CENTRE FOR HEALTH PROGRAM EVALUATION

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# The Cost-Effectiveness of GP Led Behavioural Change Involving Weight Reduction: Implications for the Prevention of Diabetes

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# ABSTRACT

The purpose of this paper is to examine from a societal perspective, the relative cost-effectiveness of diabetes prevention through promotion of behavioural change by GPs, compared to current GP practice. For policy and practical relevance, the initiative is examined as a stand-alone program, as well as nested within the context of a public health program for the reduction of cardiovascular disease(CVD). The 'piggy-backed' design reflects the joint risk factors shared by non-insulin dependent diabetes mellitus (NIDDM) and CVD, together with significant cost savings and, potentially, improved rates of participation and adherence. Results are compared to recent cost-effectiveness findings for NIDDM prevention through media campaigns and other settings (weight loss clinics and the workplace).

## Methods

A hypothetical NIDDM program is evaluated, where estimated costs are based upon recent trials of multiple risk factor reduction programs in Australia. Program effectiveness in reducing Body Mass Index (BMI), the impact of that weight reduction on the incidence of NIDDM, and the associated mortality effects, are drawn from a survey of studies reported in the literature on dietary and lifestyle change. The value of health care savings from a fall in NIDDM is estimated and deducted from program cost to provide an estimate of the net cost of the NIDDM initiative. Central to the methodology is disease modelling incorporating the literature findings. A simple Markov model has been utilised, which includes age specific all-cause mortality estimates adjusted for overweight and metabolic status.

Available evidence on current practice suggests that preventive care within GP consultations is provided to approximately 22% of those who are overweight (BMI $>$ 24.9), with verbal advice being the most usual approach. Screening for associated pathology occurs infrequently, either for cholesterol levels (6% of eligible patients) or NIDDM (25% of eligible patients). The benefits of current weight related preventive activity are assumed to be reflected in the current incidence of NIDDM. The annual cost of care for current cases of NIDDM has been estimated at $1,800 per patient. The costs and benefits of current practice are deducted from the costs and benefits of the NIDDM program to provide the incremental impact of the new initiative.

## Results

Using a 5% discount rate, net incremental cost per life year saved is estimated to be approximately $63,000, if implemented as an independent program, or $4,000 if piggy-backed onto a CVD intervention. One of the problems in considering the efficiency of the hypothetical NIDDM program evaluated is the great variability in results. Sensitivity analysis reveals a wide range of outcomes under varied but plausible assumptions. For the NIDDM program run in 'stand-alone' mode, cost-effectiveness varies from $96,000 per life year through to $18,500 per life year. In other words, the hypothetical NIDDM program could be excellent value-for-money or a white elephant. Such variability casts particular importance on understanding the nature and predictability of the program's costs and outcomes. While some cost containment measures can improve efficiency ('piggy-backing' the program, reducing set-up costs and overheads, use of nurses in patient recruitment), others can dramatically reduce efficiency (ie decreasing GP participation). Apart from the stand-alone/piggy-backing decision and reduced set-up costs, the major improvements in efficiency all come from improvements in effectiveness. The extent of GP participation, patient recruitment criteria and participation rates, as well as the level and duration of weight loss are all major determinants. Of these factors, GP participation and patient selection criteria seem the most amenable to improvement through program design. The extent and duration of weight loss will be harder to control.

The results suggest that irrespective of what improvements are achieved in GP participation and in the economy of program establishment, the share of program funding that is likely to go into program establishment and management, should focus attention on what potential exists for co-ordinating related health promotion campaigns that address shared or related risk factors, and in better utilising existing infrastructure (such as Divisions of General Practice).

Comparison with other NIDDM primary prevention programs suggests that some caution is warranted in encouraging general practitioners into behavioural modification programs. The results of our study suggest that an economic case for their involvement is yet to be demonstrated. This is consistent with the findings of other researchers on promoting lifestyle change in general practice (Ashenden et al. 1995; Salkeld et al. 1995). The answer to the question of whether GP-led behavioural change for weight reduction is 'value-for-money' is therefore: 'possibly, but proceed with caution'.

The analysis suggests that smaller health gains achieved over a more broadly defined 'at risk' group (ie only requiring one risk factor, such as overweight) is more cost-effective than larger gains achieved for a more selectively defined 'at risk' group (ie overweight plus second CVD risk factor). Further, despite the impact of discounting, weight loss maintained over a long period (ie 25 years) is more cost-effective than larger weight loss achieved for shorter periods (ie 5 years). This confirms the view that lifestyle changes that can be sustained over the longer period are better than dramatic changes that cannot be sustained. It also suggests that more effort should be put in to the maintenance of newly acquired healthy behaviours, vis-a-vis effecting the change in the first place.

Finally, while recipients of new health promotion initiatives often receive subsidised services and pay a lower percentage of total program costs than under the 'status quo', it is often forgotten that in absolute terms they are being asked to give more and maintain it over longer periods. Failure to recognise the absolute/relative cost differential may lead to unrealistic expectations of patient compliance and health cost offsets.

# The Cost-Effectiveness of GP Led Behavioural Change Involving Weight Reduction: Implications for the Prevention of Diabetes

## 1 Introduction

Diabetes is a chronic condition characterised by an inability to metabolise carbohydrates, protein and fat. It comprises the two forms of non-insulin dependent diabetes mellitus (NIDDM), which represents 85% of all diabetics (Glatthaar et al 1985; Welborn et al 1989) and insulin dependent diabetes mellitus (IDDM), which differ in aetiology, pathogenesis and age of onset. The two forms together represent a major health problem in Australia. Including those with undiagnosed diabetes, it is estimated that 3.8% of the total population, or about 750,000 Australians, currently have diabetes (Welborn et al 1996). As a consequence of increasing risk factors, it has been further estimated that by the year 2000 this number will increase to 900,000 (McCarty et al 1996).

The progress of diabetes frequently leads to coronary and peripheral vascular disease, stroke, peripheral neuropathy, retinopathy and nephropathy. Furthermore, mortality rates associated with diabetes are two to three times higher than that of the general population (Riley et al 1995). It is estimated that around 20,000 life years (undiscounted) are lost each year due to NIDDM (Australian Institute of Health and Welfare 1995).

Diabetes and its complications also has significant implications for health care costs. Data available from a joint research program of the Australian Institute of Health and Welfare (AIHW) and the Health Economics Unit (HEU) of Monash University is summarised in Table 1.

**TABLE 1** Direct Health Care Costs and Associated Morbidity Indicators of Diabetes and Its Complications, 1989/90[1]

| Disease | Hospital Separations ('000) | Medical Consultations ('000) | Pharmaceutical Prescriptions ('000) | Total Direct ($'000) |
|---|---|---|---|---|
| • Diabetes | | | | |
| – NIDDM | 13.5 | 938.6 | 1,466 | 116,352 |
| – IDDM | 4.1 | 282.9 | 422 | 27,483 |
| • Diabetes Related Diseases | | | | |
| – Hypertension | 0.4 | 168.9 | 529.2 | 15,238 |
| – CVD | 2.6 | 70.6 | 262.2 | 46,985 |
| – Cerebrovascular | 4.3 | 70.3 | 53.5 | 57,953 |
| – Peripheral Vascular | 0.8 | 21.3 | 20.4 | 7,855 |
| – Glaucoma | 0.3 | 7.8 | 21.6 | 1,328 |
| – Cataract | 2.8 | 7.6 | 0.6 | 8,982 |
| – Blindness | 0.1 | 4.8 | 0.3 | 1,109 |
| – Nephropathy | 1.1 | 16.5 | 12.4 | 6,319 |
| – Chronic Skin Ulcer | 1.6 | 85.2 | 107.2 | 19,984 |
| – Absence of Extremities | 0.1 | 5.2 | 3.7 | 815 |
| TOTAL | 31.6 | 1,679.7 | 2,919.5 | 305,398 |

**Notes** [1] A range of health service costs have not been captured, including outpatient clinics, local government and community services, direct provision of support by families and others. It has been estimated separately that the average direct health care costs attributable to NIDDM, for each person diagnosed with the disease, is at least $1,800 per annum (Dalton & Segal 1996).

Although the aetiology of NIDDM is not well understood, epidemiological evidence indicates it is a disease associated with a modern lifestyle. Major risk factors identified have been: diets high in the energy-dense foods of fat and sugar; smoking; a sedentary lifestyle; and obesity (McCarty et al 1996).

The behavioural and social nature of these risk factors has led to the proposition that NIDDM is preventable through behavioural change. Obesity in particular, has been focussed upon by many as being the most important of the modifiable risk factors (80% of NIDDMs are obese), some suggesting it is causal (Felber 1993). The proposition that NIDDM is preventable through weight control is supported by evidence from clinical trials (Eriksson 1991; Long et al 1994).

Whilst behavioural change can be promoted in a variety of settings, including non-health care settings such as schools and community groups, it is logical that general practice clinics also be considered for this role. Their candidacy reflects their dominance of our primary health care system; the fact that GPs see over 80% of the population each year (and an even higher proportion of older Australians); that patients see them as an appropriate source of health promotion advice; that patients are more likely to be receptive to preventive health messages when they have a current health concern; and the consideration that their basic training includes risk factor identification.

## 1.1 Evaluation Rationale

### 1.1.1 The Study Objective

The question this paper endeavours to answer is:
*Compared to 'routine' care for NIDDM/CVD at risk clients, what is the cost-effectiveness from a societal perspective, of a new program for NIDDM prevention through behavioural change promotion by GPs, either run independently or as part of a CVD multiple risk reduction program.*

The results are placed in the context of findings from recent work at the Health Economics Unit (HEU) which estimated the cost-effectiveness of NIDDM prevention through behavioural change in weight loss clinics, the workplace and through media campaigns (Segal et al. 1996).

### 1.1.2 Rationale for CVD Risk Reduction Context

The achievement of a reduction in a specified risk factor is likely to be associated with beneficial outcomes for a range of diseases. Whilst a program specifically implemented for the prevention of NIDDM may focus on weight reduction, for example, beneficial outcomes could also be expected for cardiovascular disease (CVD). Similarly, programs targeting CVD risk, where obesity is an independent risk factor, typically focus on cholesterol, smoking, exercise and hypertension, but could be expected to produce concomitant outcomes beneficial for NIDDM prevention.

The rationale for the CVD risk reduction context is primarily based on this commonality of risk factors, together with the important potential for decreasing program costs as set-up and management costs are shared between CVD and NIDDM initiatives. Additional practical considerations supporting this choice include the potential for increasing NIDDM program participation and adherence by GPs and their patients, and the increased likelihood of a NIDDM initiative being implemented if part of a CVD intervention, as opposed to a dedicated NIDDM program.

# 2 Description of Program Alternatives Evaluated

No public health programs in Australia exist at present in the form envisaged for our intervention. While the program described here must, therefore, be considered hypothetical, the design is based upon a recent Australian controlled trial of a GP based program for multiple CVD risk factor reduction. The clinical trial, referred to as Heartwise (Ruth 1996) was structured on the basis of previous research to identify effective strategies for increasing health promotion undertaken by GPs. This evaluation places reliance upon the Heartwise trial, particularly in the estimation of attributable costs.

In relation to health outcomes, methodological complications and insufficient statistical power of the Heartwise results, limit the inferences that can be drawn. In Heartwise the GPs were responsible for both control and intervention patients. Whilst this eliminated variations in practice between GPs, it did result in an inevitable convergence of treatment patterns, as GPs found difficulty in arbitrarily differentiating treatments between patients, thus casting doubt over whether the minimal difference in weight loss between control and intervention groups captured the full effect of the

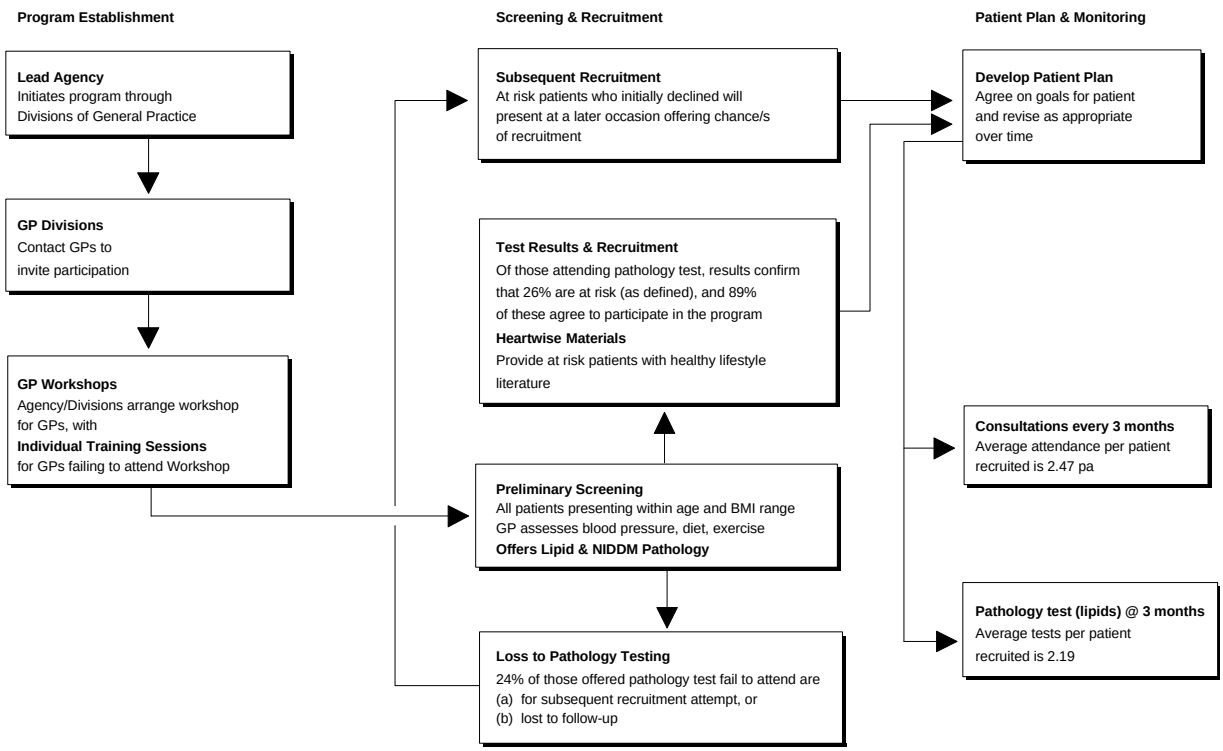
intervention. The weight loss outcomes of Heartwise were not used due to this uncertainty in interpretation.

To facilitate a better understanding of the methods used in the estimation of this program (refer Section 3), we first provide a description of the broad structure of the intervention envisaged, and what we define to be the comparator (routine care).

## 2.1 Description of the Hypothetical NIDDM Intervention Evaluated

There are four components to the program: the set-up phase involving the enlistment and training of GPs; and three stages of the behavioural modification initiative implemented by those GPs (that is, assessment of NIDDM/CVD risk, negotiation of patient plan, and assistance with achievement of goals and goal revision). An illustration of the pathway of activities envisaged for the program is given in Figure 1.

**FIGURE 1** **Intervention Activity Flowchart**




The administrative structure of the program is taken from the Heartwise program, where the lead agency staffing levels included provision to recruit and liaise with GPs. It is envisaged that the hypothetical program would be coordinated by a Department of Health or other such central administrative unit (possibly utilising regional offices where they exist).

