

Prevention of Type 2 Diabetes

A Background Paper

Prepared by the
Diabetes Prevention Working Party
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Contents

1	Background	1
1.1	Introduction	1
1.2	Diabetes prevalence and trends	2
1.3	Complications of diabetes	2
1.4	Can type 2 diabetes be prevented?	3
2	Review of current evidence	5
2.1	Preventing type 2 diabetes	5
2.2	At risk target groups	5
2.3	Screening modality	5
2.4	Recruitment of the target group for screening	6
2.5	Components of effective lifestyle interventions	7
2.6	What is the role of health promotion?	7
2.7	Is the prevention of type 2 diabetes good value for money?	8
2.8	Referral pathways for interventions	10
2.9	Evaluation and monitoring	11
3	Translation evidence research questions	12
3.1	Summary	12
3.2	Population level primary prevention initiatives	12
3.3	Cost effectiveness	12
3.4	Recruitment strategies	13
3.5	Lifestyle interventions	13
3.6	Evaluation and monitoring	13
3.7	Reaching the “hard to get”: Indigenous, remote and socioeconomic disadvantage	13
4	Risk assessment	15
4.1	What are the proposed aims and objectives of a diabetes type 2 screening and prevention program?	15
4.2	Macro risk issues for the screening and prevention of type 2 diabetes	15
5	Links to work planned or underway	16
5.1	National Health and Medical Research Council (NHMRC)	16
5.2	National Health Priority Action Council (NHPAC)	18
5.3	WHO global strategy on diet, physical activity and health	18
5.4	“SNAP” initiative	19
5.5	National Obesity Taskforce	19
5.6	Jurisdiction-based activity	19
	References	20
	Glossary	22

Tables and figures

Table 1: Estimated cost of a diabetes prevention program in the United States	9
Figure 1: One-off screening intervention: an overview of predicted numbers, with an assumption that only 50% of the target group will actually undergo screening (based on census and AusDiab data)	10
Table 2: Macro risk issues for the screening and prevention of type 2 diabetes	17

1 Background

1.1 Introduction

At its meeting in Auckland NZ on 25 March 2004, the National Public Health Partnership (NPHP) considered a proposal for a collaborative, national approach to the prevention of type 2 diabetes.

NPHP noted that a targeted secondary prevention program based on the recently published evidence from randomised controlled trials (RCTs) for lifestyle interventions targeting people with Impaired Glucose Tolerance had potential national applicability and that its optimal implementation would require community awareness and Australian Government, state governments and private sector funding and service delivery mechanisms.

A nationally coordinated type 2 diabetes secondary prevention strategy would build on Australia's investment in chronic disease prevention and enhance capacity for effective action to reduce the incidence of disease and disability. The strategy would complement primary prevention efforts in Australia to reduce the risk of major preventable chronic diseases through promotion of healthy diet and regular physical activity, and provide a vehicle for integrated action on diabetes across the continuum of care.

Supporting existing and proposed national strategies include:

- Eat Well Australia: A Strategic Framework for Public Health Nutrition 2000–2010;
- National Aboriginal and Torres Strait Islander Nutrition Strategy and Action Plan 2000–2010;
- Be Active Australia: A Framework for Health Sector Action for Physical Activity 2005–2010(draft);
- Healthy Weight 2008 – Shaping Australia's Future: The National Action Agenda for Children and Young People and their Families;
- National Service Improvement Framework for Diabetes (under development);
- National Diabetes Strategy 2004–2008 (under development);
- National Chronic Disease Strategy (under development);
- Primary Care Policy (under development);
- National Strategic Framework for Public Health Action for Children 2005–2008 (draft); and
- National Agenda for Early Childhood (under development).

NPHP agreed to establish a working party to develop a proposal for a feasibility and acceptability pilot for such a national type 2 diabetes prevention program. This Background Paper has been prepared by the Working Party to “set the scene” by reviewing recent evidence and scoping current and planned activity relevant to the prevention of type 2 diabetes.

The major objective for setting up such a secondary prevention program would be to identify individuals at high risk of having the “pre-diabetic” states: Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) in order to implement practical lifestyle interventions based on the RCT evidence to prevent or delay the onset of diabetes in these people. Case detection of undiagnosed diabetes would also be improved although the focus of interventions would primarily be on patients with IFG and IGT, and cases of previously undiagnosed diabetes would be referred to usual care.

In undertaking this work, the Diabetes Prevention Working Party was specifically directed to take into account work already done or underway through the National Health Priority Action Council (NHPAC), the National Health and Medical Research Council (NHMRC) and in the jurisdictions of Victoria and New South Wales.

1.2 Diabetes prevalence and trends

Diabetes is a common, chronic and costly condition which imposes a huge burden on the Australian community. Diabetes affects people of all socio-economic and cultural backgrounds, but with an uneven distribution across society.

Type 2 diabetes can involve both insulin resistance and impaired insulin production, either of which may pre-dominate.

In determining the risk of developing diabetes, environmental factors such as food intake and exercise play an important role. The majority of individuals with type 2 diabetes are either overweight or obese. Inherited factors are also important, but the genes involved remain poorly defined. Type 2 diabetes is strongly familial but it is only recently that some genes have been consistently associated with increased risk of type 2 diabetes in certain populations. (WHO, 2002a)

Type 2 diabetes is most common among people aged 40 years or over with the prevalence of type 2 diabetes increasing with age. The Australian Diabetes & Lifestyle Study 2001 (AusDiab) found that the prevalence increased from 6.2% (age group 45–54 years); 13.1% (age group 55–64 years); 18.6% (age group 65–74 years); to 23.6% (75 years and over). Although the AusDiab study found that the prevalence of diabetes was only 0.3% (age group 25–34 years) recent experience suggests that diagnoses of type 2 diabetes are increasingly being made in adolescents and children. Early diagnosis and treatment in the course of diabetes increases the likelihood of effective management through lifestyle modification and/or medication. There is evidence that early diagnosis reduces the lifetime accumulation of morbidity through its delay or compression. (Vita et al, 1998) Early diagnosis permits interventions to be commenced earlier in the history of the disease, and health gains from lifestyle modification are more likely to reduce lifetime morbidity.

In 2002 the Diabetes, Obesity and Lifestyle study (known as AusDiab) estimated that

diabetes affects 7.4% of the Australian population aged 25 years and over. (Dunstan et al, 2002) Only half of the people who had diabetes in this study were currently diagnosed. In other words, for every person with diagnosed diabetes in Australia there may be another person with undiagnosed diabetes.

