDDM	<ul style="list-style-type: none"> • Obtain access to key literature on NIDDM, risk factors, normal disease progression, complications, management options • Liaise with epidemiologist and clinicians
Establish the costs of disease management	<ul style="list-style-type: none"> • Directly access primary data sources eg Pharmaceutical Branch data, hospital inpatient data health service use through ABS Health Survey etc, or where primary data sources are not available using the cost attribution model developed jointly by the AIHW and CHPE (Carter 1994)
Primary prevention	<ul style="list-style-type: none"> • Collate data <ul style="list-style-type: none"> – locate and analyse evidence on preventability of NIDDM – identify and classify intervention options – search literature for reports of interventions for prevention of NIDDM – collect descriptions of intervention options, cost and effectiveness • Undertake cost-effectiveness analysis <ul style="list-style-type: none"> – estimate cost/life year gained; – estimate cost/diabetes year deferred <ul style="list-style-type: none"> • for high risk groups, morbidly obese, overweight, high risk ethnic groups, gestational diabetes, the general community, and • by alternative program types; multi-disciplinary ambulatory program, surgical intervention, community based program, media campaign • Draw conclusions and recommendations and report results with respect to <ul style="list-style-type: none"> – the role for primary prevention – relative cost-effectiveness of alternative programs for the prevention of NIDDM – policy implications in terms of resource shifts; the need for pilot programs to test conclusions (or for further analysis at other disease stages)

Broad Activity	Task
Screening/early diagnosis	<ul style="list-style-type: none"> • Preliminary analysis and data gathering <ul style="list-style-type: none"> – consider the possible role for screening; note evidence of lapse between disease onset and diagnosis, and effectiveness of early management – obtain data on screening tests, costs and accuracy – obtain data on prevalence of undiagnosed NIDDM and IGT, in total and by population subgroups • Calculate cost per case identified <ul style="list-style-type: none"> – select assumptions to incorporate in calculations <ul style="list-style-type: none"> * screening protocol * prevalence of NIDDM and IGT * cost concept (whether screening is to be fully costed or at marginal cost), reflecting whether it is a stand alone program or opportunistic, ie tied in with normal visit to GP and additional to other blood test) * whether to include publicity – undertake sensitivity analyses • Calculate cost per final outcome <ul style="list-style-type: none"> – endeavour to establish benefits of early diagnosis and relate to cost per newly diagnosed NIDDM • Develop conclusions and recommendations with respect to <ul style="list-style-type: none"> – the role for screening; (Is it likely that benefits substantially exceed costs?) – the effect of targeting and other program attributes on cost-effectiveness – the optimal screening program (or other research required to determine this)
On-going management	<ul style="list-style-type: none"> • Review the literature on alternative models of diabetes management • Establish a description of alternative care models, and particularly <ul style="list-style-type: none"> – holistic/client education approach to management through protocol based shared care program with – standard care incorporating patient initiated GP/endocrinologist visits • Develop cost-effectiveness estimates for diabetes management based on best available evidence <ul style="list-style-type: none"> – collate material on diabetes management, costs and outcomes – collaborate with primary care providers, undertake cost-effectiveness or cost-utility analyses of alternative approaches to diabetes management • Develop conclusions and recommendations <ul style="list-style-type: none"> – identify attributes that contribute to effectiveness and cost-effectiveness in diabetes management – determine the role for client education compared with traditional approach – consider health funding issues in relation to recommended resource shifts
Management of complications	<ul style="list-style-type: none"> • Establish a suitable basis for classifying complications and incorporating them into the research plan

Broad Activity	Task
	<ul style="list-style-type: none">• Analyse each major type of complication in turn<ul style="list-style-type: none">– from the literature gain an understanding of complications, presentation, progression, options for intervention and cost-effectiveness of alternatives– collaborate with pertinent clinical groups– review<ul style="list-style-type: none">* diabetic foot* neuropathy* kidneys-renal failure* eyes* CVD (cover under general management)

3 Conclusions with Respect to NIDDM

3.1 Introduction

Conclusions about the practicality of the Framework, the implementation and the need to modify the Framework were based upon the application to NIDDM. Thus, prior to describing the general conclusions, an understanding of what was involved in applying the Framework to NIDDM and the key results are presented. This material provides the basis for the more general conclusions presented in Section 5.

The task of identifying desirable resource shifts for the prevention and management of NIDDM was approached, as indicated by the Framework, through a separate research program at each major disease stage: (i) primary prevention; (ii) screening/early diagnosis; (iii) on-going disease management; (iv) prevention of specific complications; and (v) management of end stage care. The results of that research are summarised here. Due to limited research resources more complete analyses were carried out in relation to the first three elements, with only a preliminary analysis in relation to the prevention/management of complications and with no consideration of end stage care. (The cost of management, including end stage care, forms a component of the research into the attributable cost of NIDDM, used in calculating the benefit of primary prevention.) The scope of research was found, however, to be adequate to explore a range of implementation issues.

3.2 Primary Prevention¹

v **Preventability of NIDDM.** Based on disease aetiology and documented intervention programs it is clear that NIDDM is often preventable through reduction in weight, increase in activity levels, improved nutrition. For diet/behavioural change programs a reduction in the incidence rate of NIDDM of 50% (compared with controls) has been found at 5 to 6 years follow-up, even when only a modest reduction in weight and increase in fitness is achieved (Eriksson & Lindegarde 1991). For surgical intervention a reduction in the incidence of NIDDM of 90% has been reported (Long, O'Brien, MacDonald et al 1994).

v **Selection of program options.** A wide range of potential program types for the prevention of NIDDM were identified, covering all health delivery settings, target groups and the philosophy of the approach. Six program types were selected for review to cover the main program options, with two versions of each program; namely programs for general participants and for an all IGT group. Program types analysed were:

- intensive diet and behavioural for the seriously obese;
- intensive diet and behavioural for women with previous gestational diabetes;
- general practitioner based life style program;
- group behavioural for overweight men;
- bariatric surgery (stomach stapling, stomach banding etc) for seriously obese;

¹ A full report has been prepared on the role of primary prevention as a means of reducing the morbidity and mortality impact of NIDDM (Segal, Dalton & Richardson 1996b).