Once recruited, GPs attend training workshops to reinforce their risk identification skills and to introduce behavioural change techniques. This training is important given that GPs would be responsible for identification of 'at risk' patients and their subsequent recruitment. The alternative of using nurses trained to screen and interview (as in the Heartwise and three UK trials) (Family Heart Study Group 1994;

Neil et al 1995; OXCHECK 1994) is considered in the sensitivity analysis and subsequent discussion. For the hypothetical program, it was assumed that GPs would recruit patients continuously over a 12 month period, during which time their motivation and application is assumed to remain constant.

The behavioural modification approach envisaged is adopted from Freshstart and Heartwise, which were based upon the writings of Prochaska and DiClemente (1992). These researchers recognised that the path to lifestyle change is not usually characterised by constant progression towards specified goals. It more typically encompasses periods of regression of varied severity and duration, but requiring individualised support and re-setting of goals as appropriate. Reflecting this approach, the three stages of the intervention comprise:

- **Stage 1 Assess NIDDM/CVD Risk**
  GPs would offer assessment of NIDDM/CVD risk on a systematic basis. Risk factors would be measured and recorded to identify those considered at risk of NIDDM/CVD.

- **Stage 2 Negotiate a Plan with the Patient to Reduce Risk**
  Determine the lifestyle changes needed and assess the preparedness of the patient to make these changes. Encourage the patient to move to the next stage.

- **Stage 3 Assist Patient Make Lifestyle Changes**
  Provision of advice, encouragement, and printed materials. Over time, re-assess risk and offer further assistance. Help patients failing to achieve targets.

For the implementation of these stages, patients recruited to the program by their GP would be asked to re-attend for monitoring and re-setting of goals at 1, 3, 6 and 9 months after consultation. In addition to pathology tests at screening, tests would be offered at 3, 6, and 9 months to monitor progress.

## 2.2 Routine Care

Our present knowledge of GPs' preventive care activities is far from complete and reliant on self-reported data. The picture that emerges from the available survey data (Glatthaar et al 1985; Guest & O'Dea 1992; Harris et al 1987; McCarty et al 1996; Welborn 1989) is variable and hard to piece together as a coherent description of the 'status quo', particularly as precise screening/counselling rates for overweight patients.

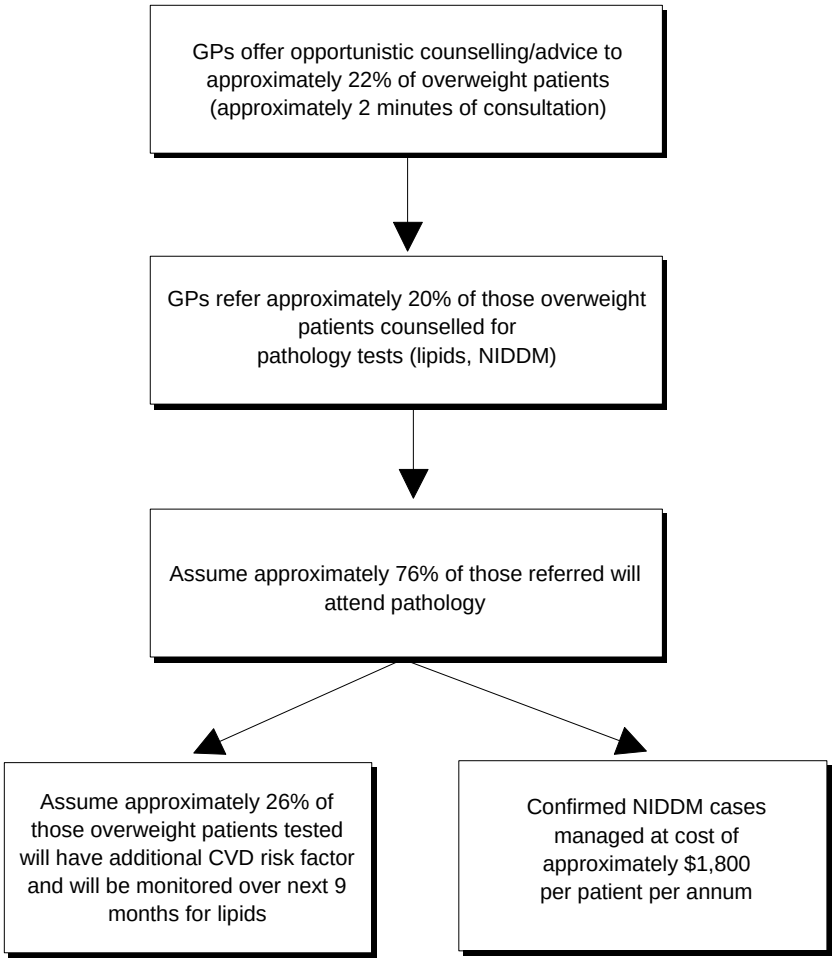
Information on treatments other than prescribing medication was collected nationally for the first time in 1990-91 in an encounter-based survey that generated 98,796 patient encounters in the final data set (Bridges-Webb et al 1992). The 'counselling/advice' treatment option was reported at a rate of 25.5 per 100 patient encounters, with counselling about 'nutrition/weight' recorded at a rate of 3.1 per 100 encounters. These rates are reported in terms of all patient visits to participating GPs in the data collection period, not in terms of patients with identified CVD risk factors. This makes the data a little hard to reconcile with other randomised survey data that reports preventative activities for 'at risk' patients (eg counselling/advice to overweight patients), and is less useful for our purposes of defining current practice for overweight patients in the 45-64 age group.

A random sample of 7,160 patients visiting 230 GPs in Queensland (Heywood et al 1994), provides the most useful data for specifying routine care (the 'base care' or status quo comparator for the economic appraisal). Based on self-reported data from both patient and doctor collected via questionnaire, the study reported that GPs counselled 22% of overweight patients, with verbal advice alone the approach used for most patients. Diet sheets were sometimes provided, with occasional referrals to weight-loss programs or prescription of medication.

The Risk Study Survey (Ruth et al 1993) of 900 randomly selected GPs (80% response rate, not encounter based) supports the finding that the most commonly utilised strategy for lifestyle counselling by GPs is giving at risk patients advice and encouragement, but added the use of follow-up appointments as an additional strategy. Data available from the control arm of the Heartwise trial (Riley et al 1995) suggests that management of at risk patients involved an average of two consultations.

Over and above preventive activity for overweight patients, the economic appraisal requires information on current practice in relation to cholesterol screening/monitoring (ie what additional activity does the hypothetical program involve?). On this point the Queensland Study (Heywood et al 1994) and the Risk Study Survey (Ruth et al 1993) both report that most GPs do not have an approach of measuring cholesterol for everyone, with the Risk Study Survey suggesting that 'most' GPs would assess cholesterol for a 'middle-aged man with a family history of CHD'. Screening for blood sugar is undertaken routinely by between 18% and 36% of GPs (Rolfe & Pearson 1996). There is no clear empirical evidence of what constitutes 'current practice'. For our overweight cohort of 45-64 year olds, we assumed current practice to involve cholesterol pathology for 20% of the group, with an average monitoring follow-up of 1.68 tests for this screened group, based on the control arm of the Heartwise trial, which was intended to conform with 'routine care' as adopted by the GPs concerned. The status quo comparator assumed for the economic appraisal is illustrated in Figure 2.

**FIGURE 2** **Base Care: Routine Care of Overweight Patients**



# 3 Methods

## 3.1 Introduction to Methods

### 3.1.1 Program Scale

Central to the operation of the hypothetical program described above is motivating GPs to: (i) *correctly* identify patients at risk of CVD and/or NIDDM; (ii) opportunistically counsel those patients; and (iii) recruit them to a planned intervention. The scale of the program, when measured in terms of the number of patients participating, is therefore highly dependent upon the number of GPs recruited to the intervention in the first instance, and subsequently upon the number of at risk patients presenting to those GPs and the rate at which these at risk patients are recruited. The approach to estimating the scale of the program is outlined in Sections 3.2 to 3.3.

### 3.1.2 Estimation of Program Costs

Having established the scale of the program, costs were estimated drawing upon the results of Heartwise, although with important adjustments. The value of health care savings from a fall in NIDDM is estimated elsewhere (Dalton & Segal 1996). Our results include allowance for deduction of these savings from program costs to provide an estimate of the net cost of the NIDDM initiative. The methods and assumptions used in estimating costs are described in Section 3.8.

### 3.1.3 Estimation of Health Outcomes

Short term — To overcome the limitations of the health outcome data from Heartwise we estimated (i) program effectiveness in reducing BMI, and (ii) the impact of that weight reduction on the incidence of NIDDM in the short term, from a survey of studies reported in the literature on dietary and lifestyle change. The intervention program envisaged here must, therefore, be regarded as a 'hypothetical' program. The methods are described in Sections 3.5 to 3.6.

Long term — In the absence of data for long term health outcomes, important assumptions were necessary in relation to the duration and impact of this weight loss. Literature reports listed in Table 2 contributed to this estimation. The methods are described in Section 3.7.

Mortality — In order to realistically estimate life years saved from the intervention, competing causes of death must be considered, thus requiring estimation of all-cause mortality for both the intervention and routine care cohorts. The methods are described in Section 3.7 and detailed in Appendix A.

The above assumptions and estimates were incorporated into a simple Markov model which comprised transition matrices between the four states of NIDDM, impaired glucose tolerance (IGT), normal glucose tolerance (NGT) and death; where

risk of death was adjusted for age, overweight and metabolic status. The methods are described in Section 3.7 and detailed in Appendix A.

### 3.1.4 Routine Care (Base Case)

The identification of what activities constitute routine care, and the incidence of those activities, were described in Section 2.2.

## 3.2 Number of GPs Recruited to Program

The chosen setting for the hypothetical program is a population of 100,000. The most recent estimate of the ratio of GPs to population suggests a population of 100,000 in Australia would, on average, be serviced by 100 GPs (Doherty 1989). The proportion of these that would agree to participate in the training was estimated from Heartwise results.

In the Heartwise trial, 114 GPs were identified in two Divisions of General Practice (chosen as being representative of the Victorian population). Some 37 (32%) declined to participate and 60 (53%) were identified as ineligible for the research trial as: (14) were not contactable; (17) were working less than 6 sessions per week; (18) had either moved or were intending to move; (5) had partners in the practice already in the study; (2) were participating in another CVD program; (3) were specialists; and (1) was deceased. Eighteen (16%) of the 114 GPs were eligible and consented to participation, although actual participation was only 14 GPs (12%).

As the criteria for participation by GPs in a public health program would be less stringent than those of a research trial, the rate of recruitment could be expected to be higher than the 12% participation rate achieved in the Heartwise trial. An assumed recruitment of 14% (that is, 14 GPs) was adopted. This assumption is considered realistic, but conservative. It also offers the convenience of coinciding with the actual number of GPs recruited in Heartwise, thereby enabling more precise estimation of program costs.

## 3.3 Number of Patients Recruited

Integral to the recruitment of patients is the definition of those ‘at risk’. The criteria for selection of the target group were those adopted by Heartwise, but with a greater age restriction in order to also conform with the intervention population reported in the NIDDM prevention trial (Eriksson 1991) used to measure the impact of weight loss and described in Section 3.6. The number of participants in the program was estimated for the number of people comprising the catchment population of our 14 participating GPs (14,000) by using survey data (Deeble 1991; Bridges-Webb 1992) to determine the proportion of these in the target age group visiting one of the 14 GPs in the program. The proportion of these who would be in the ‘at risk’ category and who would agree to participate in the program, was taken directly from Heartwise patient data and recruitment rates.

The target group was assumed to be patients aged 45-64 years who had a BMI of at least 27, together with either a cholesterol level over 6.5 mmol/L, or 5.5 mmol/L

accompanied by a second CVD risk factor. The number of participants in the program was estimated using the following six steps:

(i) the proportion of the population attending a general practice at least once each year was estimated as 84.6% (ie 11,844) patients of the catchment population of our 14 GPs (Deeble 1991);

(ii)

(iii) the proportion from (i) that would fall within the age group 45-64 years was estimated as 22.5%, (ie 2,665 patients) from a morbidity survey of general practice in Australia (Bridges-Webb 1992);

(iv) the proportion from (ii) above with a BMI not less than 27 was estimated as 63%, (ie 1,679 patients) on the basis of Heartwise findings (Ruth 1996);

(v) the group identified in (iii) was invited to obtain a lipid pathology test and it was again estimated from Heartwise results that only 76%, (ie 1,276 patients) would actually attend for testing. The proportion of these who would have a raised cholesterol level were estimated as 26%, ie 332 patients (Ruth 1996);

(vi) the proportion from (iv) who would agree to participate at first request was estimated as 89%, ie 295 patients (Ruth 1996);

(vii) the proportion from (v) who initially declined, but would be seen again that year (Bridges-Webb 1992) and, therefore, may be recruited on these subsequent occasions (assumed at a rate of 15%) or an additional 3 patients.

The number of patients recruited was derived from the sum of (v) and (vi). This yielded an estimate of 298 at risk patients enrolled in the intervention program.

Figure 3 provides a flowchart description of this approach, together with the proportions specified for each step and estimated participants in the program (ie 298 people, or 2.1% of the GPs catchment population of 14,000; 89% of the participating GPs target ‘at risk’ population; but only 0.3% of the potential catchment population of 100,000 people).

## 3.4 Patient Follow-up

Heartwise data (Ruth 1996) was used to estimate the average number of subsequent consultations per patient and pathology tests per patient for both control (routine care) and intervention groups. This was calculated for the Heartwise intervention and control cohorts respectively by dividing the total number of patients for each cohort by the aggregate number of visits to their GP over the trial period. The average frequency of pathology tests was similarly calculated from aggregate estimates over the trial period.