In South Australia, the North West Adelaide Health Study found that the overall prevalence of diabetes was 6.6% and that for approximately every five people with diagnosed diabetes, there was another person with undiagnosed diabetes. (Grant et al, 2004)

The prevalence of diabetes in Australia appears to have doubled over the past 20 years, consistent with the global increase in diabetes prevalence, which has also doubled over the same period. Type 2 diabetes accounts for 85–90% of all diabetes and therefore for the majority of the health and cost burden of diabetes in Australia. A recent study in the USA has estimated that the lifetime risk of acquiring diabetes for someone born in the USA in 2000 is approximately 38%. (Venkat et al, 2003)

The burden of diabetes is distributed unequally across society. There is a clear socioeconomic gradient in the prevalence of type 2 diabetes, with a rate almost twice as high in the lowest socioeconomic group compared with the highest. (Mathers et al, 1999) Rates in some Aboriginal and Torres Strait Islander communities of up to 30% are among the highest in the world. In 1999–2000 the hospital separation rate for diabetes for Aboriginal people in NSW was five times the non-Aboriginal rate. (NSW Health, 2002)

Due to the ageing population, increasing obesity, decreasing physical activity and the proportion of people from ethnic and cultural groups with increased diabetes risks, the burden of diabetes in Australia, unless addressed by a robust intervention program, is expected to continue to increase in the future.

1.3 Complications of diabetes

People with diabetes face considerable physical, social and psychological challenges.

If undetected or poorly controlled, diabetes can result in acute and long-term complications. It is a leading cause of vascular disease (coronary artery disease, stroke and peripheral vascular disease), visual impairment and blindness, kidney failure and dialysis, foot ulcers and amputation and impotence. These complications are potentially preventable with early diagnosis and generally available medical care.

The management of diabetes involves significant social and lifestyle adjustments for the individual and their family. These may include self-measurement of blood glucose, taking insulin or oral medications and balancing diet and physical activity. Other detrimental effects of diabetes on the individual or family include increased costs including higher life and disability insurance, possible discrimination in employment and the intrusion of the diabetes self care regimen on lifestyle and subsequent loss of social spontaneity.

While the physical burden of diabetes complications has been well documented, until relatively recently, the psychological burden has not. There is now an emerging body of evidence about the effect of diabetes on mental health. For example, depression is reported to be 2–3 times higher in people with diabetes. (Anderson et al, 2001) The recent international Diabetes Attitudes Wishes and Needs (DAWN) study focused on psychological aspects of diabetes and highlighted the stress, anxiety and burn out experienced by people with diabetes. (Rutherford et al, 2004) Of the Australian people with diabetes (both type 1 and type 2) who participated in the DAWN study 25% were on current treatment for a diabetes complication and one third were in poor wellbeing with only 17% reporting good wellbeing. Self reported anxiety; stress, and worry were most commonly related to fears about worsening of the disease, future financial worries, and the risk of hypoglycaemic events.

Type 2 diabetes carries a high financial cost to the community and the health system.

The morbidity and early mortality associated with diabetes has enormous implications for productivity, financial and social costs. The 2003 DiabCo\$t study estimated the total annual cost of diabetes in Australia to be \$2.2 billion, or \$5360 for each person with type 2 diabetes per year. (Colagiuri et al, 2003) The presence of complications was the main driver of all costs, including impact on quality of life. Even with universal health insurance, diabetes imposes a considerable financial burden on the individual and their family.

Generally speaking, people with diabetes require 2–3 times the health care resources of people who do not have diabetes and diabetes care accounts for up to 15% of national healthcare budgets. (American Diabetes Association, International Diabetes Federation, 1996)

1.4 Can type 2 diabetes be prevented?

The natural history of type 2 diabetes includes a pre-clinical phase thought to be of 5 to 12 years in duration in which people may have the clinical markers of impaired glucose metabolism. This has been termed “pre-diabetes” (Vinicor et al, 2003) and includes ‘impaired fasting glucose’ (IFG) and ‘impaired glucose tolerance’ (IGT). The AusDiab study estimated the prevalence of “pre-diabetes” as 16.3%, more than twice the prevalence of diabetes, with 5.7% IFG and 10.6% IGT. The North West Adelaide Health Study, conducted in South Australia, found the IFG prevalence to be 4.3%. The IGT was not measured for any of the participants in this study and no oral glucose tolerance tests (OGTTs) were performed.

This “pre-diabetic” state offers the opportunity to intervene to prevent or delay the development of diabetes. Without intervention, approximately one-third of individuals with either IFG or IGT and two-thirds of individuals with both will develop extant diabetes within 6 years. (De Vegt et al, 2001)

Type 2 diabetes is largely preventable. Lifestyle risk factors for the development of type 2

diabetes include socioenvironmental risk factors (such as poor material circumstances), psychosocial risk factors (such as social isolation and lack of support), behavioural risk factors (such as physical inactivity and poor nutrition, including a high dietary intake of energy dense foods, particularly fats and low fruit and vegetable consumption) and physiological risk factors (such as obesity, IGT). In the case of gestational diabetes, diabetes during pregnancy increases the risk of type 2 diabetes in later life for both mother and child.

Many of these lifestyle risk factors are potentially modifiable and thus provide opportunities for prevention. The evidence suggests that two of these modifiable risk factors, obesity and physical inactivity, are the most important contributors to the development of type 2 diabetes and should be the focus of preventive strategies. (Costacou and Mayer-Davis, 2003; Mensink et al, 2003; NHMRC, 2001)

In people with IGT, recent clinical trials have provided strong evidence that progression to type 2 diabetes can be prevented or delayed by both lifestyle modification and medication. Randomised controlled trials in the US (Knowler et al, 2002) and Finland (Tuomilehto et al, 2001) have both demonstrated reductions in the incidence of type 2 diabetes of 58% over 3 years in people with IGT who received intensive individualised diet and exercise programs compared with control groups.

In the Da Qing trial in China (Pan et al, 1997), diet and exercise interventions in people with IGT were associated with a 42% reduction in diabetes incidence over 6 years. Treatment with metformin (Knowler et al, 2002) and acarbose (Chiasson et al, 2002) has also been demonstrated to reduce diabetes incidence in people with IGT by 31% and 25% respectively.

There is also some evidence to suggest that lifestyle interventions decrease mortality in people with IGT. (Eriksson et al, 1998) Lifestyle interventions may also reduce cardiovascular disease in this group of people, independent of whether or not they actually develop diabetes, although this requires further study.

The trials described above all involved intensive, individualised interventions within a clinical research setting. The challenge now is for policymakers, population health practitioners, clinicians, researchers and health economists to drive these proven interventions from the “efficacy” design stage to implementation into routine and sustainable practice. This challenge is not to be underestimated, but given the large burden of disease and cost associated with type 2 diabetes even small gains in prevention are likely to have significant population benefits. The benefits of effectively implementing sustainable lifestyle change programs extend beyond the prevention of diabetes to the prevention of other chronic diseases, such as cardiovascular disease, and the prevention of long term vascular and neurological complications even if diabetes is diagnosed.