- media life style campaign with community based support.
-

Table 3.1 provides a brief description of program types analysed, together with the primary references from which information about program costs and effectiveness have been drawn.

Table 3.1 Program Types Analysed and Source of Information on Costs and Effectiveness

Program Type	Information Sources
I Intensive Diet and Behavioural Modification	
<i>Initial period of low/very low energy diet, combined with counselling, nutrition advice, delivered by multi-disciplinary team, with 2 to 3 year follow-up</i>	Bjorvall et al 1992 Eriksson et al 1991 Helmrich et al 1991 Kanders et al 1989 Richman et al 1992 Wadden 1993
Target All seriously obese, and seriously obese with IGT	
II Target Women with previous gestational diabetes mellitus (GDM) - mixed group, IGT only	
	Henry et al 1991 Peters et al 1996 Wadden et al 1989
III Surgery for Severe Obesity	
<i>Gastric bypass surgery plus prior counselling and 12 months active follow-up</i>	Long et al 1994 Maclean et al 1993
Target Seriously obese BMI>40, or >45kg excess weight, mixed and IGT group	Pories et al 1992 Sugarman et al 1992
IV Group Behavioural Modification Program for Men	
<i>Incorporating 5 to 6 group sessions: Aim reduction in waist size through modest change in diet and increased activity, through an empowerment philosophy, offered predominantly at the workplace</i>	Egger et al 1996 Erfurt et al 1991 Seidman et al 1984
Target Overweight and obese men - mixed and IGT only	
V General Practitioner Advice	
<i>Healthy life style advice, by specially recruited primary care physicians, supported by printed material, ~ 8 visits in 12 months</i>	Field et al 1995 Reid et al 1995 Salkeld et al 1995
Target High risk adults, BMI>27, plus one other CVD risk factor, mixed group and IGT only	

Program Type	Information Sources
VI Media Campaign With Community Support	
<i>Media campaign across a region of ~4 million people, through radio, television, print media, supported by community based activities, such as phone line, written materials, school/shopping centre based activities etc</i>	Cameron et al 1993 Dwyer et al 1986 Farquhar et al 1990 FNP 1993 Hill et al 1993
Target General population, overweight adults	
Notes: GDM = Gestational diabetes mellitus.	

v **Determination of cost-effectiveness.** Program effectiveness was established through the development of a model (a series of linked Markov sub-models) to follow an intervention and control cohort, through time in order to establish projected diabetic status (normal glucose tolerance, IGT and NIDDM) at five yearly intervals. The difference in development of NIDDM between the control and intervention cohort provided an estimate of diabetes years avoided. Survivors at each 5 year interval were estimated by applying a 3 x 1 mortality transition vector (two for each intervention type), reflecting annual all-cause mortality (ABS 1995) for the relevant age group, adjusted for diabetic status and whether weight loss achieved and followed for 25 years (by applying 5 separate mortality vectors with weight loss adjustment as appropriate).

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 on the literature, discussions with service providers and judgement of the study team. A set of the key assumptions underpinning the cost-effectiveness analyses are listed in Table 3.2.

v **Results - cost/life year gained.** Key results are presented in Table 3.3. These suggest that programs to prevent/delay onset of NIDDM may well be exceptionally cost-effective, with estimated net cost/life year saved of \$000002,600 or less for all the behavioural programs. Three programs were identified to be cost saving (discounted savings in down stream health care costs are greater than the cost of delivering the program); the media program, workplace group program for overweight men and intensive diet/behavioural program for seriously obese persons with IGT. The conclusion we draw therefore, is that the prevention of NIDDM through quality weight control programs, potentially represents a most cost-effective use of the communities health resources.

v **Policy implications.** Access to public sector weight loss services, specifically dietitians or multi-disciplinary weight loss clinics is extremely limited, certainly in Victoria, while surgery, identified as the least cost-effective program type can be accessed through public hospitals.

Table 3.2 Key Program Parameters

Program Type ^(a)	Per Cent Successful ^(b)	Reduced Incidence NIDDM	Mortality of (Relative Risk ^(c))	Mortality (Life expectancy 25 years post program ^(d))		
				NIDDM	IGT	NGT
I Intensive Diet/ Behavioural (Seriously Obese)	33% sustained weight loss	70% reducing to 30% over 25 years	C: 2.5 to 1.5 I: 1.75 to 1.2 over 25 yrs	8 10	9 11	11 12
II Intensive Diet/ Behavioural (Women Previous GDM)	33%	50%	C: 1.75 I: 1.0	19 20	21 22	23 25
III Surgery for Seriously Obese	87% who maintain >50% reduction in excess weight	85%	C: 2.5 to 1.5 I: 1.75 to 1.2 over 25 yrs	8 11	9 12	11 13
IV Group Behavioural (Overweight Men)	33%	50%	C: 1.2 I: 1.0	9 10	10 11	11 12
V GP Advice (Patients with CVD Risk + BMI>27)	20%	12.5%	C: 1.2 I: 1.1	11 11.5	12 12.5	13 13.5
VI Media with Community Support	1%	50%	C: 1.1 I: 1.0	10 11	11 12	12 13

Notes:

