National Evidence Based Guideline for the Primary Prevention of Type 2 Diabetes

prepared by:
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for the:
Diabetes Australia Guideline Development Consortium

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Diabetes Australia Guideline Development Consortium

The Diabetes Australia Guideline Development Consortium comprises Diabetes Australia; Australian Diabetes Society; the Australian Diabetes Educators' Association; the Royal Australian College of General Practitioners; and The Diabetes Unit, Menzies Centre for Health Policy, The University of Sydney.

A link to the guideline can be found on the Diabetes Australia website:
www.diabetesaustralia.com.au/For-Health-Professionals/Diabetes-National-Guidelines/

The National Health and Medical Research Council

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A link to the guideline can be found on the National Health and Medical Research Council website: www.nhmrc.gov.au/publications.

Disclaimer

This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are designed to provide information to assist decision-making and are based on the beset evidence available at the time of development.

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Glossary of Acronyms

AusDiab	Australian Diabetes Lifestyle and Obesity Study
AUSDRISK	Australian Diabetes Risk Assessment Tool
HDL	High Density Lipid
NCEP	National Cholesterol Education Program
BMES	Blue Mountains Eye Study
NWAHS	North West Adelaide Health Study
NSMS	National Social Marketing Strategy
WC	WellingTonne Challenge
QALD	Quality-adjusted life-year
ICERs	Incremental Cost Effectiveness Ratios
UKPDS	United Kingdom Prospective Diabetes Study
LSM	Lifestyle Modification
NGT	Normal Glucose Tolerance
LYG	Life Year Gained
FINDRISK	Finnish Diabetes Risk Assessment Tool
CI	Confidence Interval
HR	Hazard Ratio
RR	Relative Risk
OR	Odds Ratio
ROC AUC	Receiver-Operating Characteristics Area Under the Curve
NNT	Number Needed to Treat
BMI	Body Mass Index
CALD	Culturally And Linguistically Diverse
CHIP	Coronary Health Improvement Project
CVD	Cardiovascular Disease
DPP	Diabetes Prevention Program
DPS	Finnish Diabetes Prevention Programme
EAG	Expert Advisory Group
EBMM	Eat Better Move More Program
FFFF	Fighting Fat, Fighting Fit campaign
GDM	Gestational Diabetes Mellitus
HbA_{1c}	Glycosylated/ glycated haemoglobin
IDF	International Diabetes Federation
IDPP	Indian Diabetes Prevention Programme
IDRS	Indian Diabetes Risk Score
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
LAGB	Laparoscopic Gastric Banding
LASGB	Laparoscopic Adjustable Silicon Gastric Banding
NGO	Non-Government Organisation
OGTT	Oral Glucose Tolerance Test
PCOS	Polycystic Ovary Syndrome
RCT	Randomised Controlled Trial
WHO	World Health Organisation

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Primary Prevention of Type 2 Diabetes

Introduction

Aim of the guideline
This guideline covers issues relating to the primary prevention of type 2 diabetes in non-pregnant adults. Its aim is to inform and guide health promotion and preventative activities for type 2 diabetes with evidence based information on what works and what does not. The guideline targets health promotion and public health practitioners, planners and policy makers, and clinicians.

Methods
In addition to the methods used to identify and critically appraise the evidence to formulate the guideline recommendations which are described in detail in the *Overview of Methods and Processes* (Appendix 6), the Research Team reviewed and checked each step of the methods process and:

- repeated a selection of the searches
- double culled the yield from all the database searches
- double reviewed the majority of the articles used as evidence references
- checked all recommendations, evidence statements, evidence tables and search strategy and yield tables

Guideline Format
Questions identified by the Expert Advisory Group (EAG) and from the literature as critical to the primary prevention of type 2 diabetes are shown in point 2.2 (next page).

Each of these questions is addressed in a separate section in a format presenting:

- ***Recommendation(s)***
- ***Practice points*** - including experts' consensus in absence of gradable evidence
- ***Evidence Statements*** - supporting the recommendations
- ***Background*** - to issues for the guideline
- ***Evidence*** - detailing and interpreting the key findings
- ***Evidence tables*** - summarising the evidence ratings for the articles reviewed

For all issues combined, supporting material appears at the end of the guideline topic and includes:

- ***References***
- ***Search Strategy and Yield Tables*** documenting the identification of the evidence sources

Questions for Primary Prevention

1a. Can type 2 diabetes be prevented? If Yes

1b. How can type 2 diabetes be prevented in high risk individuals?