2 Review of current evidence

The NHMRC published Evidenced Based Guidelines for the Management of Type 2 Diabetes, including Primary Prevention, Case Detection, and Diagnosis in 2001.

Building on these guidelines, two States, Victoria and NSW have undertaken recent systematic evidence reviews on type 2 diabetes prevention. Victoria's review of evidence was undertaken by the International Diabetes Institute based in Melbourne and the NSW review was undertaken by the Australian Centre for Diabetes Strategies, based in Sydney.

Reassuringly, both these concurrent reviews of evidence have come to strikingly similar conclusions, which are summarised below.

2.1 Preventing type 2 diabetes

Both the reviews found strong evidence from recent randomised control trials (Knowler et al, 2002, Tuomilehto et al 2001) that reductions in the incidence of diabetes in the order of 58% could be achieved among people with IGT who received an intensive, individualised diet and exercise intervention.

Treatment with metformin (Knowler et al, 2002) and acarbose (Chiasson et al, 2002) has also been demonstrated to reduce incidence of diabetes in people with IGT by 31% and 25% respectively.

2.2 At risk target groups

Consistent with NHMRC Diabetes Case Detection Guidelines, the target groups for early detection and intervention strategies are:

- All adults 55 years of age and over
- People aged 45 years and over who have at least one of the following:
 - BMI greater than 30
 - Hypertension
 - First degree relative with type 2 diabetes

- People aged 35 years and over from the following ethnic backgrounds:
 - Aboriginal and Torres Strait Islander
 - Pacific Islander, Indian subcontinent, Chinese
- People with clinical cardiovascular disease (myocardial infarction angina or stroke)
- Women with previous gestational diabetes
- Women with polycystic ovary syndrome who have a BMI greater than 30.

It is recommended that people with risk factors whose blood glucose levels are in the normal range should be retested every 3 years and those who test positive for “pre-diabetes” should then be screened for type 2 diabetes every year.

Consideration should also be given to including blood pressure and blood lipid measurement as part of the screening consultation, as evidence suggests that people with a combination of these risk markers and impaired glucose metabolism will have an increased risk of cardiovascular disease.

The AusDiab study estimates hypertension prevalence in Australians over 55 years to be 61.6%, of whom 28.1% are untreated and 33.5% are on hypertensive medication. The corresponding rates for Australians over 45 years are 49% hypertension prevalence, of whom 24% are untreated and 25% are treated. Overall, there was at least one modifiable lifestyle factor in 71.7% of AusDiab study participants with hypertension.

2.3 Screening modality

The strongest evidence for the lifestyle intervention is found in studies which focus on the group with IGT, which requires an OGTT for diagnosis.

Consistent with the NHMRC evidence based guidelines for the prevention and management of diabetes, a default algorithm

for screening people in the target group would be to perform an initial fasting plasma glucose test and offer an OGTT to people with a plasma glucose concentration after an overnight fast of ≥ 5.5 mmol/l and < 6.9 mmol/l.

Community screening activity underway in some retail pharmacy settings uses a non-fasting finger prick blood test and a blood glucose meter or blood glucose test strips read by the pharmacist. This is not consistent with NHMRC guidelines for clinical testing. There are few well designed studies which have properly addressed the usefulness of random capillary blood glucose (RCGB) in screening for undiagnosed diabetes. Three studies have examined RCBG (measured by a meter) as a screening test for diabetes and performed an OGTT in the whole population irrespective of the RCBG result. (WHO, 2003) These studies have shown reasonable performance but highlighted the issues around using different cut-off values for further testing, the need to consider time since last meal in evaluating the result, and potential problems with assuring the accuracy of meter measured results. Another approach to screening has been to simultaneously combine information on age, gender, BMI, postprandial time and RCBG to calculate the probability of undiagnosed diabetes and therefore the need for further testing.

The National Public Health Institute in Finland has reported on the validity of a simple diabetes risk score as a non-invasive tool to identify individuals at risk for type 2 diabetes. (Lindstrom & Tuomilehto, 2003) Such a tool would be used as an initial population screen or to enhance recruitment.

General practitioners are the logical primary entry point for screening, supplemented where appropriate by other primary care services such as Aboriginal Medical Services (AMSs).

2.4 Recruitment of the target group for screening

Both reviews note the lack of clear evidence for strategies likely to be effective in

increasing the uptake of screening. Current screening for diabetes or “pre-diabetes” relies on passive opportunistic screening of people at risk through health service providers, supplemented by non government organisation (NGO) education and awareness raising activities.

A recent report on screening for type 2 diabetes by the World Health Organization and International Diabetes Federation concluded that in the absence of RCT evidence for whether individuals would benefit or not from the early detection of type 2 diabetes and noting that nonetheless screening activity was taking place, health authorities and professional associations should formulate policies concerning screening for type 2 diabetes, even if that policy is that screening is not currently to be advocated. (WHO, 2003)

Evidence drawn from other screening programs suggests that recruitment strategies that involve multiple components are more likely to be successful. A new Adult Health Check has been made available under Medicare for Aboriginal and Torres Strait Islander peoples aged 15 to 54 years. This item will encourage general practitioners to provide two-yearly health checks for adult Aboriginal and Torres Strait Islander peoples therefore improving the early detection, diagnosis and intervention for common and treatable conditions that cause considerable morbidity and mortality. The health check includes a fasting or random blood glucose if indicated. Because of the higher burden of disease, the target group of this new initiative is different from the NHMRC target group for screening (age 35 years +).

Both evidence reviews recommended the trialing of recruitment strategies to explore further evidence for effectiveness.

Strategies to prompt and assist self risk assessment may be a useful component to integrate into the recruitment strategy, particularly as examples of such resources have already been developed and are in use in Australia, such as the “Scratch card” in use by Diabetes Australia (NSW), or such as the

diabetes risk score tool used in Finland and referred to above.

The Australian Government Bowel Cancer Screening Pilot has utilised a register managed by the Health Insurance Commission which has the capacity to direct mail recruitment and reminder letters to all Australians over 55 years of age, and to capture the Pilot's pathology and participation data, subject to consent and privacy protections.

There are currently two projects underway involving retail pharmacies screening for undiagnosed type 2 diabetes. The Pharmacy Diabetes Care Program being conducted through the Faculty of Pharmacy, University of Sydney, includes a component of screening for undiagnosed diabetes based on assessment of risk factors and if positive, blood glucose testing (on a non-fasting blood sample) by the pharmacist using a blood glucose testing meter, with referral to a general practitioner for further evaluation if FBG > 5.5 mmol/l. A similar program is being initiated by Diabetes Australia (NSW) with the only variations in protocol being that FPG is measured using a visually read blood glucose strip, with referral to a general practitioner if the FBG is > 6 mmol/l.

The testing modalities used on non-fasting blood in the above community programs are not consistent with the NHMRC recommendations for clinical testing and are sub-optimal for use alone as a screening strategy.