- (a) Programs as described in Table 4.1: cohort age at commencement of program 40 to 45 years, except gestational diabetic women where age at commencement 30 to 35 years.
- (b) Success is taken as any sustained weight loss of 1kg or more. Average weight loss not identical across all programs. It is assumed to be at least with the GP style of program. For the surgical program, weight loss defined as 50% reduction in excess weight.
- (c) Relative risk for the control and unsuccessful intervention group relative to all-cause mortality for general population, plus relative risk for NIDDM is 2.0, IGT is 1.6 and NGT (normal glucose tolerance) 1.0
- (d) Given state of NIDDM, IGT or NGT at 25 years post program.
Normal glucose tolerance (NGT)

Table 3.3 Estimated Cost-Effectiveness of Programs for the Primary Prevention of NIDDM

Program Target	Type and	Program Cost Per Participant \$	Participant Group ^(a)	Cost Per Life Year Gained ^(b)	
				Gross Cost \$	Net Cost \$
I	Intensive Diet/ Behavioural (Seriously Obese)	2,500	IGT only	4,200	Saving
			10%IGT 90%NGT	5,900	2,600
II	Intensive Diet/ Behavioural (Women Previous GDM)	2,500	IGT only	4,400	1,200
			25%IGT 75%NGT	4,600	2,400
III	Surgery for Seriously Obese	13,300	IGT only	12,100	4,600
			10%IGT 90%NGT	19,100	12,300
IV	Group Behavioural (Overweight Men)	195	IGT only	500	Net saving
			IGT only (S)	1,600	Net saving
			10%IGT 90%NGT	700	Net saving
V	GP Advice (Patients with CVD Risk + BMI>27)	420	IGT only	3,000	1,000
			10%IGT 90%NGT	3,200	2,600
VI	Media with Community Support	\$1 million per year for 2 years	mixed population	500	Net saving ^(c)

We are unaware of any publicly funded prevention programs specifically targeted at persons at excess risk of NIDDM, in Victoria. (In fact diabetes education services may be prevented from offering their education program to persons with IGT with the possibility for prevention of NIDDM, due to excess demands on their limited service). This is neither consistent with principles of equity and obligations to minimise avoidable health inequalities and reasonable access. Nor is it consistent with efficient use of the communities health resources.

A focus on NIDDM prevention by Public Health Units would seem to be warranted, with the object of reducing the incidence of NIDDM (or slowing the rate of increase). Support for research into the costs and effectiveness of alternative intervention options, to test the preliminary conclusions derived from our research is also desirable.

The lack of intervention options from which to derive evidence on costs and effectiveness meant there was no choice but to describe 'representative' interventions and adopt indicative values for costs and effectiveness. The present analysis suggests the highest priority for further research should be: (i) intensive multi-disciplinary behavioural program for women who have had gestational diabetes and for seriously obese persons possibly targeted at those with IGT; (ii) support to existing community/work place based obesity control/life style modification programs to engage in follow-up and formal evaluation; and (iii) funding of a media campaign.

The recent inclusion of diabetes in the National and State Goals and Targets, and the Commonwealth Government allocation of funds for innovative programs for NIDDM prevention, screening or management, should assist with the achievement of this recommendation.

3.3 The Role for Screening

There is clear evidence that often a significant delay occurs between disease onset and diagnosis of NIDDM, with published studies indicating at least a 4 to 7 year delay (Harris 1992). Patients often present at diagnosis with diabetic retinopathy, a complication only of diabetes, and evidence of other complications of NIDDM. Screening to achieve earlier diagnosis and more timely management has thus been proposed.

An analysis of screening options to develop an estimate of screening costs, in terms of case finding has been undertaken as part of this research program (Easton & Segal 1996). Access to suitable data has proved a problem, with important information gaps relating to the accuracy of screening tests for diabetes (sensitivity and specificity), the prevalence of NIDDM (known and undiagnosed) and IGT amongst the population as a whole and population subgroups, and the possible effect on disease progression of early case finding. These information gaps seriously undermine attempts to assess the cost-effectiveness of screening.

Cost per case of NIDDM (and IGT) identified was estimated using a spread sheet model. The cost of screening tests based on recommended screening protocols (WHO 1985)) were combined with unit test costs based on the Medicare Benefits Schedule. The model incorporated assumed prevalence rates for undiagnosed NIDDM and IGT in population subgroups based on best available information. The results are summarised in Table 3.4, which shows cost per new case of NIDDM

diagnosed of between \$1,200 and \$3,250 on a full costing base, or between \$80 and \$170 on a marginal cost basis. (Cost concepts are defined in notes to Table 3.4.) 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 new case identified of NIDDM or IGT is lower, due to the expected higher case finding rate. It is estimated at between \$300 and \$800 on a full costing basis or \$40 to \$60 on a marginal cost basis.

Table 3.4 Screening: Indicative Cost(a) (Dollars) Per Case of NIDDM/IGT Identified

Adults 45+	Target Group (Assumed Prevalence)	Screening Cost Per Case Identified ^(b)		
		Full Cost \$	Partial Cost \$	Marginal Cost \$
Population 45+	Undiagnosed NIDDM (2.06%)	3,252	1,822	170
	+ IGT (6.65%)	792	454	63
+ BMI>30	Undiagnosed NIDDM (3.56%)	1,895	1,067	111
	+ IGT (11.5)	471	275	49
+ Italian born	Undiagnosed NIDDM (3.5%)	1,927	1,084	112
	+ IGT (11.3%)	479	279	49
+ Italian born and BMI>30	Undiagnosed NIDDM (5.7%)	1,190	675	80
	+ IGT (18.4%)	305	183	42

Source: Easton & Segal (forthcoming).

Notes:

(a) No allowance has been made for any cost of advertising/publicity.

(b) The initial screening test is fasting blood glucose, glucose tolerance performed as a confirmatory test. It is assumed that the pathology test is conducted by a pathology centre or at a cost which is 10% higher if undertaken by a GP.