2 How can individuals at high risk of type 2 diabetes be identified?

3. What population strategies have been shown to be effective in reducing risk factors (such as physical inactivity, unhealthy eating) for type 2 diabetes?
    i. Increase community awareness
    ii. Increase community skills to change behaviour and adopt a healthy lifestyle
    iii. Develop policies and create environments that support a healthy lifestyle

4a. Is prevention cost-effective?

4b. What are the socio-economic implications?

Summary of Recommendations and Practice Points

Recommendations

Lifestyle modifications that focus on increased physical activity, dietary change and weight loss should be offered to all individuals at high risk of developing type 2 diabetes (Grade A).

Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) could be considered in people at high risk of developing type 2 diabetes (Grade B).

Bariatric surgery can be considered in selected morbidly obese individuals (based on weight alone or the presence of co-morbidities) at high risk of type 2 diabetes (Grade C).

Individuals at high risk of diabetes should be identified through the use of risk assessment tools (Grade C).

Social marketing should be considered as part of a comprehensive approach to reduce risk factors for type 2 diabetes at the population level (Grade C).

Community-based interventions should be used in specific settings and target groups (eg schools, workplace, women's groups) as a strategy for reducing diabetes risk factors (Grade C).

The impact of the built environment on physical activity and food quality and availability should be considered in all aspects of urban planning and design (Grade D).

To be optimally cost-effective and cost saving in the long term, interventions to prevent diabetes should focus on lifestyle modification.

Practice Points

- Life style modifications such as physical activity, dietary change and weight loss should be trialled before considering the use of pharmacological interventions for the prevention of type 2 diabetes in high risk individuals.

- As many of the medications which have been used in diabetes prevention studies have established side effects, potential benefits and harms should be taken into account before considering pharmacotherapy for diabetes prevention.

- The Australian Risk Assessment Tool (AUSDRISK) should be used to identify people at high risk of developing diabetes.

- A risk score of ≥ 15 should be used to categorise high risk.

- Risk assessment should begin at age 40 and from age 18 in Aboriginal and Torres Strait Islanders*.

- Risk assessment should be repeated every 3 years.

* It should be noted that the AUSDRISK may overestimate risk in those under 25 years of age and underestimate risk in Aboriginal and Torres Strait Islanders.

- To be effective, a community-based intervention should:
  - have a strong theoretical base
  - be designed to send a few clear messages
  - use multiple strategies to communicate these messages
  - encourage family involvement
  - be intensive and sustained over a long period of time.

- Lifestyle modification interventions for high risk individuals should be implemented at the level of routine clinical practice.
- In absence of specific strategies targeting low socio economic people, strategies aimed at the general population are recommended.
- Culturally appropriate lifestyle interventions should be provided in accessible settings.

Section 1: Can type 2 diabetes be prevented?

Questions

a) Can type 2 diabetes be prevented?

b) If yes, how can type 2 diabetes be prevented in high risk individuals?

Recommendations

Lifestyle modifications that focus on increased physical activity, dietary change and weight loss should be offered to all individuals at high risk of developing type 2 diabetes (Grade A).

Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) could be considered in people at high risk of developing type 2 diabetes (Grade B).

Bariatric surgery can be considered in selected morbidly obese individuals (based on weight alone or the presence of co-morbidities) at high risk of type 2 diabetes (Grade C).

Practice Points

- Life style modifications such as physical activity, dietary change and weight loss should be trialled before considering the use of pharmacological interventions for the prevention of type 2 diabetes in high risk individuals.
- As many of the medications which have been used in diabetes prevention studies have established side effects, potential benefits and harms should be taken into account before considering pharmacotherapy for diabetes prevention.

Evidence Statements

- Progression to type 2 diabetes in high risk individuals can be prevented or delayed.
  Evidence Level I

- Lifestyle modification including increasing physical activity, improving diet, and weight loss are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals.
  Evidence Level I

- Lifestyle interventions in people with impaired glucose tolerance (IGT) reduce progression to type 2 diabetes beyond the intervention period.
  Evidence Level II

- Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals.
  Evidence Level I

- Bariatric surgery can prevent/delay progression to type 2 diabetes in people who are morbidly obese.
  Evidence Level III

Background – Can type 2 diabetes be prevented?