2.5 Components of effective lifestyle interventions

The evidence reviews found that the components of the effective lifestyle interventions could be summarised as:

- multiple lifestyle changes
- low fat, low calorie diet
- increased physical activity
- weight loss of at least 5–7% if overweight
- individualisation of goals and strategies
- frequent contact with participants
- supervised physical activity sessions (group or individual).

Both evidence reviews found that there was a need for “translation evidence” for strategies to implement effective lifestyle interventions “in the field” rather than in the optimal environment of the clinical trial. A particular challenge in this context is the need to establish and support appropriate referral pathways to provide the interventions and clinical management for people who would be identified with “pre-diabetes” or diabetes by the screening strategy.

2.6 What is the role of health promotion?

Health promotion strategies have evolved steadily over the last few decades from traditional health education, which focused on modifying individual behaviour, to ecological models of community development and empowerment that emphasise individuals as part of a dynamic social, community and political landscape. Community based health promotion models emphasise community participation and ownership and aim to fulfill the WHO definition of health promotion as “the process of enabling communities to take control over their own health and its determinants”.

These strategies have had varied success in improving health outcomes. (Merzel, 2003) Implementation of comprehensive intervention models that target the social environment as well as individual factors affecting health behaviours is difficult, and many past programs have not addressed normative and policy changes that could produce wider impacts on health. Additionally, the majority of health promotion programs have been more successful in affluent and educated sections of society, rather than less affluent, less educated and more socially isolated sections. (Green, 2001)

In Australia, it was clear by the 1970s that provision of information was a necessary but not sufficient component in achieving a desired behaviour change, and that other approaches needed to be harnessed to enable people to improve their health. This recognition led to the deployment of a range of policy and legislative levers to complement

awareness campaigns about particular health issues, with the purpose of making the healthier choice the easier choice. (Ritchie, 1991)

Using this approach, Australia has had a relatively successful record of population health improvements, especially in the areas of smoking cessation, road crash reduction, immunisation for childhood diseases, reduction of mortality from coronary heart disease and HIV/AIDS prevention. (Commonwealth Department of Health and Ageing, 2003)

In the last decade, health promotion strategies have become even more multifaceted and intersectoral in their approach. Recent state and national approaches to childhood obesity have recognised the concept of the “obesogenic environment” and the need for all stakeholders having a potential impact on this particular health problem – parents, schools, the food industry, the television advertising industry, the transport sector and so on, to be brought together collaboratively by the health sector to determine a way forward.

Health promotion has long acknowledged the role of developing and implementing “healthy public policy”, to ensure that there are environments supportive of health and capacity building strategies in place as fundamental keys to successful and sustained programs.

The recently adopted World Health Organization “Integrated Prevention of Non Communicable Diseases (Global strategy on diet, physical activity and health)” (2004) calls for an intersectoral approach which builds on existing structures that already address aspects of diet, nutrition and physical activity and for prevention to be “built into” health services. Increasingly, this will require new ways of working in partnership to maximise opportunities for the prevention of illness, injury and disability across government, the private sector and in the community.

A tension identified both in evidence reviews and in stakeholder consultations

was the difficulty in determining the relative investment in whole of population primary prevention strategies to support healthy eating and increased physical activity compared with investment in targeted screening and intervention strategies such as those proposed for people identified with IGT/IFG and undiagnosed diabetes.

Both reviews draw the conclusion that both types of strategy should be deployed to have maximum impact on risk factor levels in the population. The targeted interventions may be seen as evidence based secondary prevention strategies within a broader Chronic Disease Prevention Strategy and the two are therefore complementary rather than mutually exclusive.

2.7 Is the prevention of type 2 diabetes good value for money?

There is accumulating evidence about the allocative efficiency of preventing type 2 diabetes and overall the studies suggest that prevention of type 2 diabetes is good value for money. Walker et al (2003) developed an Australian population-based cost-benefit model and assessed the effect of a diabetes early detection and prevention program. The model estimated that after 8 years the program would be cost saving compared with no program and would cost \$A23,300 for each case of diabetes prevented. (Colagiuri S and Walker A, 2002)

Segal et al (1998) reported on the cost-effectiveness of various strategies for the prevention of type 2 diabetes in Australia including a mass media program focusing on diet and exercise, a behavioural modification program for the seriously obese and for women with a history of gestational diabetes, a group program for overweight men, and gastric surgery for the morbidly obese. The net cost per life-year saved was calculated based on a theoretical reduction of diabetes incidence. Lifestyle modifications such as exercise programs and diet for seriously obese persons and women with previous gestational diabetes were considered to be cost-saving

Table 1: Estimated cost of a diabetes prevention program in the United States

	Lifestyle Intervention		Metformin	
	<i>Within Trial</i> \$US	<i>Group Program</i> \$US	<i>Within Trial</i> \$US	<i>Generic Metformin</i> \$US
Cost per Quality Adjusted Life Years QALY*	31,700	8,100	99,600	35,400
Cost per Diabetes Mellitus Year Saved	15,800	4,000	31,300	11,000

* Cost utility estimated at 0.95

while gastric surgery was the least cost-effective at \$A19,100 per life year saved due to diabetes prevention.

The cost-effectiveness of the US Diabetes Prevention Program has also been evaluated and is shown in Table 1.

The in-trial costs for each case of diabetes prevented was \$US15 800 for lifestyle intervention and \$US99,600 for metformin. These costs were substantially reduced to \$US4,000 if the lifestyle intervention was provided by group programs and to \$US11,000 if generically priced metformin was used, assuming the same within trial effectiveness. (International Diabetes Federation, 1996 and Herman et al, 2003)

The recently released Wanless review for the UK Treasury: Securing Good Health for the Whole Population (2004) found that:

- there is good evidence that interventions at most stages of the type 2 diabetes pathway can be effective and cost-effective in reducing the burden of the disease;
- both lifestyle interventions and metformin can be effective and cost-effective in reducing the risk of developing diabetes over relatively short periods of follow-up (3 to 4 years);
- increasing physical activity has an independent protective effect over and above obesity reduction;
- lifestyle interventions appear most effective in older age groups and the less severely overweight, while metformin appears relatively most effective in younger cohorts and in the severely obese; and

- there is some evidence that lifestyle intervention might be more effective in ethnic minority groups.

Wanless (and other reviews) note that the main area of clinical uncertainty remains the issue of whether high-risk screening and prevention strategies prevent or delay the onset of type 2 diabetes.

While noting limitations in the evidence base for primary prevention, Wanless also concludes that “some interventions [to reduce obesity and physical inactivity in the population at large] have been shown to be cost-effective and it is simply impossible to reduce significantly the burden of diabetes without intensive primary prevention efforts”.