Full cost Assumes patient attends GP specifically for screening test.

Partial cost : Assumes patient attends GP for some other reason.

Marginal cost: Assumes patient attends GP for some other reason and another blood test is independently ordered.

A screening program targeted at communities with the highest prevalence of undiagnosed NIDDM and IGT will be the most cost-effective, unless it is substantially more costly to achieve adequate participation rates. This presupposes some knowledge of relative prevalence. The analysis highlights the cost advantage of adding screening for diabetes to a visit already being made to the GP for another reason, and more so if a blood test is to be ordered independently. An indiscriminate screening program could prove extremely costly (possibly in excess of \$65 million to screen all Victorians over 45 years of age) with health gains achievable being uncertain.

Conclusions cannot be drawn about whether screening represents an efficient use of scarce health resources without evidence on the benefits from screening. Despite this, the value of screening for NIDDM in terms of the hypothesised delay in disease progression through early diagnosis has not been established. In relation to IGT, our research into the benefits from primary prevention, suggests that screening for IGT combined with strategies for preventing NIDDM may well prove highly cost-effective.

To establish the benefits from screening for NIDDM, information is required on the extent to which screening can reduce the delay between disease onset and diagnosis and any effect of earlier management on health outcomes. While, it is generally agreed that best practice management can reduce associated morbidity and mortality, the nature of the relationship between management and health outcomes is not well established. In the absence of firm evidence, the issues can be explored through a scenario development exercise, to indicate the likelihood that screening for NIDDM may represent a valued use of the communities health resources. Such an exercise is reported in Figure 3.1.

In the absence of direct evidence of the benefits of screening gained from clinical trials, it is not strictly possible to establish that a screening program is worth while. Some preliminary conclusions can, however, be developed:

- 1 A comprehensive NIDDM screening program for all adult Victorians 45 years and older would cost an estimated \$3,252 per case found (full costing) and is unlikely to be cost-effective.
- 2 A screening test for NIDDM in high risk individuals (defined by age, overweight, ethnic group, family history) is most likely to be cost-effective, especially if the test can be provided at partial or marginal cost; that is, where individuals are:
 - already presenting to a GP for some other reason; and
 - receiving a blood test for some other purpose.
- 3 In combination with a program for the prevention of NIDDM, screening of high risk groups to identify those with IGT for prevention, (and NIDDM for early management) is likely to be cost-effective and should be encouraged.

Figure 3.1 Prefeasibility Exploration of the Role for Screening

Evidence	<ul style="list-style-type: none">• NIDDM results in 1 to 10 years reduction in life expectancy depending on the age at diagnosis and gender (Stengard et al 1992; Panzram 1987; Drenick et al 1980). Differential annual all-cause mortality has been estimated at 100% for persons with NIDDM (Simons et al 1996).• The time between disease onset and diagnosis is estimated to be at least 4 years in Australia (Harris et al 1992).• The most common age of diagnosis is 60-75 years.
Scenario	<ul style="list-style-type: none">• If we assume that the average time persons will live with NIDDM is 10 years from diagnosis or 14 years from disease onset, this would mean that typically 29% of the time a person has NIDDM it is undiagnosed and untreated.• If it is assumed that more timely management would reduce loss in life expectancy by 5%, this would extend life by 0.6 to 6 months.• Based on partial cost per new case of NIDDM identified (counting cost of blood test but not the GP visit) of \$400-\$800, the cost per life year saved would fall within the range of \$800 to \$16,000.
Conclusion	<ul style="list-style-type: none">• Under some sets of assumptions, screening for NIDDM will be highly cost-effective, and under other assumptions less so. However, while more evidence is desirable we can conclude that where NIDDM can be identified at low unit cost, through opportunistic screening, and by focussing on those with an elevated risk of NIDDM, this will be very likely to be cost-effective.

3.4 Diabetes Management

Specification of intervention options for diabetes management proved complex. The management of NIDDM is individualised, with each patient accessing a particular mix of health services and providers; including GP's, specialist (endocrinologist, ophthalmologist, cardiologist etc), allied health professionals (dietitian, podiatrist, nurse educator), self help groups etc. A decision was made to focus on two distinct philosophies of care: (i) the medical model of patient care provided through GP and physician visit; and (ii) the patient empowerment model, where medical care represents part of a multi-disciplinary approach, and where the focus of management is the achievement of effective patient self care. A third element of management, the development and active dissemination of protocols for management, was seen as complementary to both approaches.

Research proceeded through a literature review covering the role of diabetes education in the management of NIDDM (Gifford & Zimmet 1986; Kaplan & Davis 1986; Mazzuca et al 1986), GP management of NIDDM (Diabetes Integrated Care Evaluation Team 1994), the activities of ambulatory care centres and comprehensive models for diabetes management, such as the Maryland Diabetes Care Plan (Constantino et al 1994; Stuart 1994). Collaborative research was also undertaken with health service providers and included an evaluation of the Brunswick Northcote Community Health Centre Diabetes Education Program (Segal 1994) and the Otways Division of General Practice Diabetes Shared Care Program (Pirkis & Segal 1996).

This research has progressed to the point where provisional conclusions can be developed concerning the relative performance of alternative approaches to on-going diabetes management, although we have not completed a formal cost-effectiveness analysis of all the alternatives. The broad conclusion is that best practice management incorporating diabetes education and preventative care and effective patient self care represents more cost-effective care than a more narrowly focused, reactive, medically based care. Recommended protocols (NSW Health Department 1996) incorporate the scheduled use of appropriate services, such as diabetes educators and dietitian, to improve blood glucose control through more healthy behaviours, as well as appropriate medication, podiatry services, eye checks, etc. These have been shown to reduce the rate of complications and have the potential to reduce the high costs of end stage disease management for renal failure, foot ulcer management, lower limb amputation and stroke. In relation to diabetes education and patient empowerment, the literature and the collaborative studies undertaken as part of this research program support the effectiveness of diabetes education in improved patient knowledge, adoption of more healthy behaviours, improvements in clinical parameters, and improvement in perceived quality of life, at modest cost for the results obtained.