Diabetes is a global public health epidemic. The International Diabetes Federation estimates that there were 189 million people with diabetes in 2003 and predicts an increase to 324 million in 2025 (IDF, 2006). The *Australian Diabetes, Obesity and Lifestyle (AusDiab) Study* has provided data on type 2 diabetes in Australia. In a nationally representative sample, it found a diabetes prevalence of 7.4% (Dunstan et al, 2002). Moreover, the five-year *AusDiab* follow-up study indicates that the population with diabetes is steadily increasing and that, by 2006, at least 275 Australian adults were presenting as new diabetes cases every day (Barry et al, 2006). An even more disturbing development is the appearance of type 2 diabetes in overweight and obese individuals at an increasingly younger age, including adolescents and children (Craig et al, 2007). This population is at considerably increased risk of diabetes complications including coronary heart disease, kidney disease and eye disease. Through these complications, diabetes may be a contributing cause in as many as 1 in 11 Australian deaths (Australian Institute of Health and Welfare, 2008).

Type 2 diabetes is responsible for approximately 90% of all diabetes worldwide and accounts for most of the public health and cost burden attributable to diabetes. Type 2 diabetes is costly. For example, in 2004-5, diabetes related complications added nearly $1 billion to total health expenditure in Australia (Australian Institute of Health and Welfare, 2008). Not only rising health care costs but the substantially reduced quality of life associated with diabetes related morbidity indicates the importance of determining whether primary prevention of type 2 diabetes is an achievable goal (Tuomilehto, 2006).

Type 2 diabetes is a complex metabolic disorder triggered by lifestyle factors superimposed on a genetic predisposition. The principle lifestyle risk factors for type 2 diabetes include obesity, energy-dense diets, and low level of physical activity. The *AusDiab Study* reported that 80% of people with diabetes were overweight or obese compared with 59% of people without diabetes (Dunstan et al, 2002).

Type 2 diabetes is an insidious disease that develops over a long time period. The initial stages have been called ‘pre-diabetes’ or ‘intermediate hyperglycaemia’, terms that include both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) (WHO, 2006) These abnormalities occur early in the disease process but may reflect somewhat different pathologies (Rosenstock, 2007). IFG is defined by a fasting plasma glucose between 6.1 and 6.9 mmol/L and a 2-hour glucose less than 7.8 mmol/L. IGT is defined by a fasting plasma glucose below 7.0 mmol/L and a 2-hour glucose between 7.8 and 11.0 mmol/L (WHO, 2006).

The five-year follow-up to *AusDiab* found that Australians with IGT and IFG were between 10 and 20 times more likely to develop type 2 diabetes than Australians who retained normal glucose tolerance (Magliano et al, 2008). One approach to preventing type 2 diabetes is to target these individuals known to be at particularly high risk.

Some populations have also been identified as having a particularly high risk of developing type 2 diabetes. Aboriginal and Torres Strait Islanders are at least three times more likely to have type 2 diabetes than non-indigenous Australians and their overall rates of death and hospitalization from diabetes complications are also much greater (Australian Institute of Health and Welfare, 2008). Moreover, in Aboriginal and Torres Strait Islander people, type 2 diabetes appears earlier in life. Rates of diabetes in the 20-50 year old age group may be up to 10 times higher than found in the overall Australian population (O'Dea et al, 1993). Other

high risk groups are people at socio-economic disadvantage, people living in rural and remote areas, and Australians born in South-Eastern Europe, North Africa and the Middle East (Australian Institute of Health and Welfare, 2008).

Over the last decade, and most particularly since 2000, compelling evidence has accumulated about preventing type 2 diabetes in people with impaired glucose tolerance (Abuissa et al, 2005; Gillies et al, 2007; Li et al, 2008). The strategies that have been trialled to prevent diabetes in high risk groups can be grouped broadly into interventions that aim to change lifestyle through physical activity and diet, interventions based on administration of a drug (pharmacotherapy) and thirdly, various surgical approaches aimed at preventing diabetes by reducing obesity.

There is accumulating evidence that sedentary behaviour is an independent risk factor for obesity and type 2 diabetes (Bassuk & Manson, 2005). Similarly, several longitudinal studies have provided evidence of the relationship between the development of type 2 diabetes and high intake of dietary fat particularly saturated fat (Marshall et al, 1991; Moses et al, 1997).