Based on the above, Wanless proposes that:

“In addition to population primary prevention efforts, of those interventions currently not being funded or implemented, the most promising appears to be a combined program of targeted identification and screening for those at high risk of having undiagnosed diabetes or at high risk of developing diabetes. This is likely to identify hundreds of thousands of undiagnosed diabetics who would then benefit from earlier tight control of blood glucose and blood pressure. It would also identify a large pool of people at very high risk of developing diabetes (those with Impaired Glucose Tolerance (IGT) and who are overweight), to whom lifestyle and drug interventions could be offered. These have been demonstrated to be highly effective in at least delaying and possibly preventing

the onset of diabetes and could if fully implemented, make a significant dent in the prevalence of diabetes.”

The Wanless review found that the following interventions were cost-effective, using a threshold of £20,000 per QALY:

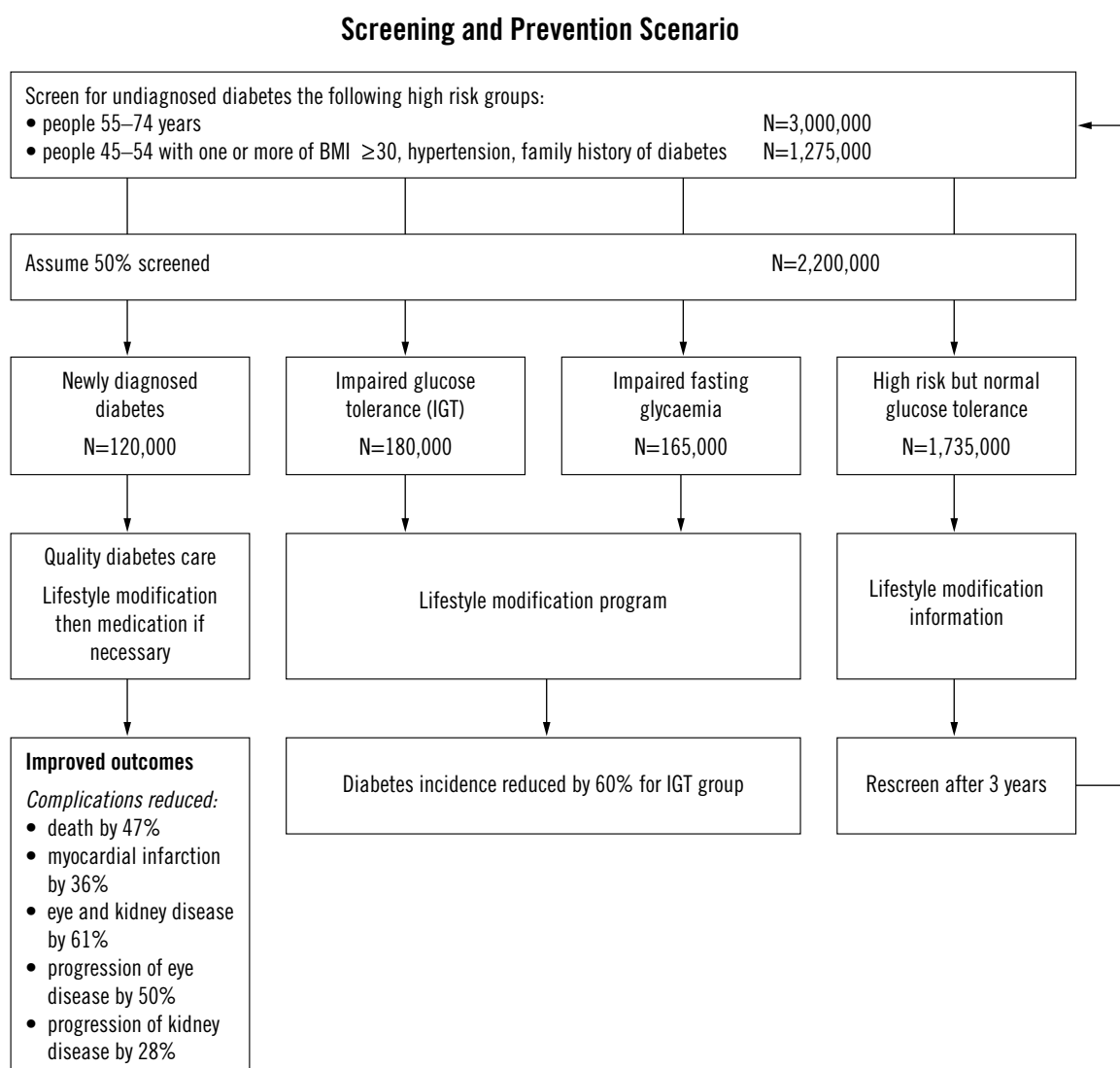
- screening obese for Impaired Glucose Tolerance and providing relevant treatment;
- multiple risk factor management;
- self-care including patient education; and
- reduction of obesity and physical inactivity in high risk groups.

2.8 Referral pathways for interventions

Both evidence reviews and stakeholder consultations identified a risk that optimal referral pathways and capacity were not currently in place to cope with the increased demand that might be created by a targeted screening program.

If successful in recruiting significant numbers of people at risk, such a screening program could be predicted to identify large numbers of individuals who would then be “indicated” to receive clinical management

Figure 1: One-off screening interventions: an overview of predicted numbers, with an assumption that only 50% of the target group will actually undergo screening (based on census and AusDiab data)*



* Population numbers rounded

Impro associated with improved outcomes? Diabetes Care 2002; 25: 1410–1417.

and/or lifestyle interventions (see Figure 1 for a model of one-off screening intervention for purposes of relating to real numbers). A failure to adequately plan for the delivery of these required programs and services would seriously compromise the effectiveness of the overall intervention and give rise to an ethical problem of screening without resources for appropriate follow-up.

Features of the effective lifestyle interventions drawn from the evidence include their relatively intensive and individualised nature in the research trial setting. Both reviews agreed that there was a lack of “translation evidence” on how to implement the interventions in a field setting with appropriate cost efficiency without losing efficacy. Consequently, both reviews suggest trialling a number of intervention modalities to explore the evidence for effectiveness and efficiency in a field setting.

2.9 Evaluation and monitoring

Both evidence reviews identified a lack of “translation evidence” for implementing the lifestyle interventions which were effective in the research trial setting to the “real world”. They also indicated that evidence for what strategies would best enhance recruitment were lacking. It also remains to be seen if and how Australians, and which Australians, would successfully adopt the necessary lifestyle modifications.

The greatest potential benefit of a national approach to type 2 diabetes prevention may therefore be to provide missing evidence to maximise the likely effectiveness of any proposed future program. For this purpose it is most important that the evaluation and monitoring framework utilised be as consistent and as rigorous as possible.

At the least, it would be highly desirable that consistent definitions be used across projects, including for target groups, screening, evaluation and monitoring data fields and frequency of data collection.

Preferably, for maximum effectiveness and efficiency it would be desirable if there was a common evaluation and monitoring framework and methodology, which underpinned any trial activity.