Further evidence on the costs and effectiveness of best practice/patient empowerment model of care are to be collected as part of a joint NSW Department of Health, Commonwealth Government initiative to implement and evaluate a program of best practice shared care for diabetes (known as the Diabetes Integrated Care). The aim is to establish the impact on health outcomes and resource use, immediate, downstream and longer term, of a comprehensive protocol driven shared care approach to the management of diabetes.

The services needed to implement best practice protocols are to be made available, with extra resourcing of multi-disciplinary ambulatory care centres where needed. At the completion of that study, which is being undertaken in three regions of Sydney, it should be possible to define the elements of a cost-effective approach to diabetes management.

3.5 Prevention of Complications

Complications of diabetes fall into several major categories, specifically:

- cardiovascular disease: resulting in heart attack and stroke;
- neuropathy: eg resulting in foot problems (ulcers which fail to heal), impotence;
- eye damage: resulting in vision impairment and blindness;
- kidney failure: requiring dialysis;
- greater infection rate: particularly among aboriginal communities;
- direct complications: hypo/hyperglycaemia.

There is evidence that complications of NIDDM can be reduced through appropriate management of NIDDM to achieve good glycemic control and through control of other risk factors and comorbidities such as smoking, hypertension, high cholesterol, obesity. There is also a range of strategies specific to each class of complication which can reduce the rate of progression of NIDDM and impact on morbidity and mortality. These specific strategies can be analysed separately.

Full implementation of the Framework would involve the description and analysis of the options for minimising harm in each of these areas. However, with the research resources available to the study, and the lack of pertinent published data, this has not been possible. Based on a review of the literature covering the major areas of complication, some preliminary insights have been gained.

Specifically, we identified reports in the literature on program options, costs (very few) and outcomes for the management of foot problems, diabetic eye disease, renal impairment, and cardiovascular disease in diabetics. Broadly, this review suggests that best practice protocols in all these areas, which generally place substantial emphasis on preventative care and greater self care, will also be most cost-effective. The complications potentially avoided or delayed, such as recurrent foot ulcer and lower limb amputation, end stage renal failure, and stroke, are not uncommon in this patient population (especially if poorly managed). They represent a major loss in quality of life, and are associated with substantial excess mortality and high costs of management. There is good evidence that preventative care, of the type recommended in best practice guidelines, will improve health outcomes, while reducing a range of health care costs. Thus, such an approach may even be cost saving, or involve relatively low net costs for the benefit achievable.

Cost-effectiveness is most well established in relation to:

- (i) screening and surgery for diabetic eye disease (Fendrick et al 1992; Dasbach et al 1991);
- (ii) preventative foot care, through regular complications screening, use of podiatry services and specialised foot clinics for persons at high risk (Edmonds et al 1986; Barth et al 1991);
- (iii) the use of ACE inhibitors to reduce rate of progression in renal failure (Melbourne Diabetic Nephropathy Study Group 1993; Lewis et al 1993); and
- (iv) modification of comorbidities and unhealthy life style attributes (especially smoking) in relation to high rates of cardiovascular disease.

Detailed research has not been completed to establish, within the broad management options, the most cost-effective intervention strategies for particular population subgroups. For example, while screening for diabetic retinopathy is demonstrated to be effective and cost-effective, the most cost-effective way of increasing screening rates has not been established. Options might include direct mail to persons known to have diabetes supported by a mobile screening unit, and publicity to GP's to achieve wider acceptance of protocol based care. Similarly, with foot care, while preventative care is demonstrated to be highly effective and probably most cost-effective, the precise nature of the most cost-effective programs has not been determined, (for example frequency of podiatry visits, how best to target podiatry services, and the precise role for specialised foot clinics).

To resolve these questions an on-going research agenda is required, ideally linked into more comprehensive data collection from normal clinical practice.

4 Conclusions with Respect to the Disease Based Framework

The NIDDM case study was undertaken to test the Disease Based Framework and, in particular, to identify implementation issues and to determine the Framework's capacity to draw conclusions about priorities for disease prevention and management. As a result of the case study we also identified some aspects of the Framework which should be modified. The Framework was successful in several important respects. In particular, it focused attention upon the issues relevant to the maximisation of health gain from limited resources. In doing so it highlighted, rather than avoided, the very serious dearth of evidence concerning the key parameters.

4.1 Information Requirements and Prioritisation of Research Effort

The Framework ensures a focus on the questions that are important to priority setting. It can provide clear guidance for the research agendas of clinical and scientific communities, highlighting the type of information needed for policy purposes. Despite the enormous and ever increasing health and medical literature, surprisingly little is of use for priority setting. The importance of this conclusion should not be underestimated. Because of the lack of information relevant to correct decision making, alternative priority setting methods (such as goals and targets, needs-based planning), have been adopted, which do not have the information requirements, but which are also unsatisfactory (see Segal & Richardson 1994b). This has deflected the focus of attention away from the important questions and the collection of critical information.

The types of information most urgently needed relate to:

- (i) *epidemiology*: normal disease progression, incidence and prevalence of disease (total and for sub-populations), disease specific morbidity and mortality (total and by population subgroups); alternative patterns of management on morbidity and mortality (in total and for population subgroups);
- (ii) *intervention options*: identification of the full range of possible ways for minimising morbidity and mortality, including prevention and management, and for each option costs (or cost savings) and effectiveness in terms of the impact on disease prevalence and incidence and immediate and ultimate health outcomes. This requires a more wide ranging clinical trial research program(not so focused on drug interventions or medical technology), but also greater access to meaningful data from normal clinical practice.