Consequently, many lifestyle interventions to prevent diabetes have examined the effect of increased physical activity. Reduced energy (hypocaloric) diets aimed at reducing obesity have also been trialled for diabetes prevention either alone or in combination with physical activity.

Several drug therapies have been trialled for prevention of type 2 diabetes in high risk individuals including oral anti-diabetic agents and the anti-obesity agent, Orlistat (Gillies et al, 2007). While the effectiveness of these agents has been demonstrated by meta-analysis, adverse responses have also been recorded particularly gastrointestinal side effects and/or hypoglycaemic symptoms (Gillies et al 2007)

Bariatric surgery can achieve substantial and sustainable weight reduction. The two most common procedures are Roux-en-Y gastric bypass which both restricts stomach volume and creates a bypass from stomach to jejunum that reduces intestinal absorption, and laparoscopic adjustable silicon gastric banding (LASGB). Here the upper part of the stomach is encircled with a saline-filled tube that can be percutaneously inflated or deflated to adjust stomach capacity. There is no accompanying intestinal diversion (Ferchak & Meneghini, 2004).

The following Evidence Section addresses two key questions:

a) can type 2 diabetes be prevented?
b) how can type 2 diabetes be prevented?

Evidence – Prevention of type 2 Diabetes

a) Can type 2 diabetes be prevented?

- **Progression to type 2 diabetes in high risk individuals can be prevented or delayed.** *(Evidence Level I)*

Since 2000 prevention of type 2 diabetes in people with impaired glucose tolerance has been demonstrated in a number of well designed prospective randomised controlled trials. Hence, a considerable body of high level evidence (systematic reviews of randomized controlled trials) now indicates that type 2 diabetes can be prevented. This evidence comes from trials employing a number of different intervention strategies (Abuissa et al, 2005; Curtis & Wilson, 2005; Gillies et al, 2007).

This section presents the highest level of available evidence, ie systematic reviews and meta-analysis of RCTs, demonstrating that type 2 diabetes can be prevented. It also presents details directly from the four major primary RCTs contributing to this evidence (Table 1). They are the:

- Da Qing Diabetes Prevention Study (Pan et al, 1997; Li et al, 2008)
- Finnish Diabetes Prevention Study (DPS) (Tuomilehto et al, 2001; Lindstrom et al, 2006)
- Diabetes Prevention Program (DPP), US (Knowler et al, 2002)
- Indian Diabetes Prevention Programme (Ramachandran et al, 2006)

Table 1: Recent prospective randomised trials in individuals with IGT

Study, Author, year	Population	Follow-up	Intervention	Reduction in diabetes incidence (95% Confidence interval)
Da Qing Diabetes Prevention Study, Pan et al, 1997	577	6 years	Diet or Exercise or Diet plus exercise or Control	56% 59% 51%
Li et al, 2008		20 years	Diet plus exercise or Control	43% (HRR 0.57; 95%CI:0.4-0.8)
Finnish Diabetes Prevention Study (DPS), Tuomilehto et al, 2001	522	Average 3.2 years	Intensive lifestyle change or Control	58% (HR,0.4, 95%CI:0.3-0.7)
Lindström J et al, 2006		Median 7 years	Intensive lifestyle change or Control	43%
Diabetes Prevention Program (DPP), Knowler et al, 2002	3234	Average 2.8 years	Intensive lifestyle program or Standard lifestyle recommendations plus metformin or Control (standard lifestyle recommendation plus placebo)	58% (95%CI:48-66) 31% (95%CI:17-43)
Indian Diabetes Prevention Programme (IDPP), Ramachandran et al, 2006.	531	Median 2.5 years	Lifestyle intervention or metformin or Lifestyle intervention plus metformin or Control	29% (95%CI:20-37) 26% (95%CI:19-35) 28% (95%CI:20-37)