The HIC data base, referred to earlier, which was utilised for the Australian Government Bowel Cancer Screening Pilot, has great potential utility as an underpinning evaluation and monitoring tool to capture participant information, including pathology tests and participation rates, should it be deployed for any trial activity.

Any proposed type 2 diabetes prevention program can be subjected to economic evaluation at each stage of its development and implementation. There is now considerable consensus around methodology for evaluating health interventions, although this is not always consistently applied. Recent cost modelling is available on the current and likely future costs of diabetes. Some cost effectiveness modelling has already been undertaken for this type of intervention in other jurisdictions and a consistent methodology can be agreed at the outset, along with the commitment that economic evaluation will be a key and necessary component of the evaluation process.

3 Translation evidence research questions

3.1 Summary

In summary, the following key research questions require further investigation to provide the necessary “translation evidence” to guide the effective implementation of type 2 diabetes prevention programs:

- Are targeted screening and prevention programs likely to be cost effective in the Australian context and at what level of investment?
- What strategies are effective and efficient at recruiting people at risk?
- How can targeted lifestyle modification interventions dealing with diet and physical activity in people at high risk of diabetes be effectively and efficiently implemented in the Australian context?
- What additional investment in population primary prevention initiatives is required for targeted interventions to be effective?
- What are the relative benefits of investing in primary prevention with a view to reducing the incidence of diabetes (and supporting better outcomes in existing diabetics), compared to the investment in secondary prevention to intervene in targeted sub-populations at high risk of progressing to disease or complications of disease?
- What robust evaluation and monitoring tools are required to underpin any trial or program activity?
- How can equity issues be addressed to ensure that any trial or program activity does not merely reinforce existing inequities?
- Are targeted screening and prevention programs sustainable over the long term?
- What are the most effective strategies for each age group?

3.2 Population level primary prevention initiatives

Current population level initiatives directed towards the benefits of following a healthy lifestyle also address issues around the primary prevention of type 2 diabetes. Highly relevant frameworks and recommendations for action include Eat Well Australia, Be Active Australia, and the primary prevention initiatives for addressing obesity recommended by the National Obesity Taskforce (Healthy Weight 2008). However there has as yet been no major new investment into the population-based strategies recommended in these documents.

In determining the basis for effective translation of RCT evidence to a population based approach to diabetes prevention, it is essential to determine the relative population health impacts of targeted interventions carried out with and without a backdrop of enhanced investment in whole-of-population primary prevention initiatives.

It is also important to evaluate the costs and benefits of intensive implementation of these population level primary prevention strategies in their own right.

3.3 Cost effectiveness

To assess the relative and combined cost-effectiveness of primary and secondary prevention of type 2 diabetes it is necessary to identify the costs and benefits of primary prevention alone, secondary prevention alone and the two approaches in combination.

The translation evidence required in relation to any proposed either targeted diabetes type 2 prevention programs or proposed targeted diabetes type 2 secondary prevention programs primarily relates to the mode of

recruitment strategy used and the method of delivering the lifestyle modification intervention.

For the purpose of cost effectiveness modeling, it is possible to agree on a methodology and cost model a variety of recruitment and lifestyle intervention scenarios for likely costs and benefits before any trial activity is undertaken.

The same methodology can be applied as part of the evaluation framework for any trial or program activity undertaken.

3.4 Recruitment strategies

Current recruitment activity for people at risk of type 2 diabetes is based on opportunistic screening by health professionals, in particular general practitioners, using the NHMRC case detection and diagnosis guidelines. This activity is complemented by NGO awareness campaigns and some screening activity using blood glucose testing meters and blood glucose test strips in retail pharmacies.

Strategies for enhancing recruitment could include for example, broader community awareness campaigns, enhanced promotion and referral activity through community health, direct mail to people at risk and workplace based programs.

General practitioners are the logical primary entry point for screening, supplemented where appropriate by other primary care services such as Aboriginal Medical Services (AMSs).

3.5 Lifestyle interventions

Currently people at risk of diabetes can be referred to existing private sector providers such as fitness centres, physiotherapists, dieticians and exercise physiologists. Access to these services may be limited in some settings and the cost would be borne by the patient, perhaps assisted in some instances by private health insurance.

Options for enhancing access to lifestyle interventions for people at risk may include community health based allied

health professionals conducting lifestyle interventions and direct funding for private allied health professionals to undertake lifestyle interventions through new Medicare prevention items or some alternative methods, or direct funding to Divisions of General Practice. These strategies could be supplemented by web and telephone based tutorials and support.

3.6 Evaluation and monitoring

As stated in 2.9 above, it would be desirable for there to be a consistent evaluation and monitoring framework to underpin any diabetes type 2 secondary prevention trial activity. A consistent national approach would make it more likely that valid and reliable translation evidence would be gleaned to inform future programs.

The HIC register (referred to in 2.4 above) utilised by the recent Bowel Cancer Screening Pilot, would have considerable utility as an underpinning evaluation and monitoring tool. It has the capacity, subject to informed consent and privacy protections, to capture participant, provider and pathology data.

At the least, it would be highly desirable that consistent definitions be used across projects, including for target groups, screening, evaluation and monitoring data fields and frequency of data collection.

As mentioned in 3.2 above, cost effectiveness analyses should also be part of any evaluation and monitoring strategy, using consistent methodology where possible.

3.7 Reaching the “hard to get”: Indigenous, remote and socioeconomic disadvantaged

We have noted earlier that the burden of type 2 diabetes prevalence is distributed unevenly across society. First, there is a clear socioeconomic gradient in prevalence almost twice as high in the lowest socioeconomic quintile compared with the highest. (Mathers et al AIHW, 1999) Many of these people will also be disadvantaged in their access to health resources generally.

Second, and linked to the first, there are specific communities at risk for higher type 2 diabetes prevalence rates. These include Aboriginal and Torres Strait Islander and Pacific Islander peoples and people from the Indian Sub-continent and China.

Last, there are people who are difficult to reach because of a barrier of distance or remoteness, or some other obstacle to their access to health information, services and support.

Failing to mount strategies to improve access to health information and services for these groups would run the risk of perpetuating the inequalities in health status that already exist. Consequently, it is envisaged there would be a specific need for a complementary set of strategies targeting the “hard to get”.

4 Risk assessment

4.1 What are the proposed aims and objectives of a diabetes type 2 screening and prevention program?

- To identify people with undiagnosed diabetes type 2 in order to improve their clinical outcomes by earlier clinical management, particularly through preventing or ameliorating complications.
- To identify people with impaired glucose metabolism or other high risk factors for type 2 diabetes and to compare the business case for offering them a lifestyle modification intervention which may prevent or delay the onset of diabetes with and without enhanced investment in population level primary prevention interventions.
- To identify people at increased risk of type 2 diabetes and/or cardiovascular disease through a combination of risk factors and to improve their clinical outcomes through earlier clinical management and/or lifestyle modification.
- To explore the feasibility of delivering intensive lifestyle modification interventions to populations at risk both with and without enhanced investment in population level primary prevention programs.
- To explore the feasibility of a multi-sector approach to lifestyle modification interventions which could be potentially “levered” to apply to wider population primary prevention efforts.
- To gather evidence to inform future practice.