Heartwise results showed that the average number of consultations in the intervention group was 2.47 compared to 2.12 in the control group. The number of pathology tests was 2.19 in the intervention group compared to 1.68 in the control group. It should be noted though that whilst these averages suggest conformity to the intervention protocol, the results comprise a mixture of frequent attenders (one

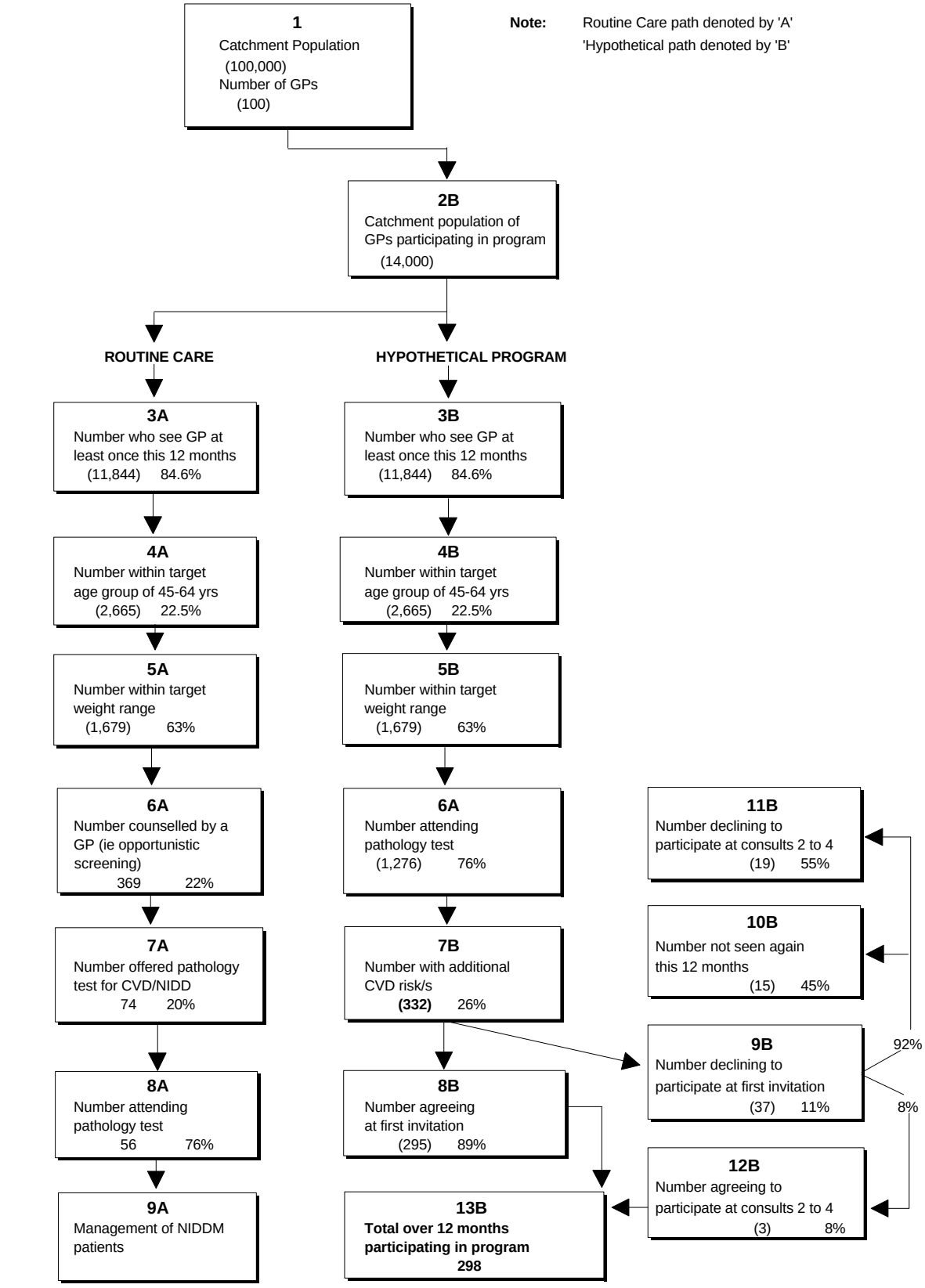
patient had nine consultations over the 9 month period and a further 11 patients had 5 or more consultations) and a number of infrequent attenders.

## 3.5 Attributable Weight Loss

Additional reports of GP based intervention trials where either BMI or weight loss was reported was required to estimate plausible outcomes. A summary of these is provided in Table 2. A conservative assumption for weight loss was adopted based on a review of this literature.

**FIGURE 3**

**Patient Flowchart: Routine Care Compared to Intervention**



Although all studies were based in general practice settings, the staff conducting the program varied between doctors, practice nurses and dietitians, to the use of printed materials only. Variations also existed in the criteria used to define target populations. It must also be noted that the magnitude of weight loss in the remaining studies are confounded by the inclusion of significant numbers of non-overweight subjects and that the study by Cupples et al. (1994) involved symptomatic patients (ie. with angina), rather than asymptomatic patients. In the studies by Baron et al (1990), Neil et al (1995), Logsdon et al (1989) and OXCHECK (1994) the proportion of subjects in most of these studies who were not overweight ranged between 58% and 100%. The subjects in the Family Heart Group (1994) and Lindholm et al (1995) studies are on average overweight, although non-overweight subjects are also included.

Following a review of the above literature, an assumed average weight loss of 1 kilogram was adopted for the first five years of the hypothetical program, compared with the control group. In view of the inclusion of significant numbers of non-overweight subjects, this assumption is potentially quite conservative. The assumption that weight is re-gained in years thereafter is based on literature findings demonstrating consistent weight increase after conclusion of the intervention (Hartman et al 1993; Jeffery & Wing 1995), particularly for those with NIDDM (Blonk et al 1994; Guare, Wing & Grant 1995). Both these assumptions are examined in the sensitivity analysis.

## 3.6 Effect of Weight Loss on Incidence of NIDDM

The rate of progression from impaired glucose tolerance (IGT) and normal glucose tolerance (NGT) to NIDDM was taken from a randomised clinical trial in Sweden (Eriksson et al 1991). The subjects comprised 222 males with an average age of 48 years (SD $\pm$ 0.7 years), an average BMI of 27.7 (SD $\pm$ 3.7), of whom 41 (18%) were asymptomatic subjects with recently diagnosed NIDDM, and 181 (82%) had IGT. The intervention comprised a five year protocol of check-ups offered at 6, 12, 18, 24, 36 and 60 months, during which dietary change and increased exercise were encouraged.

In order to estimate the impact on the incidence of NIDDM, that would be attributable to lower levels of weight loss than that achieved in the Swedish trial, it was assumed for our paper that a linear relationship exists between health outcomes and weight loss thereby enabling direct pro-rata estimation of the level of health outcomes. The application of this assumption is shown in the results below.

Eriksson et al (1991) reported the average peak weight loss in the first year of the Swedish program to be 6 kilograms, although stabilised weight loss by the 5$^{th}$ year was only 2.0-3.3 kilograms lower than at baseline. The control group gained 0.0-2.2 kilograms in weight over the 5 years.

The average 6 kilogram weight loss by the end of the first year was associated with a significant reduction in the rate of progression to NIDDM ($\approx$ 50%) for those with IGT, as well as for those with recently diagnosed NIDDM where the rate of reversion to IGT and even NGT was greatly increased. The weight loss of 1 kilogram in the intervention group assumed for this paper then represents 17% of the loss

(1.00/6.00) reported by Eriksson. Given the assumption of a linear relationship between weight loss and health outcomes, the impact of a 1 kilogram loss implies an 8% reduction (17% of 50%) in the incidence of NIDDM.

**TABLE 2** **Studies of the Effectiveness of CVD Risk Reduction Programs**

| Study | Treatment Approach | Change in BMI |
|---|---|---|
| **SIGNIFICANT RESULTS** | | |
| Family Heart Group 1994 (UK) | Nurse led program using family centred approach over 12 months. Nurses trained in learner centred techniques with intensive follow-up | -1.17 kilogram (SE 0.36) |
| Neil et al 1995 (UK) | Comparison of dietary advice given by dietitian, practice nurse, and leaflet | -0.24 BMI (for diet advice group) |
| Logsdon et al 1989 (USA) | Preventive intervention by GPs over 12 months | 38% (intervention) v 25% (control) achieved ≥ 5 pound weight loss. Odds ratio = 1.65 |
| **NON-SIGNIFICANT RESULTS** | | |
| OXCHECK Study Group, Imperial Cancer Research Fund 1994 (UK) | Provision of 12 month health checks by practice nurses *High Risk Only* | (>30 BMI) -1.6% (95% CI -0.2 to 3.4) |
| Cupples et al 1994 (UK) | Provision of health education in general practices to patients with angina < 75 years | Lost 0.5 BMI from baseline but +0.01% BMI cf Control |
| Lindholm et al 1995 (Sweden) | Provision of intensive health care advice through group sessions (+ videos) led by either doctor or nurse | -0.09 BMI (95% CI -0.29 to 0.11) |
| Baron et al 1990 | Comparison of provision of dietary advice and follow-up with follow-up only (subjects' BMI; 23.0-24.6) | Control group lost 1.1 kilogram |
| Freshstart 1995 (Australia) | Program aimed to help GPs assist their high risk patients aged 18-69 years. Achieve lifestyle change over 12 months | Not reported |
| Heartwise 1994 (Aust.) | Comparison of intensive advice and printed materials with 'routine' advice | -0.95 kilogram |

## 3.7 Long Term Health Outcomes - Disease Modelling

### 3.7.1 Progression to NIDDM

A simple Markov model was developed to estimate life years and years of diabetes over 25 years post-intervention. The parameter results derived above generated transition matrices for transition between NIDDM, IGT and NGT, for both control and intervention cohorts. Each matrix related to a five year period which reflected the clinical follow-up period reported by Eriksson. These matrices are shown in Appendix A.

The performance of the disease model using the assumed transition matrices (but without mortality) is shown in Table 3. It shows the divergence in incidence of NIDDM between the routine care and intervention cohorts over the first five years, as assumed, followed by resumption of identical relative risks of NIDDM for years 6-25.

**TABLE 3** **Predicted Progression of NIDDM (No Mortality) in Intervention Population over time**

| | Number of persons with NIDDM | | | | |
|---|---|---|---|---|---|
| | 5 years | 10 years | 15 years | 20 years | 25 years |
| Intervention cohort | 8.06 | 15.59 | 23.64 | 31.51 | 38.97 |
| Control cohort | 8.82 | 16.60 | 24.69 | 32.53 | 39.93 |
| Difference | 0.76 | 1.01 | 1.05 | 1.01 | 0.96 |

### 3.7.2 Methods: Mortality Estimates

Each five year period in the model included a mortality vector as the literature suggests that excess weight as a risk factor for mortality is widely accepted (Rissanen et al 1990; Manson 1987). NIDDM confers a higher relative risk of mortality, further evidence that IGT status alone is responsible for increased relative risk of mortality. Thus estimation of mortality rates for both control and intervention groups required accommodation of both the impact of overweight and metabolic status on premature mortality. This was achieved in the model by first utilising age adjusted mortality rates for the general population in Australia (AIHW 1996). These were then manipulated to estimate the relative contribution to these average mortality rates from those who are NGT, IGT and NIDDM respectively. This required estimation of the prevalence of IGT and NIDDM in Australia which was based on the ABS Health Survey, 1989-90 (Welborn et al 1989). These rates were then weighted according to assumed relative risks to reflect the impact of excess weight.

Therefore, within each five year period, the mortality rates used comprised an individual age adjusted rate for each of the three metabolic states, weighted for assumed degree of overweight.

The relative risk of mortality for those with IGT was taken to be 1.6 and 2.0 for those with NIDDM (Balkau 1993). To incorporate the effects of excess weight, the model assumes that the control group had a constant relative risk of mortality of 1.2 (Losonczy et al 1995) compared to the general population. It was assumed that weight loss resulted in reduced risk of mortality (Pamuk et al 1993; Williamson et al 1995). However, the evidence on this issue is contentious (Higgins et al 1993; Williamson & Pamuk 1993) and therefore these assumptions are also tested in the sensitivity analysis. Reflecting this uncertainty, a conservative assumption of the intervention group achieving a modest reduction in relative risk of mortality from 1.2 to 1.1 following weight loss was adopted. It was further assumed that this reduction in relative risk only applied for the actual period of weight loss (the first 5 year period only), thereafter the mortality vectors were the same for control and intervention groups.

The complete table of mortality rates used are shown in Appendix A.

Table 4 shows the implications of the mortality assumptions upon estimated mortality in the model.

**TABLE 4** **Estimated Mortality**

| | Years of Life Lost | | | | |
|---|---|---|---|---|---|
| | 5 years | 10 years | 15 years | 20 years | 25 years |
| Control Group | 4.02 | 6.53 | 11.22 | 18.29 | 29.14 |
| Intervention Group | 3.57 | 6.51 | 11.19 | 18.26 | 29.12 |
| Years gained per specified period (Control minus Intervention) | 0.45 | 0.02 | 0.03 | 0.03 | 0.02 |

### 3.7.3 Progression of NIDDM Allowing for Mortality

When the mortality estimates are included in the Markov chain estimating the incidence of NIDDM, the number of people over time with NIDDM from the intervention and control cohorts are shown in Table 5.

**TABLE 5** **People with NIDDM (with Mortality Effects)**

| | Number of persons with NIDDM | | | | |
|---|---|---|---|---|---|
| | 5 years | 10 years | 15 years | 20 years | 25 years |
| Intervention cohort | 7.92 | 14.81 | 21.18 | 25.47 | 26.19 |
| Control cohort | 8.65 | 15.74 | 22.06 | 26.21 | 26.75 |
| Difference | 0.73 | 0.93 | 0.89 | 0.75 | 0.55 |

Consistent with the assumptions, Table 5 shows a rising number of cases of NIDDM in both cohorts, although with slightly greater numbers in the control group as a consequence of greater relative risk during the first five year period. Beyond 10 years, the absolute difference between control and interaction groups diminishes as a consequence of smaller numbers in each group due to the effects of mortality assumptions.

## 3.8 Identification and Measurement of Costs

Costs were identified from a societal perspective, and therefore included costs impacting upon the patient, GPs and government. These included not only the more routine items such as GP consultations, pathology and patient booklets etc, but also time and travel costs for patients and for GPs attending training sessions.

Costs were grouped by the pathway of activities that characterised the intervention (refer Figure 4) and measured, wherever possible, in terms of the value of the resources being utilised rather than the Medicare payment rate (ie using 'economic' costs rather than 'financial' costs). The dollar amount in (1996 prices) and data source for key cost items are given in Table 6 below. A 5% discount rate has been used for those costs (or cost savings) that are not incurred in the first year of the program.

Full recording of financial costs during the Heartwise trial assisted in estimation of the likely economic costs of administering our hypothetical public health program. Consultations were assumed to be standard consults and both the time spent on identification of risk factors (5 minutes), and recruitment to the program/development of plans (5 minutes), were estimated on the advice of Heartwise research staff.

Alterations to trial costs were necessary to reflect the likely economic costs and an assumed simplified administration of the program in routine application (ie costs specific to the conduct of a research trial were deleted). GP training costs were based on invoices to Heartwise for professional services and training facility rental with GP time valued at $95.41 per hour for after hours attendance (DHS&H 1995).

Development costs of the Heartwise Program were not included as, from both an economic and a policy perspective, these are 'sunk costs'. The program, together with its associated resource materials, was not tailored to the regions targeted by the trial and as such is readily transferable to other regions of Victoria and Australia.

The salary cost for the lead agency of administering the program was estimated from Heartwise records. As a hypothetical program, overhead costs are difficult to estimate precisely, but were assumed to be 75% of salaries (a cost variation assuming overheads to be 25% of salaries is analysed in the sensitivity analysis below).

The health care savings from NIDDM cases prevented, or direct costs avoided, were estimated from previous work which estimated the average attributable cost of diabetes per patient per annum (Dalton & Segal 1997). This estimate is believed by the authors to be conservative.