The first significant randomised controlled trial was carried out in the city of Da Qing, China and showed that a lifestyle intervention program can reduce the rate of conversion from IGT to type 2 diabetes (Pan et al, 1997). In this study, 577 men and women with IGT were randomised either to a control group or intervention groups (exercise, or diet, or exercise plus diet). After 6 years, the incidence of diabetes was 68% (95% CI 60-75%) in the control group but only 41% (95% CI 33-49%) in the exercise group ($p<0.05$) and 44% (95% CI 35-52%) in the diet group (Pan et al, 1997). Recently published data from 20-years follow-up of the Da Qing Study indicated that the benefits of the lifestyle interventions continued with a 43% lower incidence of type 2 diabetes in subjects who had participated in the combined lifestyle intervention (diet and exercise) than the control group over the 20 year period (HR 0.57; 95%CI: 0.41-0.81)(Li et al, 2008). This group had a 51% lower incidence of diabetes (HR 0.49; 95%CI 0.33-0.37) during the intervention period. Less positive was their finding that 80% of the intervention group eventually developed diabetes, while 93% of those in the control group went on to develop the disease. However, subjects in the intervention group spent an average 3.6 fewer years with diabetes than those in the control group.

The Finnish Diabetes Prevention Study (DPS) (Tuomilehto et al, 2001) included 522 middle-aged, overweight men and women with IGT who were randomly assigned to either an intensive lifestyle intervention group or a control group. The control group received general dietary and exercise advice at baseline and had an annual physician's examination. The subjects in the intervention group received additional individualised dietary counselling from a nutritionist. They were also offered circuit-type resistance training sessions and advised to increase overall physical activity. The intervention was the most intensive during the first year, followed by a maintenance period. The intervention goals were to reduce body weight, reduce dietary and saturated fat, and increase physical activity and dietary fibre. After an average 3.2 years of active intervention, the cumulative incidence of diabetes was 11% in the intervention group and 23% in the control group, thus, the risk of diabetes was reduced by 58% ($P<0.001$) in the intervention group. The effect of the intervention on the incidence of diabetes was most pronounced among subjects who made comprehensive changes in lifestyle (Tuomilehto et al, 2001). The extended follow-up of the Finnish Diabetes Prevention Study assessed the extent to which the originally-achieved lifestyle changes and risk reduction remain after discontinuation of active counselling. After a median of 4 years of active intervention, participants who were still free of diabetes were further followed up for a median of 3 years, with a median total follow-up of 7 years. Diabetes incidence, body weight, physical activity, and dietary intakes of fat, saturated fat, and fibre were measured. During the total follow-up, the incidence of type 2 diabetes was 4.3 and 7.4 per 100 person-years in the intervention and control group, respectively ($p=0.0001$), indicating 43% reduction in relative risk (Lindstrom et al, 2006). The risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre, and increased physical activity. Beneficial lifestyle changes achieved by participants in the intervention group were maintained after the discontinuation of the intervention, and the corresponding incidence rates during the post-intervention follow-up were 4.6 and 7.2 ($p=0.0401$), indicating 36% reduction in relative risk.

The Diabetes Prevention Program (DPP) (Knowler et al, 2002) conducted in the US randomised 3,234 people with IGT to standard lifestyle recommendations plus metformin, standard lifestyle recommendations plus placebo, or an intensive program of lifestyle modification. The standard lifestyle recommendations were provided as written information and in an annual 20-to-30-minute individual session that emphasized the importance of a healthy lifestyle. Participants were encouraged to follow the Food Guide Pyramid. The goals

for the participants assigned to the intensive lifestyle intervention aimed to achieve and maintain a weight reduction of at least 7% of initial body weight through a healthy low calorie, low-fat diet and to engage in physical activity of moderate intensity, such as brisk walking, for at least 150 minutes per week. A 16-lesson curriculum covering diet, exercise, and behaviour modification was designed to help the participants achieve these goals. The mean age of the participants was 51 years, mean BMI 34.0, 68 % were women, 45 % were members of minority groups and the average follow-up was 2.8 years. The incidence of diabetes was 11.0, 7.8, and 4.8 cases per 100 person-years in the placebo, metformin, and intensive lifestyle modification groups, respectively. Intensive lifestyle-modification reduced the incidence of type 2 diabetes by 58% (95% CI:48-66%) and metformin reduced diabetes by 31% (95 % CI: 17-43%) (Knowler et al, 2002). This study also demonstrated the applicability of these findings in an ethnically and socio-economically diverse population.