The Framework provides a focus for the collation of evidence on a range of aspects to do with a particular disease: clinical, epidemiological, health status, resource use, which are necessary for evidence based decision making. It enables major information gaps to be more readily identified to provide a sound basis for a research agenda to address the most critical information gaps.

4.2 Capacity to Draw Robust Policy Conclusions

Despite the above, an important lesson from this case study is that while the appropriate information and research evidence is not always available, it may be possible to derive robust conclusions from cost effectiveness analyses based on limited and/or indicative data. The application of scenario development and modelling cannot be avoided and some uncertainty will remain. This is particularly so if the aim is to express effectiveness in terms of final, rather than intermediate, health outcomes. The use of modelling incorporating best estimates for parameters, together with sensitivity analysis, is then an essential analytical tool.

The capacity to draw conclusions about resource priorities, in the face of incomplete evidence and prior to the completion of the analyses at all disease stages, will depend upon whether:

- (i) *Outcomes can be expressed in terms of ultimate health objectives* specifically life years gained or quality adjusted life years.
- (ii) *Options are highly cost-effective.* This is the case where health gain is generated whilst simultaneously reducing health service cost (due to projected savings in downstream costs of management). With this outcome the desirability of program expansion is unequivocal. (We found a number of programs of his type and think it unlikely that this result is unique to diabetes. Preliminary work on the cost-effectiveness of prevention of colorectal cancer suggests the possibility of downstream savings in excess of program costs here.)

A similar conclusion can be reached if it is estimated that the cost/life year gained is very low. While there is no economic principle or consensus governing the value of a life year, a conservative judgement can be made, in relation to low cost, highly effective programs. For instance, a non competitive program yielding a cost per life year saved of less \$5,000 would be said to represent a worthwhile use of the communities resources, based on the presumption that a life year has a value greater than \$10,000. Such a conclusion could be drawn without the need to consider cost-effectiveness of possible alternative interventions at other disease stages.

- (iii) *Options are cost ineffective.* Where it is estimated that cost/life year gained is extremely high (say greater than \$150,000), or where a review of the literature indicates health outcomes are invariably negative, clear conclusions can be drawn about the desirability of contracting such programs.

4.3 Implementation Issues

v Role for Collaborative Research and Pilot Implementation of Recommendations

While the published literature is the major data source on intervention options and costs and effectiveness, this was found to be inadequate and had to be supplemented by access to internal reports of health service providers and original collaborative work with health service providers. The need for primary data collection can substantially increase the research effort and time required to complete a priority setting program.

The limited literature, and especially with respect to studies where outcomes are taken to meaningful health end points, is extremely disappointing and highlights a major limitation in worldwide research agendas. Because of this, the final recommendations of a priority setting exercise may be for the implementation of suggested pilot studies, in order to gain more evidence to test, what can only be, preliminary conclusions of the cost-effectiveness analysis. This represents a departure from the initial expectation of the model which envisaged recommendations for a significant redeployment of resources from one program area to another. Because of the paucity of evaluation data, an intermediate research stage may be unavoidable, to provide further information on costs and effectiveness.

We note that this conclusion is not limited to diabetes. Current application of the Framework to options for the management of hypertension, an extremely well studied area, is similarly encountering limitations as a result of the paucity of published cost-effectiveness analyses and the limited scope of intervention types for which data are available. For instance, the possibility of intermittent therapy with anti-hypertensive agents (supported by appropriate life style advice) does not seem to have been the subject of clinical trials, despite preliminary analysis which suggest this may well be highly cost-effective.

v Selection of the Health Outcome

The health outcome attribute chosen as the primary measure of effectiveness is critical. It determines the capacity to draw conclusions about priorities beyond the disease stage. Ultimate, or final health outcome, specifically life years or quality adjusted life years gained is the preferred measure of effectiveness, allowing comparisons across a diverse range of programs, disease stages and across the health sector. By contrast intermediate outcome measures (eg blood pressure, weight, new cases diagnosed, effect on the tumour) provide for a far more limited scope for comparison. Despite this, most clinical trials express results in terms intermediate health outcomes. The capacity to use final rather than intermediate health outcome measures depends on either access to clinical trial results expressed in terms of final health outcome or a confirmed relationship between the intermediate outcomes measure(s) and final health outcomes.

Intermediate health outcomes enable a ranking of programs directed at a specific intermediate objective. For example, the percent of the population screened in a sensible intermediate outcome where the intermediate objective is the implementation of a screening program. The use of such intermediate outcomes will be most appropriate where there is a wide range of directly substitutable

interventions and a well established view that some services must be offered, to meet the nominated intermediate health objective.

These outcome measures cannot, however, establish whether a program should be offered at all, or at what level, unless the intervention is so overwhelmingly advantageous as to generate health gain while achieving a saving in net health care costs to warrant program expansion, or if the program is deleterious in which case cessation is clearly appropriate. Normally, conclusions concerning desirable resource shifts ultimately require translation into final health outcomes.

v Definition of Program Options

A central task of the Framework is the identification of the full range of intervention options for improving health gain in relation to particular diseases. The steps nominated for developing this list proved to be workable, but substantial judgement was still required. The suggested steps are:

- (i) Gain an understanding of disease - incidence and prevalence, rates of disease progression, risk factors etc.
- (ii) Define opportunities to intervene by disease stage based on theoretical possibilities and a consideration of current service provision.
- (iii) Develop a classification system pertinent to the disease and disease stage to incorporate possible intervention attributes. For example, the classification could include:
 - the target group - population or high risk group, with sub-populations reflecting issues, highlighted in the clinical and epidemiological literature, (eg age, ethnicity, family history, co-morbidities, socio-economic status, lifestyle attributes);
 - the health delivery setting (eg hospital-in-patient, out-patient; community-health centre, patient's home, private rooms, residential care facility);
 - the health professional and whether a single professional or multi-disciplinary team is employed;
 - the philosophy of care (eg empowerment, traditional);
 - the approach to care (behavioural, surgical, drug, etc).
- (iv) Make a selection of program options for review: to include a wide range of program types, whilst keeping the total number of options manageable. Ideally the list would include programs which are commonly available, (including some thought not to be cost-effective), as well as possible new programs, (preferably those expected to be highly cost-effective). Access to information from which to develop program descriptions and estimates of program costs and effectiveness may also need to be considered.