**FIGURE 4**

**Economic Pathway Mapped Against Activity Pathway**

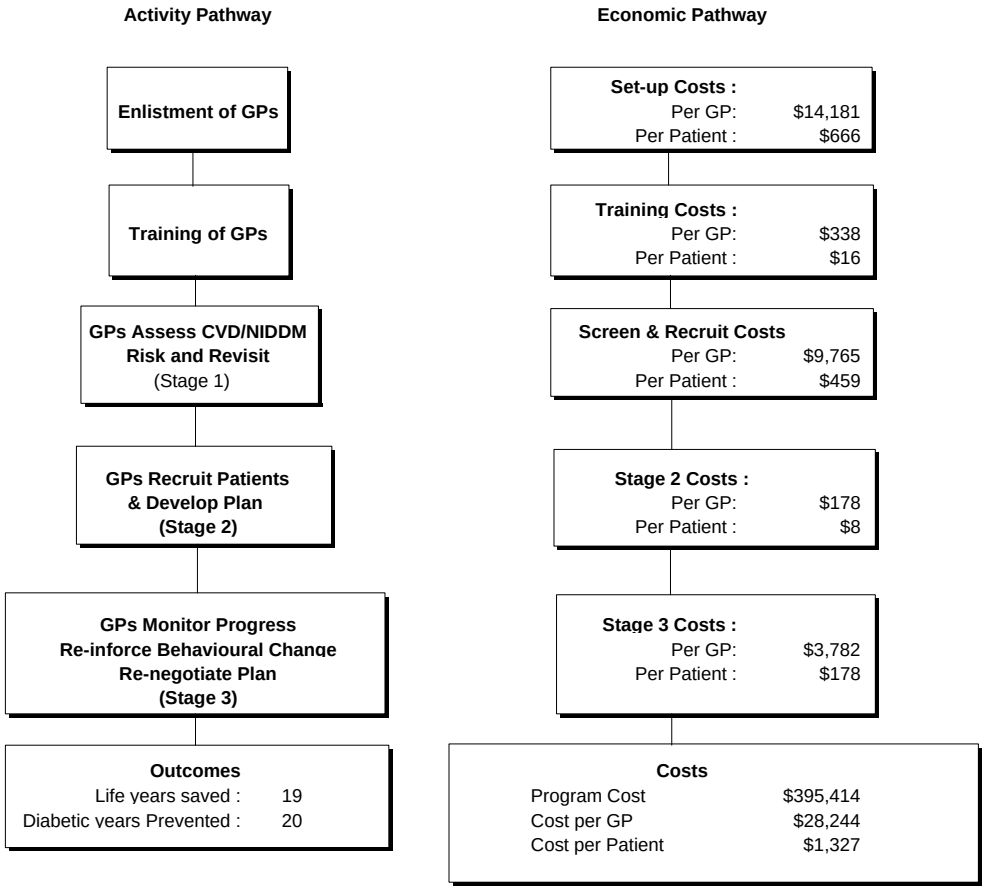


**TABLE 6** **Cost Assumptions and Their Source**

| Item | Cost | Source |
|---|---|---|
| Standard GP consultation | $23.35 | Commonwealth Medical Benefits Schedule, 1996 |
| GP time (work hours) | $1.10 per minute | Commonwealth Medical Benefits Schedule, 1996 |
| GP time (after hours) | $95.41 per hour | Divisions of General Practice Guidelines (1995) |
| NIDDM pathology test (Medicare item no 66201) | $30.44 | Cost study by Easton and Segal (1996) |
| Lipids pathology test (Medicare item no 66331) | $34.50 | Actual fee charged in Victoria |
| Cost of NIDDM management | $1,800 per diagnosed patient per annum | Cost study by Dalton and Segal |
| Average visit and test rate per patient for follow-up management and pathology | Intervention<br>:Visits 2.47<br>: Tests 2.19 | Heartwise intervention group |
| Average visit and test rate per patient for follow-up management and pathology | Routine Care<br>:Visits 2.12<br>:Tests 1.68 | Heartwise control group |
| Travel costs for both GPs and patients | Average of 3 km per trip for patients and 40 km per training session for GPs at cost of $0.50 per km | Assumption based on travel during Heartwise trial |

# 4 Results

## 4.1 Cost Estimates

The estimated gross cost of the hypothetical program, that is, without any allowance for shared joint costs, for cost off-sets from prevention of NIDDM, or for costs incurred in the 'status quo' base case (ie routine care), is described in Table 7.

**TABLE 7** **Estimated Gross Costs - Hypothetical Implementation of NIDDM Prevention Program**

| Activity | Cost Item | Cost Estimate ($) |
|---|---|---|
| Recruitment of GPs | • Management organisation | |
| | - Overheads | 82,052 |
| | - Non-labour consumables | 3,675 |
| | - Labour expense | 109,403 |
| | - Printed materials (Heartwise Kit) | 1,718 |
| | • GP Divisions | |
| | - Labour expense | 1,690 |
| | *Recruitment of GPs: Sub-total* | 198,538 |
| GP Training | • GP invitations and conduct of workshops | 1,328 |
| | • GP time and travel | 3,398 |
| | *GP Training: Sub-total* | 4,726 |
| Screening and Recruitment | • Cost Additional Risk Assessment | |
| | - Additional 5 minutes each | 11,487 |
| | - Screening pathology test - lipids | 56,207 |
| | - Pathology tests (glucose tolerance) | 38,789 |
| | • Patient Recruitment | |
| | - Assume additional 5 minutes per patient | 30,236 |
| | *Screening and Recruitment: Sub-total* | 136,718 |
| Plan Development | • Setting objectives and strategy | |
| | - Assume additional 5 minutes per patient | 2,488 |
| | *Planning Development Sub-total* | 2,488 |
| Patient Management | Patient Management | |
| | - Consultations | 17,182 |
| | - Pathology tests (cholesterol) | 22,504 |
| | - Patient time and travel | 13,258 |
| | *Patient Management: Sub-total* | 52,944 |
| TOTAL | | $395,414 |

Notes: (1) Includes salary and oncosts for Senior Lecturer (FTE 0.2); Research Assistants (FTE 1.5); Secretary (FTE 0.2); and National Heart Foundation Project Officer (95 hrs included, 105 hrs excluded as attributed to trial).

(2) The development costs of the information kit (over $35,000) have been excluded, as these are 'sunk costs', and would not be applicable to further applications of the Heartwise program.

### 4.1.1 Gross Cost Results by Activity Pathway

Table 8 provides a summary that highlights expenditure according to where it was incurred in the pathway of activities. It is noticeable that even though costs associated specifically with the conduct of a randomised trial (as opposed to routine application) were excluded, the GP recruitment stage still dominates gross cost estimates for the intervention. This, in turn, reflects the assumed establishment costs and the assumed poor recruitment rate of GPs (only 14 out of 100; refer Section 3.2), and the consequential dominance of fixed costs (particularly program establishment) over variable costs (which are strongly related to patient numbers). The importance of GP recruitment and its effect upon patient recruitment are analysed further in the sensitivity analysis. Irrespective of gains made here however, the high percentage of resources that are likely to be consumed by the management/organisation of such health promotion activities, should focus attention upon what potential exists for co-ordinating campaigns that address common risk factors.

**TABLE 8** **Gross Cost of Intervention by Pathway of Activities**

| Key Pathway Steps | Cost $ | Percentage % |
|---|---|---|
| Recruitment of GPs | 198,538 | 50 |
| Training of GPs | 4,726 | 2 |
| GP assessment of CVD/NIDDM risk | 106,483 | 26 |
| GP recruitment of 'at risk' patients and patient plan development | 32,724 | 9 |
| GP monitoring of progress and behavioural change reinforcement | 52,944 | 13 |
| TOTAL | 395,414 | 100 |

### 4.1.2 Gross Cost Results by Incidence

Patients were estimated to pay 26% of the hypothetical program's gross costs (ie $103,284) consisting of the Medicare gap for consultations and pathology, together with time and travel costs associated with physician attendance. By contrast patients in the 'status quo' base case were estimated to pay 57% of routine care (but only $4,126). It is interesting to note that while patients (recipients of health promotion initiatives) often receive subsidised services, such interventions , particularly those that involve medical services, can often increase the absolute cost of patient participation/adherence vis-a-vis the status quo (refer to Table 9 for details). Appearances of 'free' services can sometimes be deceptive and may help account for poor patient adherence rates.

**TABLE 9** **Incidence of Gross Costs for Intervention and Status Quo**

| Incidence | Intervention | | Status Quo | |
|---|---|---|---|---|
| | $ | % | $ | % |
| Patient costs | 103,284 | 26 | 4,126 | 57 |
| GP costs[(1)] | 11,272 | 3 | 874 | 12 |
| Government costs[(2)] | 280,858 | 71 | 2,201 | 31 |
| Total | 395,414 | 100 | 7,202 | 100 |

**Notes: (1) Includes travel costs, training time for GPs who receive training visit, and time devoted to intervention during**

**patient visits to clinic. The opportunity cost to Gps of the time devoted to health promotion is income forgone (from foregoing extra patient consultations).**

**(2) Includes the costs borne by Divisions, as the Commonwealth is funding the GP Divisions under the Divisions and Projects Program of the General Practice Initiative.**

### 4.1.3 Gross Cost Results from Gross to Incremental to Net and Beyond!

The estimated gross cost of the hypothetical program is $395,414 in 1996 dollars. Taking this figure as the 'economic cost to society', however, would be quite misleading for a number of reasons. Firstly, it includes no deduction for the costs associated with the routine health promotion activities that GPs provide for their overweight patients. As the new program would supplant these activities for participating GPs, these costs (estimated to be $7,202 per annum for all 14 GPs), should be deducted from the cost of the hypothetical program to give the 'incremental' cost of the new initiative. Viewed another way, the costs involved in the status quo activities can be regarded as one source of the resources needed for the new activities.

Secondly, the gross cost, or indeed the incremental cost includes no allowance for the value of savings achieved through the reduction in the number of new NIDDM cases. These savings, or cost off-sets, are estimated to be $36,122 (undiscounted) or $20,671 (discounted at 5%).

Finally, even this net incremental cost (ie $395,414 less $7,202 status quo resources, and less $20,671 cost off-sets) includes no allowance for the fact that many of the costs are potential 'joint' costs which could be shared with a companion CVD intervention. In fact, the only costs that are purely attributable to the NIDDM prevention initiative are the NIDDM pathology tests and associated time and travel costs. The decision, therefore, as to what percentage of costs should be borne by the NIDDM initiative vis-a-vis the companion CVD intervention, has a dramatic impact upon the costs of both programs. Table 10 provides estimates of the resultant cost shares if either a 20:80; 50:50, or 20:80 attribution of relevant costs is assumed for the NIDDM initiative.

**TABLE 10** **Cost Shares of the Hypothetical NIDDM Initiative Attributed to the Companion CVD Program and to the NIDDM Program Assuming Different Attributions for Joint Costs**

| | NIDDM/CVD 20%/80% $ | NIDDM/CVD 50%/50% $ | NIDDM/CVD 80%/20% $ |
|---|---|---|---|
| CVD | 294,104 | 200,323 | 106,541 |
| NIDDM | 101,310 | 195,091 | 288,873 |
| TOTAL | 395,414 | 395,414 | 395,414 |

Table 11 provides a summary of the arithmetic for arriving at the cost estimates for undertaking our hypothetical NIDDM initiative either on its own, or 'piggy-backed' onto a CVD intervention, assuming that 20% of joint costs are attributed to NIDDM prevention.

**TABLE 11** **Summary of 'True' Economic Cost of NIDDM Initiative as Independent Program or as Piggy-backed onto CVD Programs**

| Economic Cost Analysis | Independent Program (100% Attribution) $ | Piggy-backed Program (20% Attribution) $ |
|---|---|---|
| • Gross cost | 395,414 | 101,310 |
| • Incremental cost | | |
| - Gross less base case costs of $7,202 | 388,212 | 94,108 |
| • Net incremental cost | | |
| - Incremental cost less cost savings from NIDDM prevention ($20,671) | 367,541 | 73,437 |
| • Net incremental cost per patient recruited to program | 1,233 | 246 |

## 4.2 Health Outcomes

The application of the disease model yielded health outcomes which are summarised in Table 12. The table shows the aggregates of the chosen measures of health outcome accrued over time for specified time intervals. These results show that the greater proportion of 'life years saved' are accrued late in life, while benefits measured as 'years of diabetes prevented' are more evenly distributed. The difference in the pattern of benefits is explained by the lag between the onset of diabetes and the premature mortality that it causes.

The convention in economic analysis is to apply discounting in order to factor into the analysis the time streaming of when costs and benefits are experienced. The essential logic of this is that benefits are preferred sooner rather than later, while costs are preferably incurred later than sooner. However, as shown in Table 12, the application of discounting to the stream of benefits greatly reduces the aggregate of benefits and significantly alters the proportional distribution over time of these benefits. Different approaches to discounting in the economic evaluation of health care programs needs to be carefully monitored (Cairns 1992, Parsonage & Neuberger 1992, Richardson 1995 ). In general, the implications include the possibility that a program generating fewer life years saved than an alternative program, when benefits are undiscounted, may become more effective if discounting is introduced (ie depending on when the benefits are received). For this reason, we provide estimates of both discounted and undiscounted aggregates in the table.

Neither of the above indicators is really satisfactory as a measure of health outcome as they are both incomplete. 'Years of Life Saved' is a mortality indicator that omits any morbidity effects such as disability, pain and suffering. 'Years of NIDDM Prevented' is a quasi morbidity indicator that flags the absence of disease, but omits any survival effects, as well as the impact of preventing diabetes on the patient's quality of life. In an attempt to provide an outcome that includes both mortality and morbidity effects, we have combined the two indicators by giving a quality adjusted life years (QALY) value of 10% to the prevention of diabetes, that is to say, life without diabetes is assumed to be equivalent to a 10% improvement in the quality of life. We computed this by taking 10% of the number of diabetes free years yielded by the intervention, and added these to the number of life years saved from the prevention of premature mortality. It should be noted that the utility value of 10% is merely a researcher imposed guess, and the study would be improved by the availability of empirically derived utility weights.

## 4.3 Cost-Effectiveness and Cost-Utility Results

The pursuit of efficiency requires the analysis of the relationship between costs and outcomes within the context of what alternatives are available to the project under consideration. The sensitivity analysis in Section 5 will demonstrate that efficiency is not the same objective as cost containment, and that further it cannot be achieved by a single-minded focus on clinical outcomes without regard to the resources that are being consumed.

In this section, the cost results presented in Section 4.1 and the health outcome results presented in Section 4.2, are brought together to facilitate a discussion of what the potential efficiency of our hypothetical program might be. This discussion is further extended in the sensitivity analysis (Section 5) where a number of the basic

cost and outcome assumptions used in the analysis are varied in order to examine their impact on various objectives (cost containment or affordability, effectiveness or health gain, and efficiency), and hence their likely policy relevance.

**TABLE 12** **Summary of Estimated Health Outcomes**

| Health Outcome | Undiscounted (Years) | Discounted at 5% Per Annum (Years) |
|---|---|---|
| • Life Years Saved | | |
| - At 15 years | 5.93 | 3.88 |
| - Over life expectancy | 18.82 | 5.83 |
| • Years of Diabetes Prevented | | |
| - At 15 years | 12.96 | 8.80 |
| - At 25 years | 20.07 | 11.48 |
| • QALY Adjusted Life Years Saved[(1)] | | |
| - At 15 years | 7.23 | 4.76 |
| - At 25 years | 20.83 | 6.98 |

**Notes** [(1)] Assumes life without diabetes is equivalent to a 10% improvement in the quality of life.

Given the importance of the attribution of joint costs to the estimated 'cost' of our hypothetical program, the results of the economic appraisal are presented in two ways. Firstly, in terms of those results that would apply if the hypothetical NIDDM initiative were run as an independent program (refer Table 13), and secondly, where the results assume piggy-backing of the NIDDM initiative onto a CVD program (refer Table 14). The results in Tables 13 and 14 are again presented both with and without discounting.

While a variety of efficiency results are presented in order to see the impact of different cost and outcome estimates, the preferable indicator from an economic perspective is 'Net incremental cost per QALY'.

The most important points coming from an examination of Tables 13 and 14 are:

- the very large difference between the potential 'value for money' of the NIDDM prevention program according to whether it is run as an independent program ($52,700 per QALY) or piggy-backed onto a CVD prevention program ($10,500 per QALY).

- the large impact discounting makes to the cost-effectiveness and cost-utility results (particularly using the 'life expectancy' outcome indicator) due to the lag between NIDDM prevention and mortality gains ($17,600 undiscounted versus $52,700 discounted per QALY as an independent program; and $3,500 undiscounted versus discounted $10,500 per QALY when piggy-backed).