In the Indian Diabetes Prevention Programme (IDPP) (Ramachandran et al, 2006) 531 subjects with IGT (421 men, 110 women, mean age 45.9±5.7 years, mean BMI 25.8±3.5 kg/m^2) were randomised into four groups. Group 1 was the control, Group 2 was given advice on lifestyle modification, Group 3 was treated with metformin and Group 4 was given advice on lifestyle modification plus metformin. After a 30 months median follow-up period, the 3-year cumulative incidences of diabetes were 55.0%, 39.3%, 40.5% and 39.5% in Groups 1–4, respectively. The relative risk reduction was 28.5% with lifestyle modification (95% CI 20.5–37.3, p=0.018), 26.4% with metformin (95% CI 19.1–35.1, p=0.029) and 28.2% with lifestyle modification plus metformin (95% CI 20.3–37.0, p=0.022), compared with the control group. The number needed to treat to prevent one incident case of diabetes was 6.4 for lifestyle modification, 6.9 for metformin, and 6.5 for lifestyle modification plus metformin. The authors concluded that both lifestyle modification and metformin significantly reduced the incidence of diabetes in Indians with IGT but there was no added benefit from combining them.

Abuissa and colleagues (2005) carried out a systematic review of the literature published between January 1990 and December 2004, using MEDLINE, EMBASE and the Cochrane Library to select randomised trials of at least one year duration. Six trials were identified including a total of 9,303 people with IGT at baseline. New onset diabetes was shown to be reduced by 31-58% through lifestyle change (exercise and/or diet), by 25-75% through the use of anti-diabetic agents and by 37% through the use of the anti-obesity medication, orlistat. A further 16 trials were identified in a total of 158,608 subjects who were treated with a number of different anti-hypertensive agents. In 11 of these 16 studies, over 20% decrease in the incidence of type 2 diabetes was observed (range 2%-87%).

Similarly, Curtis and colleagues (2005) systematically searched MEDLINE for articles relating to diabetes prevention published between January 1965 and January 2004. From a review of 18 relevant studies, they concluded that a lifestyle intervention aimed at inducing a 5-7% weight loss can prevent type 2 diabetes in people with IGT (strength A). This review highlighted that the preventive strategy with the best supporting evidence was intensive lifestyle intervention with interdisciplinary, individualised programs designed to produce modest weight loss. Metformin, acarbose and orlistat can also help prevent type 2 diabetes in people with IGT (strength B).

The results of a recent systematic review of RCTs and meta-analyses Gillies et al (2007) have strengthened recommendations from earlier reviews. Gillies et al (2007) conducted their review to quantify the effectiveness of pharmacological and lifestyle interventions to prevent

or delay type 2 diabetes in people with IGT. They identified 21 relevant studies through searching MEDLINE (1966 until July 2006) and EMBASE (1980 until July 2006) supplemented by searches in the Cochrane Library and by consultation with expert opinion. The analyses were strengthened by the inclusion of studies published in languages other than English, translated by interpreters familiar with medical literature. Seventeen randomised controlled trials comprising 8,084 participants with IGT were included in the meta-analyses which provided overwhelming evidence that diabetes is preventable. From the meta-analyses the pooled hazard ratios were 0.51(95% CI 0.44-0.60) for lifestyle interventions compared with standard advice, 0.70 (95% CI 0.62-0.79) for oral diabetes medications compared with control, 0.44 (95% CI 0.28-0.69) for orlistat compared with control, and 0.32 (95% CI 0.03 - 3.07) for the herbal remedy jiangtang bushen recipe compared with standard advice.

The evidence that type 2 diabetes can be prevented was also found in other populations. In a Japanese trial of 458 males with IGT were randomised to a lifestyle intervention or control group. The cumulative 4 year incidence of diabetes in the lifestyle group was 3% compared with 9.3% in the control group (Kosaka et al, 2005). The development of diabetes in the lifestyle intervention group was reduced by 67.4%.

b) How can type 2 diabetes be prevented in high risk individuals?

1. Lifestyle modification

- **Lifestyle modification including increasing physical activity, improving diet, and weight loss are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals.** *(Evidence Level I)*

The literature for evidence of the role lifestyle modifications play in prevention of type 2 diabetes have examined changes in physical activity; weight loss; and dietary changes. As described above, Gillies et al (2007) recent meta-analysis of 12 randomised control trials of lifestyle interventions in people with IGT clearly demonstrated that lifestyle interventions (ie diet alone, exercise alone or diet and exercise combined compared with routine advice) can prevent or delay diabetes in half the subjects (HR 0.51; 95% CI 0.44-0.60, P <0.001). Diet alone, exercise alone or diet and exercise combined all produced similar reductions in risk of diabetes. Lifestyle interventions effectiveness increased in severely overweight participants. Thus each one unit increase in mean BMI at baseline led to a decrease in the HR of 7.3% (95% CI:13.6%-0.9%). The calculated number of people needed to treat to prevent or delay one case of diabetes through lifestyle intervention was (NNT) 6.4 (95% CI 5.0-8.4).