Where there is an extremely large number of potential program types, it may be necessary to collapse the alternatives into a smaller number of manageable options. Even where the number of

broad program types is not excessive, within each broad program type there are likely to be innumerable possible variations (substantial or subtle) in program characteristics. Selection of the particular version of each program type for review should be guided by a preliminary prefeasibility assessment to identify the attributes likely to constitute the marginal programs (most and least cost-effective). This 'first cut' should be made as explicit as possible. The inclusion of options which reflect documented 'best practice' and 'common practice' is desirable due to likelihood of available information, interest from clinicians and policy makers in their cost-effectiveness, and the possibility of these forming marginal programs.

v Other Issues

An important insight gained through the application of the model is that intervention options will often be interdependent and not perfect substitutes. Even interventions with the same objective may well be differentially suited to various population subgroups, or complement each other in such a way that health gain will be maximised if they are implemented together. For example, in relation to the primary prevention of NIDDM the least cost, most cost-effective strategy is not highly effective, and a suite of interventions is likely to represent the desirable solution, with, for example, a media campaign which has the potential to be highly cost-effective (but with limited total effectiveness), supported by other direct interventions. This suggests a hierarchy whereby patients are referred initially to lower cost intervention strategies (such as a dietitian), and then moving to higher cost options (intensive behavioural program) if the lower cost program fails to achieve the desired result, and finally to the highest cost option (stomach banding). In theory, the process is iterative, with resources allocated to the most cost-effective program first, but as program size increases marginal cost-effectiveness ratio is expected to fall such that eventually the next option becomes more cost-effective, and so on. In practice a decision is likely to be made at the same time about allocating resources to a suite of programs, guided by the average cost-effectiveness ratios, at current activity levels such that progress with cost-effectiveness ratios below a certain level, would be supported.

All program options will not be strictly competitive and especially when they are directed at different population subgroups. Differentiation may be based on a region, an ethnic grouping, or upon patient gender. Only programs which can be targeted at the same subgroup represent true substitutes. As a consequence, a number of options directed at the same objective may all form part of the optimal set, even if they yield different cost-effective estimates. This conclusion would not apply if issues of equity and access were irrelevant. (Reasonable access by all to health services on the basis of care needs and reduction of avoidable health inequalities (to ensure an acceptable average standard of health for all groups) are fundamental requirements of the health sector.

The specification of intervention options is likely to be a far more complex research task than initially envisaged. In defining program choices, the capacity to consider options for specific sub-populations is important to meet both equity and access objectives as well as for allocative efficiency.

4.4 Suggested Modifications to the Framework

It is clear that health service options may often need to be defined in the context of patient or population subgroups. This reflects equity and access as well as efficiency issues. Equity in health cannot be achieved by income transfers through the social security system, but must be built into service provision. Health gain cannot be traded across individuals or over time. Death is final. A program which denies health improvements to some but enhances the health of others cannot achieve redress through income transfers. Health is a primary or ultimate component of quality of life. Unlike most consumer goods and services which are indirect contributors to individual wellbeing. Thus in relation to health, unlike other goods and services the equity issues cannot be addressed as a subsidiary matter. We thus propose that equity, be included explicitly via definition of sub-populations and consideration of intervention options for each sub-population. Equity and access are a fundamental objective of the health sector. Achieving increased total community health by redirecting resources away from disadvantaged groups is unlikely to be considered acceptable.

There is evidence that some programs work best with particular subgroups. This also supports the need for subgroup analysis. Rather than determine in advance which programs will best service which groups, the 'market solution' would be to increase choice and responsiveness in the service system, so that individuals can select from a range of program options that are most relevant to their circumstances. This does not imply that everything is provided irrespective of cost-effectiveness, but that the optimal solution is likely to include a range of services. The efficiency question then becomes for each population subgroup, how can resources be allocated to maximise health and welfare status, and with no expectation of a single intervention providing the answer to that question.

This suggests a revision to the initial health sector classification structure. Once a disease has been selected for review the description of intervention options and cost-effectiveness analyses should explicitly take account of relevant subgroups. This does not necessarily imply the separate application of the model for each sub-group. Rather the special characteristics of each sub-group should be considered explicitly and the applicability of the general conclusions considered for each subgroup. When special characteristics invalidate the general conclusions then a separate analysis may be necessary with recommendations specific to each subgroup.

v Non-hierarchical Priority Setting

An expectation of the model, explicitly stated in the theoretical paper was the development of a hierarchy of health interventions with interventions ranked from more to less cost-effective. (see Figure 1.2). This was to apply, ultimately, at each disease stage, across disease stages, and across the health sector.