- the large impact the choice between time frames of 15 years, and life expectancy has for the measurement of benefits, ameliorated to some extent by the effect of discounting ($50,800 per QALY versus $17,600 per QALY as an independent program undiscounted; and $77,200 per QALY versus $52,700 discounted).

**TABLE 13**

**Summary of the Results of the Economic Appraisal When NIDDM Intervention Run as Independent Program**

| Efficiency Indicator | Benefits Undiscounted $ | Benefits Discounted at 5% Per Annum $ |
|---|---|---|
| • Gross incremental cost per life year saved | | |
| - At 15 years | 65,400 | 100,100 |
| - Over life expectancy | 20,600 | 66,600 |
| • Net incremental cost per life year saved | | |
| - At 15 years | 61,500 | 96,000 |
| - Over life expectancy | 18,700 | 63,000 |
| • Gross incremental cost per year of diabetes prevented | | |
| - At 15 years | 30,000 | 44,100 |
| - At 25 years | 19,300 | 33,800 |
| • Net incremental cost per year of diabetes prevented | | |
| - At 15 years | 28,200 | 42,300 |
| - At 25 years | 17,500 | 32,000 |
| • Gross incremental cost per quality adjusted life year | | |
| - At 15 years | 53,700 | 81,600 |
| - Over life expectancy | 18,600 | 55,600 |
| • Net incremental cost per quality adjusted life year | | |
| - At 15 years | 50,800 | 77,200 |
| - Over life expectancy | 17,600 | 52,700 |

**TABLE 14**

**Summary of the Results of the Economic Appraisal When NIDDM Intervention is Piggy-backed onto a CVD Program**

| Efficiency Indicator | Undiscounted $ | Discounted at 5% Per Annum $ |
|---|---|---|
| • Gross incremental cost per life year saved | | |
| - At 15 years | 17,100 | 26,100 |
| - Over life expectancy | 5,400 | 17,400 |
| • Net incremental cost per life year saved | | |
| - At 15 years | 12,400 | 18,900 |
| - Over life expectancy | 3,900 | 12,600 |
| • Gross incremental cost per year of diabetes prevented | | |
| - At 15 years | 7,900 | 11,500 |
| - Over life expectancy | 5,000 | 8,800 |
| • Net incremental cost per year of diabetes prevented | | |
| - At 15 years | 5,700 | 8,300 |
| - Over life expectancy | 3,700 | 6,400 |
| • Gross incremental cost per quality adjusted life year | | |
| - At 15 years | 14,000 | 21,300 |
| - Over life expectancy | 4,900 | 14,500 |
| • Net incremental cost per quality adjusted life year | | |
| - At 15 years | 10,200 | 15,400 |
| - Over life expectancy | 3,500 | 10,500 |

- the relatively small impact on the efficiency indicators of the cost savings from prevention of new cases of diabetes (compare 'gross' versus 'net' results) compared to the large impact of the choice of outcome indicator ('life year' versus 'year of diabetes prevented' versus 'quality adjusted life year').

# 5 Sensitivity Analysis

## 5.1 Methodology Assumptions Varied and Rationale

The sensitivity of the assumptions used in the model was tested for:

### 5.1.1 Health Outcomes

***The Amount of Weight Loss***

The 95% confidence interval for weight loss from Heartwise is -1.8 to 0.38 kilograms. A loss of 1.8 kilograms would represent a reduction of approximately 30% of that achieved in the Swedish trial (Eriksson 1991), or a 15% reduction in the rate of progression to NIDDM. To represent this outcome, Matrix 3 of Appendix A was used for years 0-5.

***The Duration of Weight Loss***

Duration was tested by extending the use of Matrix 2 in Appendix A (representing an 8% reduction) and Matrix 3 (representing 15% reduction) to year 25.

### 5.1.2 Patient Selection Criteria

If those patients with a BMI $\geq$ 27, but with no other risk factors were recruited to the program, participants would number 1,276 rather than 298. Assuming that they are at equal risk of NIDDM as those with additional CVD risk factors and that they would also achieve an average 1 kilogram weight loss, the impact on cost-effectiveness is determined.

### 5.1.3 GP Participation Rate

As mentioned previously (refer Table 8), the major share of costs absorbed by 'set-up' and 'GP recruitment', raises the important program design and policy issue of what impact increasing or decreasing the number of participating GPs would have on program efficiency. Accordingly, the extent of GP participation was varied from 14 to 7 and from 14 to 28 GPs.

### 5.1.4 Costs

***Use of Nurses Rather Than GPs for Patient Recruitment***

In both the Oxford and Collaboration Health Check (OXCHECK 1994) and the Family Heart Study (Family Heart Study Group 1994) GPs were supported by nurses trained to screen and intervene. A modification to the design of our hypothetical program along these lines is an important parameter to consider for three reasons. Firstly, it may yield significant cost savings where cost containment or affordability was a consideration. Secondly, it may lead to a more efficient program where nurses are judged equally as effective as GPs (or marginally less effective[1]) in encouraging behavioural change leading to weight reduction. Thirdly, the assistance of nurses

[1] As efficiency is a relationship between costs and outcomes, an improvement in efficiency may result where nurses are less effective than GPs, but the reduction in effectiveness is outweighed by the cost savings from the lower salary cost of nurses.

may increase the likelihood of GPs participating in the program, which would have the effect of spreading program fixed costs over more participants, thereby improving program efficiency.

***Reduce Establishment Costs and/or Overhead Costs***

In Table 8, it was shown that program 'set-up' and recruitment of GPs accounted for 50% of program costs. Overheads alone account for 42% of these set-up/GP recruitment program costs. As future overheads are not known with any precision, this is an important parameter to examine in the sensitivity analysis. Accordingly, overhead costs of the lead agency have been reduced from 75% of staff costs to 20%. Labour expenses accounted for 55% of set-up/GP recruitment costs and similarly needed to be examined in sensitivity analysis, to reflect any cost savings that could be gained in applying Heartwise in a real life application. To explore this potential the lead agency staff costs were trimmed by reducing the Senior Lecturer/Project Leader from 0-2 FTE to 0.1 FTE the NHF Project officer and Secretary remained the same, but the Research Assistants were cut from 1.5 to zero. Overheads were correspondingly reduced as they are calculated as a % of staff costs.

***GP Case History Time***

The other major expenditure category in Table 8 was the 'screening, recruitment, plan development' for at risk patients, which accounted for 35% of the hypothetical program's gross cost. To investigate the impact of cost containment in this area, we varied the time GPs devoted to the intervention at the initial consultation from 5 to 2 minutes. Further, as our knowledge of what GPs currently provide for their overweight patients in terms of health advice is not extensive, we varied the base case from 2 to 5 minutes.

***Joint Costs***

The implications of viewing relevant costs as 'joint costs', and the effect of differing attributions has been emphasised previously. The attribution percentage when taken as a 'piggy-backed' program was varied from 20:80, to 50:50 and 80:20 in terms of attribution to CVD and NIDDM prevention respectively.

## 5.2 Sensitivity Analysis Results

Summary results for these variations are presented in Table 15 for the NIDDM program run as an independent program, that is, with full attribution of costs to NIDDM prevention (except for the variation of the joint cost assumption itself). From a policy perspective the sensitivity results can usefully be analysed by the extent to which the changes to the assumptions impact on the three key objectives of cost containment (or affordability); effectiveness (or health gains); and efficiency (or cost-effectiveness).

### 5.2.1 Cost Containment (or Affordability)

Of those variations which result in cost savings, by far the most important relates to whether the NIDDM program is run on a stand-alone or piggy-backed basis. This design issue has the potential to save the NIDDM program $106,541, $200,323 or $294,104

depending on whether 20%, 50% or 80% of joint costs are attributed to the companion CVD program. Apart from the issue of joint costs which is clearly far reaching in its impacts, the variation that produces one of the biggest drops in gross expenditure ($97,457) is a reduction in the number of participating GPs from 14 to 7. Such an eventuality, however, would drastically reduce the effectiveness of the program and considerably worsen the cost-effectiveness result (by approximately 52%). It illustrates the important message that cost containment is not the same thing as efficiency, and that program variations should be considered in terms of their impact on both costs and outcomes.

**TABLE 15** **Sensitivity Analysis Results**

| Assumption | Variation | Net Cost Per Life Year Saved (5% Discount Rate) $ |
|---|---|---|
| **Independent Program (Standard Assumptions)** | | 63,000 |
| • Costs | | |
| - Overheads for lead agency | Decreased to 20% of salary cost | 58,300 |
| - Reduce establishment costs | Reduce staffing levels/associated overheads by 75% | 42,296 |
| - Initial consultation in base case | Increased to 5 minutes | 62,800 |
| - Initial consultation in intervention case | Decreased to 2 minutes | 62,300 |
| - Recruitment of GPs | Decreased to 7 GPs only | 96,100 |
| - Recruitment of GPs | Increased to 28 GPs | 46,700 |
| - Recruitment of patients | Conducted by nurse instead of GP | 59,200 |
| • Patient Recruitment | | |
| - Recruitment of patients | Attempt to recruit all patients with BMI ≥ 27 | 18,500 |
| • Health Outcomes | | |
| - Duration of weight loss | 8% reduction in rate of progression to NIDDM achieved for years 0-25 | 44,000 |
| - Amount of weight loss | 15% reduction in rate of progression to NIDDM achieved for years 0-5 | 47,800 |
| - Amount and duration of weight loss | 15% reduction in rate of progression to NIDDM achieved for years 0-25 | 19,900 |
| **'Piggy-backed' Program** | | |
| • Joint costs | 20% of joint costs attributed to NIDDM prevention | 3,900 |
| • Joint costs | 50% of joint costs attributed to NIDDM prevention | 11,600 |
| • Joint costs | 80% of joint costs attributed to NIDDM prevention | 44,800 |

The next most important design issue is potential savings in establishment costs (at $148,830 from reducing staffing levels (85,046) and the associated overhead reductions ($63,784) for the lead agency; followed by whether nurses or GPs are used for the initial patient contact. The use of nurses offers a potential cost reduction of 7% in gross expenditure (or $29,120). A reduction in overheads (without changing staffing levels) also offers the possibility of a 7% cut in gross expenditure ($27,351 for the nominated change) with little, if any, associated reduction in effectiveness. A reduction in counselling time by GPs from 5 minutes to 2 minutes on the other hand does not have a large impact on costs (only 1% reduction or $3,693) and may well affect patient participation rates. It should be noted, however, that if larger numbers of GPs were participating, this result may change.

By way of comparison with these program cost variations, the cost offsets available from the prevention of NIDDM are a useful but not major factor at 5% of gross expenditure (or $20,671 discounted). Similarly, the adjustment for 'status quo' expenditure is not a significant cost factor in this evaluation (at 2% of gross expenditure or $7,202), as the level of activity involved is assumed to be minor.

### 5.2.2 Effectiveness (or Health Gain)

Of those variations which result in improved health outcomes, the most significant is the assumption of an improved weight loss (15% reduction in BMI, rather than 8%) maintained over a long period (25 years rather than 5 years). This variation leads to a major increase in program effectiveness (of 347% measured in terms of life years saved). Of a similar order of impact (at 328% increase in life years saved) is the variation that ***all*** overweight patients are recruited, irrespective of the presence or otherwise of additional CVD risk factors. There is then a large drop to a 121% improvement in health gain (assuming the standard 8% weight reduction lasts for 25 years rather than 5 years); then to a 100% improvement (assuming the number of participating GPs rises from 14 to 28); and lastly to a 63% improvement (for a larger weight loss - 15% rather than 8% - but only for 5 years).

These results suggest that the extent of GP participation, patient recruitment criteria, as well as the level and duration of weight loss, are all major determinants of program effectiveness. This applies for all measures of program effectiveness, although only 'life years saved' results are reported above. Of these various factors, GP participation and patient selection criteria would seem the most amenable to improvement through program design and implementation. The level of weight loss, and particularly its maintenance through time, is heavily subject to individual variation, and no doubt the hardest to achieve.

### 5.2.3 Efficiency (or Cost-effectiveness)

Only three variations bring the NIDDM program into the range of what would normally be regarded as being 'cost-effective' (ie $\leq$$35,000 per life year).[2] These are:

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[2] It should be noted, that with cost-effectiveness analysis no program is cost-effective per se, but rather more or less cost-effective in relation to some norm as to what is acceptable expenditure. The term 'cost-effective' is thus a subjective term that requires a judgment in relation to some guideline as to what constitutes 'value-for-money'. Such guidelines are normally established by examining current expenditure patterns (see Discussion, Section 6). The '$\leq$ $35,000' and '$35,000 to $50,000 per life year' guidelines are rough 'rules of thumb' for average cost-effectiveness results.

1 running the initiative in concert with a CVD program and attributing a percentage of joint costs to the CVD intervention (50% attribution of joint costs yields a result of $11,600 per life year; 80% yields a result of $3,900 per life year);

2 recruiting all patients that are at risk in terms of their weight, irrespective of the presence or absence of additional CVD risk factors (yielding a cost-effectiveness result of $18,500 per life year); and

3 achieving and maintaining a BMI reduction of 15% (yielding a cost-effectiveness result of
$19,900 per life year).

It should be noted that while the result of each variation is worked out assuming all other assumptions are held constant, there is no reason in real life why the variations could not be combined. Thus, the NIDDM program could be run collaboratively with a CVD program, recruiting all patients with a BMI ≥ 27 in the NIDDM arm, and striving to achieve and maintain a 15% or better weight loss.

There are an additional four variations, that if achieved, would improve the NIDDM intervention in 'stand-alone' mode from $63,000 per life year, into the marginally 'cost-effective' zone[2] of $35,000-$50,000 per life year. These are:

1 achieving staff and associated overhead savings for the lead agency (vis-a-vis the Heartwise experience) achieves a cost-effectiveness result of $42,296 per life year (ie. a $20,704 improvement in cost-effectiveness over the $63,000 per life year result with standard assumptions);

2 achieving maintenance of the 8% weight loss (assumed in the standard settings) for a 25 year period, rather than 5 years achieves a cost-effectiveness result of $44,000 per life year;

3 doubling the number of GPs recruited from 14 to 28 (ie from 14% response rate to 28%), achieves a cost-effectiveness result of $46,700 per life year (ie $16,300 improvement in cost-effectiveness over the $63,000 result with 14 GPs); and

4 achieving an improved weight reduction (from 8% to 15%), but only over a 5 year period, yields the cost-effectiveness result of $47,700 per life year.

The variations that have the least impact on efficiency (with other assumptions held constant), are the use of nurses rather than GPs to recruit patients (yielding a $59,200 per life year result, or $3,800 per life year improvement in average cost-effectiveness); and a reduction in the overheads (yielding a $58,300 per life year result, or $4,700 per life year improvement in average cost-effectiveness). Both these variations do rank well, however, as measures to contain costs, but the saving is not a sufficiently large component of total expenditure to make a significant impact on cost-effectiveness. The result assumes that nurses are as effective as GPs in this part of the intervention, and even though the improvement is not dramatic with the patient throughput assumed, it does constitute a more efficient program design, particularly if it also encourages more GPs to participate.

# 6 Discussion

The pursuit of efficiency requires the analysis of the relationship between costs and outcomes within the context of what alternatives are available to the project under consideration. Efficiency has two crucial but related elements: firstly, 'allocative efficiency', which focuses on the choice of whether to do something at all; and secondly, 'technical efficiency', which focuses on the choice of how to do the something you've chosen. The two aspects are related, because in deciding whether the program under consideration is 'value for money' compared to other options, the choice is biased if the program is not designed in such a way as to maximise its potential. The discussion therefore considers both these aspects, starting with issues of project design and its policy implications and ending with a discussion of the comparative performance of this program vis-a-vis other programs to effect weight reduction.