4.2 Macro risk issues for the screening and prevention of type 2 diabetes

A number of macro risk issues have been identified for a type 2 diabetes prevention program including target population issues and economic considerations. The issues are set out in Table 2 together with brief commentary on the potential impact of the risk and a risk management strategy.

5 Links to work planned or underway

The NPHP specifically asked the Working Party to take into account work done or underway through the National Health and Medical Research Council (NHMRC), the National Health Priority Action Council (NHPAC) and in the jurisdictions of Victoria and New South Wales.

In addition, the proposed national approach to the secondary prevention of type 2 diabetes is linked to a number of other current national and international strategies, such as the Global strategy on diet, physical activity and health, the “SNAP” initiative, and the National Obesity Taskforce. Other related work includes the development by RACGP and NACCHO of a national guide to a preventive health assessment in Aboriginal and Torres Strait Islander peoples. The guide will include recommendations for screening for diabetes.

5.1 National Health and Medical Research Council (NHMRC)

The NHMRC has published evidence-based guidelines for the management of type 2 diabetes including primary prevention, case detection and diagnosis. (NHMRC, 2001)

The proposed screening is consistent with the NHMRC Case Detection and Diagnosis recommendations, which recommend active case detection of type 2 diabetes through the measurement of fasting plasma glucose of people with risk factors, followed by an oral glucose tolerance test for those with a result between 5.5 mmol/L and 6.9 mmol/L.

In regard to evidence for physical activity decreasing and a sedentary life increasing the risk of diabetes, the guidelines find level III-2 evidence that physical activity can reduce the risk of diabetes in men and women, level II evidence that exercise programs can slow progression from IGT to type 2 diabetes and level II evidence that exercise can reduce diabetes-related mortality.

A suite of nine national evidence-based guidelines is currently being prepared for the prevention, detection and management of type 2 diabetes. The first four guidelines covering prevention, detection, blood pressure control and macrovascular disease have already been approved by the NHMRC.

Table 2: Macro risk issues for the screening and prevention of type 2 diabetes

Risk	Potential Impact	Comment	Risk Management Strategy
<p>The prevalence estimates for un-diagnosed diabetes, pre-diabetes and people with risk factors and normal glucose prove to be inaccurate, either too low or too high.</p>	<p>If too high the necessary capacity to respond with appropriate services and support will be under estimated potentially creating significant logistical and ethical problems. If too low, the cost effectiveness of the proposed program could be seriously compromised.</p>	<p>The AusDiab study estimates are consistent with earlier studies in Australia and comparable studies overseas. They represent the best available data in Australia at this time.</p>	<p>Cost effectiveness modeling pre pilot to be undertaken to establish indicative prevalence cut off points for likely cost effectiveness. A pilot program provides an opportunity to validate in a “field” setting the AusDiab prevalence estimates. Prevalence outcomes of the pilot activity should be closely monitored.</p>
<p>The association between diabetes, cardiovascular disease, complications of diabetes and other serious health outcomes is weaker in the Australian population than hitherto predicted.</p>	<p>The complications of type 2 diabetes and its association with cardiovascular disease are significant drivers of health and societal costs. Should these associations not be as strong as previously believed the cost effectiveness of the proposed program could be compromised.</p>	<p>Evidence for a strong association between type 2 diabetes, serious complications and increased risk for cardiovascular disease is available in multiple peer-reviewed studies, in both Australia and overseas.</p>	<p>Consider cost effectiveness modeling, which excludes cardiovascular risk. Monitor pilot activity for complication and cardiovascular outcomes of participants compared to predicted outcomes from the literature.</p>
<p>There proves to be insufficient capacity to deliver:</p> <ul style="list-style-type: none"> • Screening and recruitment strategy • Clinical management • Lifestyle modification interventions • Lifestyle modification information and support • Support for recipients of false positive and false negative results • Equity and access • A multi sector approach 	<p>Insufficient capacity to deliver these programs or services would compromise the intended outcomes of the program and potentially create significant logistical and ethical problems.</p>	<p>The proposed interventions seek to build on existing networks and facilitate new ways of working in partnership across sectors. Deployment of a “fully engaged” scenario in which there is community awareness, an inter sectoral approach and prevention integrated cross the continuum of care provides the maximum opportunity to meet the demands for services and programs.</p>	<p>Fully cost model the required service delivery capacity and service delivery mechanisms in advance for each scenario. Identify contingencies where possible. Reality test assumptions and mechanisms during the pilot phase.</p>
<p>The “right to be diagnosed” with a serious condition or risk factor, versus the rights of privacy and to avoid being harmed.</p>	<p>Ethical issues may arise about the relative benefit or cost of a proposed screening and prevention program for individuals.</p>	<p>Duty of care issues arise for both doing something and doing nothing or too little. The evidence that years of healthy life could be increased for people at risk through compression of morbidity and mortality argues that a prudent intervention should be explored.</p>	<p>Due consideration be given to assessing the balance of potential benefit versus harm for individuals. Ethical protocols for the proposed program to be established and cleared by an appropriate ethics committee. Assessment to be undertaken of the merits of this program against other potentially competing priorities.</p>
<p>The proposed screening and prevention program may prove to be not cost effective, cost neutral or only marginally cost effective.</p>	<p>Investment in an intervention that is not cost effective or only marginally cost effective may be at the expense of other interventions with greater cost utility or greater health priority with the same cost effectiveness.</p>	<p>The high burden of illness associated with chronic diseases such as diabetes and CVD, their relatively high prevalence and incidence and evidence for effective interventions, all argue that preventive interventions will be cost effective if implemented efficiently and effectively.</p>	<p>Appropriate methodology for evaluating cost effectiveness of the proposed program to be agreed in advance. Cost modeling using this methodology and agreed assumptions to be undertaken prior to commencing any pilot. Pilot activity to be designed to enable sufficient capture of costs and benefits to facilitate cost effectiveness evaluation.</p>

5.2 National Health Priority Action Council (NHPAC)

NHPAC overviews the National Diabetes Strategy 2000–2004. A process is currently underway through the National Diabetes Strategy Group of NHPAC to develop a new National Diabetes Strategy.

The Diabetes Prevention Pilot Initiative funded under the National Diabetes Strategy is underway. Three type 2 diabetes prevention demonstration projects have been funded. These projects are intended to provide “translation evidence” for type 2 diabetes prevention interventions and are therefore directly relevant to any proposed national approach.