While differential cost-effectiveness estimates can be calculated these should not, or rather cannot, be used to suggest a simple hierarchy in interventions. This point also follows from the discussion of identifiable sub-groups and the fact that interventions are not, generally, perfect substitutes for

each other. It may be the case that a less cost effective option may be justified after a more cost effective option has failed that patient. Decision making should **always** be guided by cost-effectiveness ratios, at the margin, that is reflecting performance associated with a small increase or decrease in service level. For most (if not all programs) average and marginal cost-effectiveness will not coincide along the full range of possible service levels, service attributes, target populations. Typically performance is likely to worsen as programs expand and are extended to groups for whom the indication for the intervention is weaker.

Thus categorical resource allocation decision making constructs of the form: Only those interventions with an average cost-effectiveness ratio below \$X should be funded and that programs with an average cost-effectiveness ratio above the 'cut-off' funding should be withdrawn, (a common interpretation of QALY league tables) are not always appropriate.

In short it is not likely that application of the Framework will result in a simple hierarchy of services and an arbitrary cut-off to select programs that are 'in' and others that are 'out'. Rather, the aim should be to identify interventions to be expanded and those to be contracted, the circumstances in which services should be used, and only sometimes to identify services to be abandoned.

An additional step in the Framework is therefore:

- (i) to determine whether particular interventions are absolutely dominated and unambiguously less cost-effective than an alternative for a particular population sub-group;
- (ii) to consider whether there is an intervention protocol, in which the most cost-effective option is employed first, with the more expensive option made available after failure of the first option, provided the latter option has an acceptable marginal benefit cost ratio, (as defined by society);
- (iii) to consider, the possibility that programs may be complementary, such that health gain is maximised through joint provision of a number of strategies be considered.

These factors suggest that the optimal solution may involve the provision of a wide range of service options that can be targeted appropriately to particular population subgroups. The level at which services are to be provided can only be established iteratively, after redistribution has occurred and requiring an on-going program of cost-effectiveness analyses.

v **The Two Stage Process**

The Framework proposes a two stage process of: first indicative cost-effectiveness analyses, and second a more comprehensive cost-utility analysis of the most marginal (best and worst) programs. This presupposes reasonable access to a cost-effectiveness literature or at least adequate information from which to develop estimates of cost-effectiveness suitable for developing a provisional ranking of programs.

Based on the literature we have reviewed (eg prevention, screening and management of NIDDM; prevention of colorectal cancer; management of advanced breast cancer; management of hypertension) evidence is not necessarily adequate to allow even indicative estimates of cost-effectiveness to be developed. A more substantial initial research effort, involving collaborative research with service providers and/or scenario development with modelling is required for even preliminary cost-effectiveness estimates to be developed across a range of interventions.

The logic of the Framework and the two stage procedure remains intact, but its practical application is limited by these gaps in the literature and the imperfect substitutability of options. A three stage research process is now suggested. The first, described earlier is to identify possible marginal interventions either by an explicit review of the literature, by the conduct of indicative cost-effectiveness analyses, or, as a last resort, a more subjective/preliminary review reflecting best and common practice and clinician views on the relative effectiveness of options in combination with a simplified costing exercise. The second stage is the more substantive research effort, namely to establish robust cost-effectiveness estimates, using final health outcomes (life years or QALYs) where possible. As a result of the paucity of evidence, the second stage is likely to include a number of indicative analyses, which can at best result in a recommendation for the introduction of pilot programs. This then requires a third stage in which the programs are re-examined through additional evidence gained from the pilot programs.

v Iteration of the Analysis

The iterative process recommended in the model for identifying the most marginal programs (least and most cost-effective) and then assuming resource redistribution and establishing the next most marginal programs while theoretically correct, has no practical relevance in cases where there are few established programs and where these are not close substitutes. The iterative process will be most relevant where existing (or potential) programs are numerous and competitive.

Most of the resource shifts indicated as desirable will be difficult to achieve without a change in health service delivery and funding arrangements. Distortions in the health service mix reflect predictable distortions in funding and health service delivery arrangements (eg see Segal & Richardson 1994b). A complementary research program into health service delivery and funding arrangements that support rather than frustrate resource movements consistent with allocative efficiency is required. Unless health service delivery and funding arrangements are changed, the distortions responsible for the inefficiencies in the health service mix will remain and continue to provide perverse incentives.

4.5 Final Comments

With some qualifications the disease based Framework has provided a structure within which to generate important conclusions about resource priorities. This is primarily because of the economic perspective that it adopts and consequently its focus upon costs and outcomes at the margin. It is also because of its focus on a particular disease which, while highlighting major data deficiencies, also provides a context for the collation of the available evidence on a particular disease. It is truly astonishing that, with the amount of medical/clinical scientific research world wide and the sheer

volume of the medical literature, how little is known that is relevant to resource allocation for health. None-the-less, despite the data limitations the Framework has allowed conclusions to be drawn regarding priorities in diabetes resource allocation and research.

The chief qualifications to the Framework arise, firstly, because of the paucity of published data with respect to interventions (their costs and effectiveness and effect on disease progression) and, secondly, due to the need to accommodate the possible complementarity of health interventions.

The chief practical consequence of these changes is that where it is not possible to carry out the envisaged first stage of an indicative ranking of options using the literature then preliminary cost-effectiveness analyses must incorporate assumed values informed by the available evidence (including discussions with clinicians). Where no programs exist it is necessary to conduct indicative analyses based on hypothetical programs.

Perhaps the most important conclusion from this research is that the magnitude of the task is tractable. The results reported here (and elsewhere) were based upon the efforts of a small research team of 0.5 EFT senior research fellow, and 0.6 EFT research fellow/research assistant, over 3 years. This is a modest commitment and indicates that implementation of the Framework could be replicated for other disease categories within existing research budgets. The present research has demonstrated the practical benefits of the Disease Based Framework and its potential for achieving significant health gains through a reallocation of resources. The Framework could be used to develop a productive research agenda, for the on-going review of health interventions which could eventually encompass all classes of disease.

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