## 6.1 Technical Efficiency

One of the problems in considering the efficiency of the hypothetical NIDDM program evaluated is the great variability in results. The cost-effectiveness results vary from over $100,000 per life year down to $4,000 per life year, or even less depending upon what combination of design characteristics and cost/outcome assumptions is made. In other words, the hypothetical NIDDM program could be excellent 'value-for-money' or very poor 'value-for-money'. Such variability casts particular importance on understanding the nature and predicability of the program's costs and outcomes. The importance of considering both costs and outcomes together, can be seen in Table 16, where the rankings for potential cost improvements are listed alongside the potential health outcome improvements, together with the potential efficiency improvements. The table demonstrates that while some cost containment measures can improve efficiency (eg piggy-backing the program, reducing overheads, use of nurses for patient recruitment), they are often less important than achieving outcome improvements, and if misconceived can savagely reduce efficiency (eg reducing the number of participating GPs). Apart from the piggy-backing/stand-alone decision, which totally dominates all other design variations, the next five rankings in the efficiency column are all sourced in outcome improvements.

**TABLE 16** **Cost, Outcome and Efficiency Rankings for the Sensitivity Analysis**

| Rank | Source of Cost Savings | Source of Effectiveness Gains | Source of Efficiency Gains |
|---|---|---|---|
| 1st | Piggy-back program | Achieve BMI reduction of 15% for 25 years | Piggy-back program |
| 2nd | Reduced lead agency set-up costs | Recruit all patients with BMI ≥ 27 | Recruit all patients with BMI ≥ 27 |
| 3rd | Reduce number of GPs to 7 | Achieve BMI reduction of 8% for 25 years | Achieve 15% BMI reduction over 25 years |
| 4th | Nurses for recruitment | Increase number of GPs to 28 | Reduced lead agency set-up costs |
| 5th | Reduce overheads | Increase BMI reduction to 15% for 5 years | Achieve 8% reduction over 25 years |
| 6th | Cost offsets | | Increase number of GPs from 7 to 14 |
| 7th | Base case adjustment | | Achieve 15% BMI reduction for |

| | | |
|---|---|---|
| | | 5 years |
| 8th | Reduce GP recruitment time from 5 minutes to 2 minutes | Reduce overheads |

### 6.1.1 Key Findings on Technical Efficiency

- The NIDDM program's set-up costs (including GP recruitment) dominates gross expenditure (constituting approximately 50%). This in turn reflects the dominance of fixed costs over variable costs, due to poor GP participation rates (only 14 of 100) and stringent patient selection assumptions. Irrespective of what improvements are achieved in GP participation and in the economy of program establishment, the share of program funding that is likely to go into program establishment and management, should focus attention on what potential exists for co-ordinating related health promotion campaigns that address shared or related risk factors, and in better utilising existing infrastructure (particularly the Divisions of General Practice).

- While recipients of new health promotion interventions often receive subsidised services and pay a lower percentage of total program costs than they do under routine health promotion care, it is often not appreciated that in absolute cost terms they are being asked to give more than before and to keep up their commitment for much longer time periods. This is somewhat analogous to the absolute/relative risk differential in epidemiology, and may help to explain why the modified behaviour is hard to sustain. Insufficient attention to the incidence of costs in both relative and absolute terms, often leads to the potential cost offsets for health care providers being overplayed due to unrealistic expectations of patient adherence.

- The sensitivity analysis suggests that:

  - smaller health gains achieved over a more broadly defined at risk group only requiring one risk factor, such as (ie overweight) is more cost-effective than larger gains achieved for a more selective population base (ie requiring overweight plus a second CVD risk factor); and

  - the maintenance of smaller gains over a longer period is more cost-effective than achieving larger gains for a short period (despite the impact of discounting). This strongly suggests that more effort should be focussed on the maintenance of newly acquired healthy behaviours, vis-a-vis effecting the change in the first place.

- The effectiveness (or health gain) results suggest that the extent of GP participation, patient recruitment criteria and participation rates, as well as the level and duration of weight loss, are all major determinants. Of these factors, GP participation rates and patient selection seem the most amenable to improvement through efficient and acceptable program design and implementation. Improvements in the level and maintenance of weight loss would seem the hardest to achieve, and the most subject to variation.

### 6.1.2 The Disease Model

Critical to the evaluation of technical efficiency is the performance of the model. The model necessarily makes some major assumptions in the absence of suitable data. Discussion of these assumptions and their implications is given in the Appendix A.

## 6.2 Allocative Efficiency

The issue of allocative efficiency involves a comparison of the cost-effectiveness results discussed above for our NIDDM initiative, with the likely results for alternative applications of the resources available. In our case, we are assuming that the decision context is NIDDM prevention – that is to say, how can the resources available for NIDDM prevention be best utilised.

Economic evaluation results are also often presented as league tables, such as Table 17. Caution should be exercised in making direct comparisons between different studies due to differences in evaluation methodologies. Particular care should be taken when the comparison is with international results, as studies based in different countries, or even different regions, may be subject to different prevalences of disease & population characteristics, and to different protocols in the treatment of disease. Each of these variations, whether methodological or derived from different settings, can render results of limited relevance.

The objective of economic evaluations, whether cost-effectiveness or cost-utility studies, is to identify opportunities to increase overall health outcomes by the re-allocation of resources from less cost-effective health care programs or treatments to more cost-effective activities. Continual application of this principle must yield higher levels of health outcomes from the same resources.

### 6.2.1 Comparison with Other NIDDM Prevention Programs

A recent study by staff at HEU examined the cost-effectiveness of a range of primary prevention programs for NIDDM (Segal, Dalton and Richardson 1996) and is used here to compare cost-effectiveness results with those of widely different strategies for the prevention of NIDDM. Selective results from Segal, Dalton, Richardson are shown in Table 17 below and a brief description of each of the programs evaluated is given in Appendix B.

The study results reported by Segal et. al. have strong methodological similarities to our own. They are based upon the same underlying epidemiology reports of diabetes prevalence in Australia and use, where possible, current Australian clinical practice and costing data. The results for the likely cost-effectiveness of GP led behavioural change, are however, quite different, with the Segal et. al. results being far more optimistic than our own.

A fundamental difference between our results and those of Segal et al. involves the treatment of program establishment costs. Segal et al. did not include program establishment costs on the assumption that, over time, the initial establishment costs would become inconsequential as a proportion of recurrent costs. The size of these establishment costs will certainly vary between programs, but have been estimated by us for the GP program to be almost $200,000 (or 50% or total costs). Subtraction of these costs would generate a cost per patient of around $600 and a net cost per

life year saved (retaining all other assumptions adopted here) of approximately $25,000. Segal et al. still estimated a much lower cost-effectiveness as it was assumed that a greater number of doctors were recruited to the program and that weight loss was maintained. Our sensitivity analysis demonstrated that such optimistic results are potentially achievable if the associated cost, GP/patient participation, and outcome assumptions are realised.

A demonstration of the value of the application of the economic principle of allocative efficiency, and the role of QALYs, can be seen from considering the implications for resource allocation from documents relating to national goals and targets, including a national diabetes plan (Diabetes Australia 1995) where specified goals typically relate to what is considered clinically possible, rather than what may be cost-effective. Based upon effectiveness criteria, the results shown in Table 17 suggest that the pursuit of NIDDM prevention should give high priority to gastric by-pass surgery (with an 87% intervention success rate and an 85% reduction in the incidence NIDDM). However, the economic evaluation results suggest that while the surgical intervention is 'cost-effective' in a generic sense (ie $12,300 per life year), it is less cost-effective than other NIDDM primary prevention measures. This suggests that allocation of the same level of resources to other programs, such as behavioural modification based programs, would in fact yield a greater absolute number of life years saved.

**TABLE 17** **Reported Results for Primary Prevention of NIDDM (Segal, Dalton, Richardson 1996)**

| Intervention | Cost per participant | Target Group [(a)] | Assumed Effectiveness % success[(d)] | Cost/diabetic year @ 5% discount rate | | Cost/life year saved @ 5% discount rate | |
|---|---|---|---|---|---|---|---|
| | | | | Gross cost | Net cost | Gross cost | Net cost |
| Gastric by-pass Surgery | $13,300 | IGT | } | $3,200 | $1,200 | $12,100 | $4,600 |
| | $13,300 | Mixed | } 87% | $5,500 | $3,500 | $19,100 | $12,300 |
| Behavioural change for morbidly obese | $2,500 | IGT | } | $1,900 | Saving | $4,200 | Saving |
| | $2,500 | Mixed | } 33% | $3,600 | $1,600 | $5,900 | $2,600 |
| GutBusters | $195 | IGT | } | $300 | Saving | $500 | Saving |
| | $577 © | IGT +Screen | } | $800 | Saving | $1,600 | Saving |
| | $195 | Mixed | } 33% | $1,200 | Saving | $700 | Saving |
| Behavioural change for gestational diabetes | $2,500 | IGT | } | $2,700 | $800 | $4,400 | $1,200 |
| | $2,500 | Mixed | } 33% | $4,100 | $2,100 | $4,600 | $2,400 |
| Media Based Campaign | $2 million over two years | all overweight adults | } 1% | $400 | Saving | $500 | Saving |
| General Practitioner based behavioural change[(a)] | $420 per patient | CVD Risk Adults cohort BMI 27 + & IGT only | } 20% | $3,000 | $1,000 | $3,000 | $1,000 |

| Intervention | Cost per participant | Target Group [(a)] | Assumed Effectiveness % success[(d)] } | Cost/diabetic year @ 5% discount rate | | Cost/life year saved @ 5% discount rate | |
|---|---|---|---|---|---|---|---|
| | $473 per patient [©] | CVD Risk Adults BMI 27 + (mixed) | } } | $10,600 | $8,700 | $3,200 | $2,600 |

(a) Target group comprised either a mixture of IGT and NGT, referred to as a 'mixed group', or a higher risk group of IGT only.
(b) Based on assumptions of 50 GPs and 750 patients recruited, a program cost of $650 per GP recruited and weight loss maintained for life expectancy.
(c) Cost includes cost of pathology for glucose tolerance screening.
(d) Defined as % success: per cent of participants achieving long term weight reduction of at least 1 kg (for all programs except surgery), for surgery success defined as reduction of at least 50% excess weight.

Caution however, is also needed, to avoid over-simplistic conclusions from such economic data. If a cost-utility analysis were conducted for this surgery, for example it may be that the loss of weight would yield additional 'psychic' benefits from perceived cosmetic improvements, increased mobility etc. such that conversion of life-years to QALYs would generate a larger denominator and thus an improved cost-effectiveness. Alternatively, as gastric by-pass surgery has many unpleasant side-effects, patients may place little value on the additional years, thus generating a worsening of the cost-effectiveness result. The strengths and limitations of the outcome measure being utilised, in terms of its ability to capture all relevant outcomes for the technology in question, needs to be carefully considered.

The implications of introducing patient preferences through QALYs to this analysis is unclear; it may reinforce the conclusion to allocate resources elsewhere, or it may improve cost-effectiveness results to the extent that the program warrants increased resourcing.

An additional consideration that must be considered before drawing conclusions from any of these program evaluations, is the lack of uniformity between, and potentially within, target groups. For instance, it is obvious that the prevention of gestational diabetes can only apply to women in their reproductive years. The possibility also arises that sub-groups exist within each of these target groups, such that the generalisation of results, even within the nominated target group, is restricted. For instance, the GutBusters program comprises the delivery of lifestyle modification program to men with a high waist to hip ratio (a risk factor for both CVD and NIDDM). However, participation is voluntary and participants are therefore likely to be significantly more motivated than non-participating peers with a similar waist to hip ratio who, if subjected to the GutBusters program may yield very different results. Methodologies for the identification of those who are motivated and will respond well to programs of the GutBusters type are not well developed.

The strength of the results in Table 17 derives from the very low cost-effectiveness results, even cost-savings from some of the hypothesised interventions; so low that any set of more conservative assumptions (within broadly plausible ranges), are still likely to yield cost-effective results. With respect to the role of general practitioners in behavioural change programs, however, caution is warranted. As a consequence of the variation in results presented in this paper, the efficiency of General Practitioners in behaviour modification initiatives for weight reduction is yet to be demonstrated.

This is consistent with the findings of other researchers on GP-led behavioural change (Ashenden et al. 1995; Salkeld et al. 1995).

## 6.3 Other Issues in Interpreting Results

### 6.3.1 The level of weight loss in the long run.

It is important to note that the BMI reductions in our hypothetical intervention group were based on results of CVD multiple risk factor reduction trials, not NIDDM prevention trials. Where the intervention focuses on CVD risk reduction, the reduction in the incidence of NIDDM will be less than if the primary goal of the behavioural change program was weight reduction. This is primarily due to the different roles of the joint risk factors in respect of the two diseases. The implications of this assumption and of measures to modify it, are also canvassed in the discussion and sensitivity analysis.

Unfortunately, the literature provides no clear answer as to what level of weight loss is sustainable in the long run from health promotion interventions. It has been shown that maintenance of weight loss is positively related to the length of program. Furthermore, whether weight loss increases longevity also remains contentious, and a conservative assumption of an additional 0.25 months was made for the intervention group. That weight loss can reverse metabolic disorders, which itself alone has mortality reduction effects, is better established (Balkau 1993).

### 6.3.2 The Impact of a Reduction in BMI on NIDDM

The Swedish program upon which the Matrices were based referred to a male population only. Encounters with males aged 45-64 years in general practice clinics in Australia, however, comprise only 9.7% of total encounters, compared with 12.8% for women of the same age (Bridges-Webb 1992) Women are likely to be at least as highly represented in the recruited population. The effect of this factor on the analysis is unknown.

### 6.3.3 The Impact of a Reduction in BMI on Mortality

There is limited literature on the existence or otherwise of a clinically significant weight loss. Williamson et al (1993) used proportional hazards regression to estimate mortality rate ratios for those who had intentionally lost weight, as indicated in a questionnaire completed in 1959-60, compared with those who had not. They found that in overweight women (n = 28,388) with no pre-existing illness that an intentional weight loss of at least 9.1 kilograms within the previous year was associated with reduction in all-cause mortality of approximately 25%. However, loss of less than 9 kilograms was generally associated with small to modest increases in mortality. They concluded though that for overweight middle age women, weight loss enhances longevity for those with obesity related conditions, whilst for those with no pre-existing illness, the association is uncertain.

### 6.3.4 Recruitment over-time.

In research trials, recruitment is typically terminated within a short time frame. For a public health program, clearly the benefits of an intervention have the potential to extend for much longer periods. Estimating the duration of the benefits flowing from the initial GP training is quite complex. Benefits may diminish over time as a consequence of reducing retention of knowledge learnt. Alternatively, positive and successful responses from patients may reinforce the behaviour and increase efforts to promote and facilitate behavioural change. The evaluation here examines a finite period (12 months), given the uncertainty as to longer term behavioural patterns of participating GPs. Further research would be required to conduct an evaluation taking into account the dynamics over a longer period.

### 6.3.5 Number of Consultations

The average number of follow-up consultations was estimated as 2.4 per patient (compared with a protocol of 3) for Heartwise. However, the average includes a small number of patients who had as many as 7 visits over this period. Whilst it was recorded whether or not CVD risks were discussed at each consultation, it was not possible to determine from GP records whether this was the primary purpose of the visit or merely incidental.