The National Diabetes Strategy Group which reports to NHPAC is represented on the Working Party by an expert member.

NHPAC also overviews the development of national service improvement frameworks that are high level guides intended to drive health service improvements and improve health outcomes. These frameworks span the continuum of care, embracing prevention, screening, diagnosis, management, rehabilitation and palliation (if required). National Service Improvement Frameworks are currently being developed for Diabetes, Cardio Vascular Disease and Stroke, Asthma, and Arthritis and Musculoskeletal Conditions.

NHPAC also has carriage of the development of the National Chronic Disease Strategy. The Strategy will provide an overarching, consistent and practical approach to the prevention, diagnosis and management of chronic disease across Australia.

Since NHPAC and the Australian Government Department of Health and Ageing are both represented on the NPHP Diabetes Prevention Working Party it will be possible to ensure that activities in diabetes prevention complement other activities. The proposed national approach to targeted secondary prevention is a sub-set of the broader chronic disease strategy, which in turn could be seen as an example of the broader chronic disease

strategy and the Integrated Prevention of Non-Communicable Diseases approach of the WHO Global strategy on diet, physical activity and health.

5.3 WHO global strategy on diet, physical activity and health

The recently endorsed Global strategy aims to counter the rising incidence and prevalence of noncommunicable diseases in both developing and developed countries.

There has been a profound global shift in the burden of disease. The Director-General of the World Health Organization reported that in 1998 alone, noncommunicable diseases are estimated to have contributed to almost 60% (31.7 million) of deaths in the world and 43% of the global burden of disease. Further, it was estimated that, based on current trends, by the year 2020 these diseases are expected to account for 73% of deaths and 60% of the disease burden. (WHO, 1999) Much of this mortality and morbidity is driven by three risk factors, over nutrition, lack of physical activity and tobacco smoking.

The strategy aims to use an intersectoral approach to create environments which support healthy eating and physical activity. It also seeks to re-orient health services to integrate prevention across the continuum of care.

The targeted secondary prevention of type 2 diabetes is well suited to integration into the primary health care setting, given the logical role for general practice in screening and the potential for multi-disciplinary involvement in delivering lifestyle interventions.

Trialing the optimised delivery of lifestyle interventions on healthy eating and physical activity to people with IFG/IGT has the potential to provide valuable translation evidence on how to effectively and efficiently implement such interventions in other settings and to different populations.

There are also opportunities for opportunistic screening and secondary and tertiary

prevention activities to be enhanced in the acute care setting.

5.4 “SNAP” initiative

The Smoking, Nutrition, Alcohol and Physical Activity initiative (SNAP) aims to provide a framework and tools for the behavioural risks for non-communicable diseases to be addressed in the primary health care setting.

The development of “Lifestyle prescriptions” for general practitioners is an example of a resource that can be deployed in the management of physical inactivity. Further support for lifestyle prescriptions was announced by the Australian Government in the 2003–2004 Federal Budget as part of the “Focus on Prevention” initiative. Focus on Prevention was intended to further strengthen Medicare by taking steps to integrate prevention across the health system, making prevention a “fundamental pillar of Medicare”.

The goal of integrating prevention across the health system and the focus on the primary health care setting are consistent with the approach of the Global strategy.

5.5 National Obesity Taskforce

The National Obesity Taskforce is an initiative of the Australian Health Ministers’ Conference. Its initial focus is on healthy weight in children and it has adopted an intersectoral approach across a range of settings, which is consistent with the WHO Global strategy. Early interventions to facilitate healthy weight in childhood have the potential to achieve long-term health gains by ameliorating the growing rates of chronic non-communicable disease attributable to poor diet and lack of physical activity.

Type 2 diabetes is increasingly being diagnosed in adolescence and childhood, whereas it has previously been known as “adult onset diabetes”.

5.6 Jurisdiction-based activity

Victoria recently commenced a trial of the Diabetes Prevention – Go For Your Life Program. The program has two major

components; detection and intervention. It targets individuals at high-risk and provides an evidence-based lifestyle intervention course for people with identified “pre-diabetes”.

The objectives of the Program are to improve detection of “pre-diabetes” in high risk individuals in three pilot sites; and to provide an evidence-based intervention (the Healthy Living Course) for people in those catchment areas identified with “pre-diabetes”.

Work in NSW at this point has primarily consisted of the evidence review and scoping paper, although plans are in train to trial a type 2 diabetes secondary prevention initiative as part of the roll out of the NSW Chronic Disease Strategy 2003–2007.

The Department of Health Western Australia has funded Diabetes Australia WA (DAWA), to facilitate the development of consensus guidelines for the screening, diagnosis and management of IFG and IGT in Western Australia.

The NPHP Diabetes Prevention Working Party has undertaken a “mapping exercise” of relevant diabetes prevention activity underway in jurisdictions. There is a diverse range of primary prevention programs and projects across a wide range of settings that emphasise promotion of healthy lifestyles especially through good diet and physical activity. Secondary prevention programs focus on good practice in early detection and intervention of diabetes and also include smoking cessation programs, identification of foot problems and a trial of “pre-diabetes” register and recall system. Tertiary prevention programs are concerned with reducing symptoms and improving quality of life through such initiatives as improving community support structures for diabetics, enhancing capacity for self-management, improving service pathways and providing for a systematic and coordinated approach to prevention in some instances through a statewide chronic disease strategy.

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Glossary

Type 2 diabetes	(formerly named non-insulin-dependent) which results from the body's inability to respond properly to the action of insulin produced by the pancreas (WHO, 2002b)
Pre-diabetes	impaired glucose tolerance and impaired fasting glucose have been called "pre-diabetes". This term may not be perfect but it can effectively inform the general public and health professionals about a modifiable risk factor, which if reversed, could reduce the likelihood of type 2 diabetes. (Vinicor et al, 2003)
Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG)	refer to levels of blood glucose concentration above the normal range, but below those which are diagnostic for diabetes. People with IGT and IFG are at substantially higher risk of developing diabetes and cardiovascular disease than those with normal glucose tolerance. (WHO, 2002b)
Oral Glucose Tolerance Test (OGTT)	the diagnostic test for IGT. Requires an oral challenge with glucose and subsequent plasma glucose test two hours after an initial fasting plasma glucose test.
Primary prevention	involves the protection of health by measures that eliminate or reduce the causes or determinants of departures from good health, control exposure to risk, and promote factors that are protective of health. (adapted from Brownson et al 1998)
Secondary prevention	consists of early detection of asymptomatic biological changes, disease precursors or asymptomatic disease, and prompt and effective intervention to correct these departures from good health. (adapted from Brownson et al 1998)
Tertiary prevention	consists of measures to reduce or eliminate long-term impairments, disabilities and complications from established disease and prevent or delay subsequent events. (adapted from Brownson et al 1998)