Heartwise also recruited much younger patients, but data limitations on the effect of NIDDM prevention targeting those less than 45 years meant a reduced age band was selected to enable more reliable disease modelling. It is possible that those patients who were within the target age group of our hypothetical program would have a significantly different rate of consultation to the average found amongst Heartwise patients.

### 6.3.6 Numbers Recruited

The success rate of subsequent ‘rounds’ of recruitment of patients who declined participation at the first encounter is an unknown. The assumption of 15% was arbitrarily selected, but the effects of variations from this rate are likely to be minimal.

### 6.3.7 Choice of Comparator

The reasons Heartwise did not achieve the impact hoped for is not yet clear. However, it can be noted that the results were confounded by changing drug therapies over the 12 months and convergence of treatment patterns of control and intervention groups. The consequence of this convergence of treatment practices is that the true impact on CVD risk factors of ‘routine care’ is not still not known.

With regard to the generalisability of results, the prevalence of risk factors will vary between Divisions of General Practice . Whilst the proportion of patients eligible for recruitment is based upon Heartwise, which chose Divisions for their representative nature, it must be noted that implementation in other Divisions could yield different results. Establishing the degree of variance though would require further research.

### 6.3.8 Background influences.

Another complication arises from the contribution of other 'background' health programs, such as 'Life Be In It' or other programs promoting healthy lifestyles, to the weight loss. It may be that the program results should be interpreted as an incremental cost-effectiveness to existing efforts, rather than as a possible substitute for them (Dunt, Crowley & Day 1995).

### 6.3.9 Use of international data sources

By necessity, both this study and that of Segal, Dalton & Richardson (1996), draw upon clinical trial data from different populations, most commonly USA and Sweden. Although predominantly Caucasian populations and similar socio-economic status to that of the general population in Australia, different dietary habits and 'background' promotion of health behaviours (media campaigns etc) may lead to different responses in terms of incidence reduction of NIDDM. The implications of any such introduced errors are unknown as the consequences may not only affect the relationship of our results to other economic evaluations reported in the literature, but also affect the ranking of individual programs reported in Table 17 and of this study, should the error have differing proportional effects on the health outcome response.

# 7 Conclusion

The results suggest that reliance upon GPs to prevent NIDDM in the context of more general health promotion aimed at multiple CVD risk factor reduction is less cost-effective than prevention of NIDDM by alternative means such as weight loss programs in the workplace, or weight loss clinics. It is clear though that piggy-backing a NIDDM initiative onto a CVD intervention has the potential to vastly reduce costs of the NIDDM campaign (by approximately 80%) and turn an intervention that is only marginally cost-effective at $63,000 per life year saved (refer Table 13), compared to other uses for the resources involved, into one that is potentially very cost-effective at $12,600 per life year saved (refer Table 14 and Footnote page 27).

The results perhaps also reflect that different approaches may be required for different risk factors, with a population approach likely to be most cost-effective for some (for example; hypercholesterolaemia as concluded by Crowley, Dunt et al 1995), whereas successful weight loss through behavioural change needs individual support over an extended period (Prochaska & Diclemente 1992). The economic credentials of a role for general practitioners in such behavioural change, remains to be demonstrated in weight loss.

This is consistent with the findings of other researchers who have examined the effectiveness of general practitioners in effecting behavioural change (Ashenden et. al. 1995; Salkeld et al. 1995). However, given the importance of GPs in the health system, it may be that a role exists nevertheless, given the results could be within the full range of current health procedures receiving funding support. The challenge is to

identify those sub-groups of the ‘at risk’ population for whom GPs are effective, design a program that maximises GP participation, and encourages maintenance of health behaviour through time. The answer to the question of whether GP-led behavioural change for weight reduction is ‘value-for-money’ is therefore: ‘possibly, but proceed with caution’.

Any conclusions though must be tentative. Fundamental problems remain in determining if indeed GPs can induce clinically significant weight loss and whether this weight loss can be maintained. Furthermore, financial and structural barriers identified in the literature continue to inhibit health promotion by GPs.

# APPENDIX A

## The Disease Model

This appendix provides an overview of the approach and methodology used to model NIDDM, the results of which are utilised in the cost-effectiveness estimates contained in the report.

### 1 Model Overview

When modelling a disease such as NIDMM, the complexities arising from the potential for subjects to progress/regress between metabolic states, particularly between those of IGT and NGT, is overcome simply by adopting a Markov model approach which allows for transition between health states over time.

Markov chains use matrix algebra where the multiplication of two matrices, B and C, yield matrix A as follows.

$$a_{ij} = \sum_{k-1}^{n} b_{ik} c_{kj}$$

where i is the $i^{th}$ row, j is the $j^{th}$ column and k is the sequential element concerned.

Markov chains comprise the multiplication of fixed transition matrices comprising the probabilities of transition between the nominated health states. Markov processes are similar except that they recognise that transition probabilities themselves can be a function of some other parameter, such as time (that is, the age of the subjects) or weight change. A Markov process therefore comprises the sequential multiplication of a series of different matrices, each reflecting the transitional probabilities for a given period and/or new state. A Markov chain was essentially used for the control group (although with adjustments to mortality rates as explained below) and a Markov process for the intervention group to reflect weight change (re-gain).

The simple disease model for this study was developed using Excel v5.0 as follows.

### 2 Identify Health States

An important element of any Markov disease model is appropriate identification of the health states. For diabetes mellitus, the states are relatively simple, being NGT, IGT and NIDDM. These states require the development of 3x3 ‘metabolic state’ matrices for each of the control and intervention groups as shown in Table A1.

## 3 Determine Probabilities

As explained in the body of the report, the transition probabilities were derived from a Swedish trial which reported metabolic states for a group a males whose average age was 47 years. Based on the rate of transition between metabolic states over 5 years found in the trial, the probabilities derived for use in the model were as shown in Table A1. Using the control group matrix as an example, the interpretation that may be made is that: of all patients with IGT (row 2) at the beginning of the given period, after a period of 5 years, some 21.4% will have developed NIDDM, 42.8% will remain in the same state (IGT), and 35.8% will have improved their metabolic status to NGT. Similar interpretations can be made in respect of those with NIDDM (row 1) and NGT (row 3).

A sequence of 5 multiplications of this transition matrix (a Markov chain as performed for the control group in our model) simulates a 25 year period (5 x 5 years) post intervention. Implicit in the use of a Markov chain is the assumption of constant probabilities over multiple periods.

**TABLE A1** **Metabolic Transition Matrices**

| | NIDDM | IGT | NGT |
|---|---|---|---|
| • Control Group Matrix | | | |
| - NIDDM | 0.950 | 0.040 | 0.010 |
| - IGT | 0.214 | 0.428 | 0.358 |
| - NGT | 0.010 | 0.070 | 0.920 |
| • Intervention Group Matrix (» 8% reduction in progression) | | | |
| - NIDDM | 0.8740 | 0.0564 | 0.0696 |
| - IGT | 0.1968 | 0.2056 | 0.5976 |
| - NGT | 0.0920 | 0.0326 | 0.9582 |

The model assumes the probabilities within each matrix cell represent a linear progression within that 5 year period. However, as age (time) is itself a risk factor for NIDDM it is more likely that the rate of progression within each five year period was accelerating slightly. Whilst an annual probability could have been estimated from these results by application of:

$$P_A = 1 - e^{-x/5}$$

where $P_A$ is the annual probability of existing patients moving to another specified stated, and x = the progression over a 5 year period, a linear progression was retained as it remains a close approximation and the true progression over the period of the trial is unknown in any event.

Depending upon the use of the model results, a potential weakness of Markov models is that the forecasting of a health state over the forthcoming period for a given individual does not take into account the previous health states of that individual, which may affect the transition probability in reality. This lack of 'memory' is not considered important, as the application of the model here incorporated

transitional probabilities reflecting observed proportions from a trial population and are not used to infer probabilities for specific individuals.

## 4 Incorporate Mortality

The model endeavours to estimate at 5 year intervals what the actual aggregate number of people in each metabolic state would be for much of the adult life of the subjects. It is necessary, therefore, to include all-cause mortality estimates in the model. Failure to incorporate mortality would over-estimate the number of diabetic years prevented by including those from the cohort who would have succumbed to competing causes of mortality. Additionally, mortality estimates are obviously necessary for cost per life year saved estimates.

Mortality rates are in effect a fourth health state. A 4x4 matrix incorporating death as an ‘absorbing’ state (that is, a state from which further transitions are not possible), could have been used instead of the 3x3 matrix described above. In the model, they have been incorporated for convenience of manipulation as an additional vector applied at the beginning of each transition period. As the matrix algebra used is the same as described in ‘Overview’, the effect is the same.

**TABLE A2** **Estimation of Mortality Rates**[1]

| Column | 1 | 2 | | 3 | | 4 | |
|---|---|---|---|---|---|---|---|
| Age Group | AIHW Rates for General Population | AIHW Rates for General Population Adjusted for Metabolic Status [IGT (1.6) & NIDDM (2.0)] | | Relative Risk of 1.1 (for Overweight) | | Relative Risk of 1.2 (for Overweight) | |
| 45-49 | 0.0240 | NIDDM | 0.044 | NIDDM | 0.048 | NIDDM | 0.053 |
| | | IGT | 0.035 | IGT | 0.039 | IGT | 0.042 |
| | | NGT | 0.022 | NGT | 0.024 | NGT | 0.026 |
| 50 - 54 | 0.0409 | NIDDM | 0.076 | NIDDM | 0.084 | NIDDM | 0.091 |
| | | IGT | 0.061 | IGT | 0.067 | IGT | 0.073 |
| | | NGT | 0.038 | NGT | 0.042 | NGT | 0.046 |
| 55 - 59 | 0.0680 | NIDDM | 0.126 | NIDDM | 0.139 | NIDDM | 0.151 |
| | | IGT | 0.101 | IGT | 0.111 | IGT | 0.121 |
| | | NGT | 0.063 | NGT | 0.069 | NGT | 0.076 |
| 60 - 64 | 0.1113 | NIDDM | 0.206 | NIDDM | 0.227 | NIDDM | 0.247 |
| | | IGT | 0.165 | IGT | 0.181 | IGT | 0.198 |
| | | NGT | 0.103 | NGT | 0.113 | NGT | 0.124 |
| 65 -69 | 0.1823 | NIDDM | 0.340 | NIDDM | 0.374 | NIDDM | 0.408 |
| | | IGT | 0.272 | IGT | 0.299 | IGT | 0.326 |
| | | NGT | 0.170 | NGT | 0.187 | NGT | 0.204 |

**Notes** (1) Assumed life expectancy after twenty five years from intervention, that is, from age 70+ years, was assumed to be, on average, a further 10 years for diabetics surviving at that time, 11 years for those with IGT and 12 years for those with NGT. This was assumed for both control and intervention groups.

The process of estimating the age adjusted mortality rates used in the model from the observed mortality rates of the Australian population is described in Table A2 where each element represents the annual probability of mortality for each metabolic state. Mortality over each five year period was therefore estimated by $M_t = S_t.1\text{-}e^{m5}$ where, for the five year period t, $M_t$ is the number of deaths, $S_t$ is the number of survivors at the beginning of the period t, and m is the annual probability of mortality. The mortality vectors used were taken from Columns 3 and 4 of Table A2.

For example, the mortality vectors used in the model for the age group 45-49 years (for the first five years after commencement of the intervention), are shown in Table A3.

**TABLE A3** **Mortality Vector Application**

| Control Group Age 45-49 Mortality Rates | | | Intervention Group Age 45-49 Mortality Rates | | |
|---|---|---|---|---|---|
| NIDDM | IGT | NGT | NIDDM | IGT | NGT |
| 0.053 | 0.042 | 0.026 | 0.048 | 0.039 | 0.024 |

## 5 Life Expectancy

Modelling of the progression of the cohort through the application of the above matrices was performed for a total period of 25 years post intervention, by which time the cohort survivors would be aged between 70 and 75. Literature reports reveal that relative risk for overweight diminishes greatly after this age, although higher mortality rates remain for those with NIDDM. Consequently, simplifying assumptions were made as to the remaining life expectancy.
It was assumed that the average life expectancies of survivors after year 25 would be:

| Control Group and Intervention Group | | | Implied Average Life Span |
|---|---|---|---|
| NIDDM | : | 10 | 80-85 |
| IGT | : | 11 | 81-86 |
| NGT | : | 12 | 82-87 |

## 6 Estimation of Health Outcomes

The application of the control and intervention, matrices respectively (together with the age adjusted mortality vectors), enabled an estimation of outcomes for each of the Control and Intervention Groups in terms of :

- the aggregate number of survivors at the end of each 5 year period (and by implication the number of deaths) together with a cumulative total;

- the aggregate number of people within each metabolic state at the end of each 5 year period together with a cumulative total.

## 7 Estimation of Costs

The cost per patient was estimated exogenously to the model as described in the report. The aggregate cost of the program was derived within the model by multiplying the number of program participants by this estimate. This method implies a constant (average) cost.

## 8 Discounting

Consistent with common practice in the conduct of economic evaluations, the results presented reflect the use of different discount rates (0%, 5% and 10%) applied to the *flow* of benefits where the present value of a stream of future benefits, in this case additional life years or years without NIDDM, is estimated as:

$$PV = P(1+r)^{-n}$$

where PV is the equivalent 'value' of the stream if realised today, r is the discount rate and n is the number of years over which discounting occurs.

Had costs extended over the assumed 12 month period of the intervention, the discount rate would have also been applied to costs as well.

## 9 Discussion

### Use of Fixed Matrices Overtime

Ideally the transitional probabilities used would reflect that age is a risk factor for NIDDM. Data limitations, however, on the actual rates of transition between the three states of NIDDM, IGT and NGT did not make an age adjustment of the probabilities possible. Of importance though to the evaluation is the estimation of the magnitude of the difference between the outcomes of intervention and control groups. As increasing age is common to both control and intervention groups, we have no reason to think that the difference between the groups would be significantly greater from this refinement.

### The Level of Weight Loss in the Long Run

Unfortunately, the literature provides no clear answer as to what level of weight loss is sustainable in the long run from health promotion interventions. It has been shown that maintenance of weight loss is positively related to the length of program. Furthermore that weight loss increases longevity also remains contentious, hence a conservative assumption of an additional 0.25 months was made for the intervention group. That weight loss can reverse metabolic disorders, which itself alone has mortality reduction effects, is better established (Balkau 1993).

### Mortality Rates

If the adjustments made for overweight and metabolic status are not additive, the model will overstate the mortality rates for both control and intervention groups. The impact of estimation errors will again be reduced though as the key to cost-

effectiveness is the difference between the two groups rather than the absolute levels.

**Number of Consultations**

The average number of consultations was estimated as 2.4 per patient (compared with a protocol of 3) for Heartwise. However, the average includes a small number of patients who had as many as 7 visits over this period. Whilst it was recorded whether or not CVD risks were discussed at each consultation, it was not possible to determine from GP records whether this was the primary purpose of the visit or merely incidental.

**Target Population**

Most multiple risk factor reduction programs including Freshstart and Heartwise, recruit much younger patients. However, data limitations on the effect of NIDDM prevention targeting those less than 45 years meant a reduced age band has been selected to enable more reliable estimation through modelling.

**Numbers Recruited**

The success rate of subsequent 'rounds' of recruitment of patients who declined participation at the first encounter is an unknown. The assumption of 15% was arbitrarily selected. However, the effect of variations from this rate are likely to be minimal as a small number of patients is involved.

**Choice of Comparator**

The reasons both Heartwise and Freshstart did not achieve the impact hoped for are not yet clear. However, it can be noted that the results were confounded by changing drug therapies over the 12 months and convergence of treatment patterns of control and intervention groups. The consequence of this convergence of treatment practices is that the true impact on CVD risk factors of 'routine care' is not still not known. Whether routine care would be more cost-effective is therefore not known either. This reasoning led to the choice of another setting for a cost-effectiveness comparator, the 'Gutbusters' program. The convergence of protocols also obscured the impact of the additional patient materials. Although included in the hypothetical program, as the cost of additional materials was proportionally small, their deletion will have little impact on cost-effectiveness results here.

**Generalisability of Results**

With regard to the generalisability of results, the prevalence of risk factors will vary between Divisions of General Practice . Whilst the proportion of patients eligible for recruitment is based upon Heartwise which chose Divisions for their representative nature, it must be noted that implementation in other Divisions would yield different results. Establishing the degree of variance though would require further research.

**Extent of BMI Reduction**

It is important to note that the BMI reductions in our hypothetical intervention group were based on results of CVD multiple risk factor reduction trials (refer Table 2), not

NIDDM prevention trials. Where the intervention focuses on CVD risk reduction, the reduction in the incidence of NIDDM will be less than if the primary goal of the behavioural change program was weight reduction. This is primarily due to the different roles of the joint risk factors in respect of the two diseases. The implications of this assumption and of measures to modify it, are also canvassed in the discussion and sensitivity analysis.

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**Body Weight Results**

The estimated weight loss at 18 months is almost identical to that reported for the Swedish study. It was thus assumed that over the longer term weight loss will be similar to that observed in this study.

The focus of the analysis is the prevention or deferral of diabetes and impact of weight loss on expected all-cause mortality. The estimated reduction in weight has been translated into a reduction in incidence of diabetes, annual mortality and life expectancy. As noted earlier, the expectation that a reduction in obesity will defer onset of diabetes is based on sound scientific and empirical evidence. Rates of progression between diabetic states described in the Swedish study (Eriksson 1991) are used as the basis for estimating possible deferral of diabetes.

**All Cause Mortality**

A modest relative risk for all-cause mortality between overweight and normal weight of 1.2 has been assumed for this program type. This is based on the expectation that this type of program would attract a mixed group including the modestly overweight and the seriously obese.

Beyond 25 years (the period of the model), remaining life expectancy is taken at 12 years for the successful intervention group with NGT equal to average life expectancy for men at age 70/71. A reduction of 10 percent is assumed to be associated with IGT and 20 percent with NIDDM. For the control group, life expectancy after 25 years is assumed to involve a 10 percent penalty at each diabetic state (rounded), for example to be 11 years for those with NGT, 10 years for those with IGT and 9 years for persons with NIDDM.

# APPENDIX B

This appendix provides a description of the programs evaluated by Segal et al 1996. Six broad program types are described, together with expected costs. Outcomes were estimated in terms of diabetes years deferred, and life years saved. This work was based on limited information about program options, their costs and effectiveness such that cost-effectiveness ratios could not be calculated with certainty. Nevertheless, it was possible to calculate with some confidence the order of magnitude of the ratios implied by the current state of knowledge.

## Program I

### Workplace Lifestyle Modification Group Program For Men: GutBusters.

#### Introduction and Program Description

The cost-effectiveness analysis of this intervention type (workplace based group program for overweight men) for the prevention of NIDDM is based on GutBusters. This is a lifestyle program developed with assistance from the Royal Prince Alfred Hospital Endocrine Unit, to target males with abdominal obesity (a risk factor for NIDDM). The program was originally trialed at BHP, Newcastle. The focus of the program is reduction in abdominal fat, with a target 5% reduction in waist measurement and a waist measure of <100 cm. As the prevalence of overweight is higher amongst men than women, and men have higher all-cause mortality rates than women, particularly in diseases amenable to lifestyle change, the need for targeted weight loss programs for men was a major motivation in developing this program.

Participants are usually recruited at the workplace, with the program often implemented at the workplace. The program is educational and knowledge based and aims for modest change in energy balance while not drastically interfering with lifestyle. Its five tenants are: increased movement, decreased dietary fat, increased dietary fibre, modification of behavioural habits, and trading off indulgences (such as reduction in alcohol consumption).

The program consists of one hour sessions per week, for five or six weeks. A follow-up course is optional. Companies may also encourage and facilitate participants to form on-going support groups. GutBusters is taken to approximate best practice for community based group programs for overweight males. The program is run commercially at a fee and thus cost can be inferred from the fee charged (not including program development).

The target of the program is overweight working males.

### Body Weight Results

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The focus of the analysis is the prevention or deferral of diabetes and impact of weight loss on expected all-cause mortality. The estimated reduction in weight has been translated into a reduction in incidence of diabetes, annual mortality and life expectancy. As noted earlier, the expectation that a reduction in obesity will defer onset of diabetes is based on sound scientific and empirical evidence. Rates of progression between diabetic states described in the Swedish study (Eriksson 1991) are used as the basis for estimating possible deferral of diabetes.

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# Program II

## Media-Based Lifestyle Program With Community Support

### Source of Information on Costs and Effectiveness

The use of the media specifically to prevent NIDDM is extremely limited in Australia, and from overseas reports, elsewhere as well. Media based programs for NIDDM, in Australia have largely focussed on general awareness, with recent programs to encourage screening for diabetes. In the absence of actual media programs on which to base cost-effectiveness estimates, this analysis of a media-based program for the prevention of NIDDM is largely hypothetical. Major media based health promotion campaigns directed at other diseases have been used to assess the possible cost and effectiveness of this type of approach to the prevention of NIDDM. This analysis is thus exploratory and should be considered a prefeasibility analysis not a full cost-effectiveness analysis.

Four Australian media based health promotion campaigns and one international campaign were used as the basis of this exploratory study. Programs were chosen if they: are directed at the general population, rely on behaviour change, have some

published data on costs and/or effectiveness, and represent a combination of media campaign with other community based components:

The programs were;
- 2 Fruit n 5 Veg ;
- SunSmart;
- Sydney Quit For Life;
- Transport Accident Commission (Victoria) road safety campaigns,
- Stanford USA five-city project.

**Key assumptions:**

- Success rate 10,000 overweight adults achieve long term weight loss - approximately equal to 1% of all overweight Victoria adults;
- Impact on diabetes progression - incidence of diabetes reduced by 50% within successful group (ie 10,000 adults).;
- Program cost - $1 million/year for two years, that is a $2 million program, to cover media costs and community based component;
- Program type - Mass media with some community based activities and support

# Program III

## Bariatric Surgery For The Seriously Obese

### Program Description

A program comprising bariatric procedures for the morbidly obese, preceded by counselling sessions and followed by post-operative assistance with consequent morbidities is envisaged. Long et al 1994, reported on 136 severely obese individuals (more than 40 kg excess body weight) with IGT. The intervention group consisted of 109 patients who had bariatric surgery, with 27 in the control group. The subsequent rates of conversion to NIDDM in the control and intervention groups reported at an average of 4.8 years of follow-up have been used in the cost-effectiveness analysis, and are summarised in Table B.1. In the control group, that did not receive surgery, six had developed NIDDM (22%), while in the surgery group only one person out of 109, developed NIDDM. This study demonstrates that substantial and sustained weight loss in morbidly obese persons with IGT can virtually eliminate, what is otherwise a high risk of progression to NIDDM.

**TABLE B.1** **Results of Gastric Bypass Surgery Progression to NIDDM.**

| | At 4.8 years average follow up for seriously obese persons with IGT at study entry | |
|---|---|---|
| | **Intervention** | **Control** |
| Number in sample | 109 | 27 |

| | | |
|---|---|---|
| Cases of NIDDM | 1 | 6 |
| Incidence of NIDDM (%/annum) | 4.7 | 0.15 |

Source: Long et al 1994

Also, a post-operative mortality of 1% has been applied. The effectiveness of surgery, in terms of successful weight loss has been adjusted, down from the 99% reported by Long to 87%, reflecting a recent study (Pories et al 1992) reporting that 13% of patients undergoing gastric by-pass surgery (of 479 patients) failed to achieve substantial long term weight loss.

### Expected Cost

The program is more extensive than surgery, involving also several sessions of prior counselling and assessment and several follow-up sessions to support behavioural modification, to maximise the chance of success. The cost of this intervention has been estimated at $15,000 per person as given in Table B.2.

**TABLE B.2** **Average Cost of Treatment for Bariatric Surgery**

| Activity | Cost per patient $ |
|---|---|
| * Counselling prior to acceptance for surgery, including assessment of suitability for procedure (psychological & physical). | 400 |
| * Pre-surgical tests | 100 |
| * In patient procedure, including immediate post-operative care. | 2,000 |
| * Care for Morbidities | 600 |
| * On going behavioural/nutritional support,. | 900 |
| TOTAL | 15,000 |

### Effect on Incidence of NIDDM: Surgical and Behavioural Interventions for the Seriously Obese

Reduction in rate of progression to NIDDM has been taken to be 85%, reflecting the large reduction in incidence of NIDDM reported by Long, (down from 4.7%pa to 0.15% pa).

### Life Expectancy and Mortality Rates

The differential all-cause mortality due to severe obesity is based on a relative risk of around 2.2. Adjustment to mortality rates to reflect the three states of NIDDM, IGT

and normal glucose are from Balkau et al (1993). Life expectancy at 25 years post intervention, is noted below.

**Key assumptions**

success rate for the surgical intervention group is 87%, with 12% failure and 1% operative mortality,

- annual death rate for control group or unsuccessful intervention group based on literature reports and related to total Australian death rates by age group, annual death rate for successful intervention group midway between rates for control group and Australian all-cause death rates
- life expectancy at 25 years post intervention: Control = 8 years, NIDDM, 9 IGT, 12 NGT), Intervention = 11 years NIDDM. 12 IGT, 13 NGT.

# Program IV

## Behavioural Modification For Seriously Obese Persons

**Program Description**

The cost-effectiveness analysis of behavioural modification for the seriously obese, is based broadly on:

- the obesity control service offered by the Endocrine Unit at the Royal Prince Alfred Hospital, (RPA) Sydney, (Richman et al 1992 and direct communication), and
- a four year behavioural modification program for persons with severe obesity, provided by the Department of Internal Medicine and Obesity Unit, Karolinska Hospital, Stockholm, (Bjorvel and Rossner 1985, 1992).

These programs comprise various activities with common elements including:

1. In-patient/day-patient or outpatient hospital attendance at program commencement,
2. Standard kilojoule reduction regimen or very low energy diet replacement (VLED) - the latter regimen commonly used in the Royal Prince Alfred program, and instruction in low energy food preparation and nutrition;
3. Individualised exercise program to maintain activity levels, and group activities appropriate to severely obese persons;
4. Education to encourage and facilitate behavioural modification through one-on-one and/or group sessions. Teaching of stress management and relaxation techniques, and methods for improving self esteem, coping strategies etc.

In the Royal Prince Alfred program, patients receive counselling and support sessions over a period of 12 months, from a team of dietitians, physiotherapist, psychologist and nurse, with approximately 14 sessions over 12 months. There is little active follow-up beyond 12 months.

The Swedish program incorporated a four year follow-up period with the opportunity for participation in weekly sessions and weigh-ins, with advise available from the dietitian. Patients not attending for scheduled sessions were actively followed up.

In the Swedish sample only, 39 participants also had jaws fixed for a median of five months, supported by an intensive two week behavioural modification program and on-going support.

**Expected Weight Loss**

In the cost-effectiveness analysis, it was assumed that 33% of participants maintain clinically significant weight loss, over the long term, in response to an intensive diet and behaviour modification program, offering support for at least 2.5 years. In applying the model, it was however assumed that reducing effectiveness on incidence of NIDDM over time, (from 70% in the first 5 year period down to 30% in the $5^{th}$ five year), reflecting expectation of weight gain.

**Cost of Program**

Treatment is described as intensive, and delivered through a multi-disciplinary team over at least 2.5 years. It is expected many entering the program would have a history of failed weight loss. The treatment program costed involves administration of diet, commencement of exercise program, education for empowerment to achieve and maintain behaviour change, plus counselling and other support over at least a 30 month follow up period. The program is expected to extend up to 3 years, with reducing intensity over that period.

Table B.3 lists the chief costs associated with the intensive diet/behavioural modification program. Unit costs have been attributed to each cost component to develop a total program cost estimate of $2,500 per person. This figure should be generous.

**TABLE B.3** **Program Cost of Behaviour Modification Program**

| Program costs (a) | Dollars |
|---|---|
| • Initial counselling/education/etc (3-4 sessions) | 240.00 |
| • Consultation with endocrinologist (2-3 sessions) (a) | 215.00 |
| • Initial pathology tests and follow-up pathology | 145.00 |
| • Follow-up sessions with members of multidisciplinary team (sessions first 6 months plus 10 sessions next 2.5 years) | 1,900.00 |
| **Total** | **2,500.00** |

**Effect on the Incidence of NIDDM: Diet/Behavioural Program for the Seriously Obese**

Because with most weight loss programs there is some weight regain, it was assumed that the effect on incidence of NIDDM will vary from a 70% reduction in the first 5 year follow-up period down to 30% in the fifth 5 year period. (Three separate transfer matrices have been applied to the successful intervention group)

The transition probabilities for the successful intervention group are applied to 33% of the intervention group, as it has been assumed that 33% of participants will maintain significant weight loss over the long term.

**Life Expectancy and Mortality Rates**

The target group is severely obese persons, with age at program entry 45 to 49 years. The same relative risks for mortality have been applied to the severely obese participants for the behavioural as the surgical program. The key differences are that with the surgical program 87% of participants are expected to be in the successful group compared with 33% for the behavioural program.

**Key assumptions:**

- program cost is $2,500 per participant
- the transfer probabilities between diabetic states vary from 70% reduction in incidence to 33% reduction in incidence for successful intervention participants.
- success rate is 33%, who maintain long term weight loss,
- annual death rate for control group and unsuccessful intervention group: relative risk based on literature reports ranging from 2.85 for the 45 to 54 age range down to 1.85 in the 65 to 74 age range; for successful intervention midpoint between control and population rate;
- relative risk for annual mortality imposed by NIDDM =2 and IGT =1.6 confers relative risk of group (to 25 years),
- additional life expectancy at 25 years post reduction for IGT and a further 10% reduction for NIDDM plus 10-20% reduction for failure to maintain weight loss.

# Program V

## Program For Women Who Have Had Gestational Diabetes

### Program Description

An hypothetical intensive behavioural modification program of the type described in Program IV, consisting largely of several consultations with allied health professionals and endocrinologists who are members of a multi-disciplinary team. The focus of the intervention is nutrition, education concerning the risks of NIDDM and associated morbidities, evidence on how risks can be reduced, strategies for personal empowerment, tailored exercise program and diet, with on-going follow-up, preferably over at least 3 years, but possibly up to 10 years (or for life).

### Progression to NIDDM

Based upon 17 year data received from the Melbourne University/Mercy Unit.

### Program Costs

Without a program on which to base costs, program costs were taken as $2,500 per person  equal to the cost estimate for the intensive behavioural modification program, targeted at the severely obese.  Only with the development of a pilot intervention program, can actual program costs be ascertained.

Mortality Rates are based on ABS all-cause mortality data adjusted for diabetic status and for effect of weight loss on the intervention group.

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