This result confirmed earlier findings of a meta-analysis of five RCTs (Yamaoka & Tango, 2005) which included studies of six months duration that compared interventions of diet alone or diet and exercise combined against 'conventional education' (advice to exercise without diet advice). The random effects model show that a lifestyle intervention, approximately halve the incidence of type 2 diabetes (RR 0.55; 95%CI 0.44-0.69).

A systematic review by Curtis (2005) also reported that a 5-7% weight loss can prevent type 2 diabetes in people with IGT. Another systematic review which analysed three studies

describing diet and exercise interventions in a total of 4,333 people with IGT also concluded that diabetes can be prevented or delayed by lifestyle change (Abuissa et al, 2005).

The systematic review by Norris et al (2005) examined long-term non-pharmacological weight loss strategies using dietary, physical activity, or behavioural weight loss interventions for adults with IGT or IFG and demonstrated that a weight loss of 2.6 kg (95% CI 1.9-3.3) at two years. This was associated with a significant decrease in the cumulative incidence of diabetes in participants assigned to interventions compared with those assigned to usual care (RR reduction from 43-58%) at 3 to 6 years follow-up (Norris et al, 2005). This evidence was further confirmed in another systematic review of lifestyle interventions (Burnet et al, 2006) which identified the same diabetes prevention trials. These studies set modest goals for weight loss and physical activity but the reduction in diabetes incidence was quite significant.

A larger review, although one not strictly confined to randomized control trials (Liberopoulos et al, 2006) examined 10 lifestyle intervention studies for prevention of type 2 diabetes, mainly in people with IGT. They identified relevant articles (review articles, RCTs, large cohort and case control studies) through a Medline search (up to March 2005) This review found that in two studies of 5-6 years duration, where no weight reduction was achieved, there was no observed reduction in the progression to diabetes. In other studies, however where weight loss was achieved, the risk of type 2 diabetes was reduced up to 67%.

Further analysis of the lifestyle arm of the US DPP by Hamman et al (2006) explored the contribution of changes in weight, diet, and physical activity on the risk of developing diabetes among intensive lifestyle intervention participants (1,079 participants, aged 25–84 years, mean 50.6 years and mean BMI 33.9 kg/m^2). The researchers found that weight loss was the dominant predictor of reduced diabetes incidence (HR per 5-kg weight loss 0.42 ; 95% CI 0.35–0.51; $P < 0.0001$). For every kilogram of weight loss, there was a 16% reduction in risk, adjusted for changes in diet and activity. Weight loss was predicted by lower percent of calories from fat and increased physical activity. Increased physical activity was important to sustain weight loss. Among 495 participants not meeting the weight loss goal at year 1, those who achieved the physical activity goal had 44% lower diabetes incidence.

A post hoc analysis has examined the role of leisure-time physical activity in preventing type 2 diabetes in 487 men and women with IGT in the Finnish DPS (Laaksonen et al, 2002). Individuals who increased moderate-to-vigorous leisure time physical activity or undertook strenuous, structured leisure time physical activity were 63-65% less likely to develop diabetes. An increase in walking for exercise during follow-up also decreased the risk of diabetes. The researchers concluded that at least 2.5 hours/week of walking for exercise during follow-up decreased the risk of type 2 diabetes by 63-69%, largely independent of dietary factors and BMI.

The 7-year follow-up of the Finnish DPS showed a 43% reduction in relative risk (Lindstrom et al, 2006) in developing diabetes and that the risk reduction was related to the success in achieving the intervention goals of weight loss, reduced intake of total and saturated fat and increased intake of dietary fibre, and increased physical activity.

- **Lifestyle interventions in people with impaired glucose tolerance (IGT) reduce progression to type 2 diabetes beyond the intervention period.** *(Evidence Level II)*

The 20-years follow-up analysis of the Da Qing Study reported the benefits of the lifestyle interventions continued with a 43% lower incidence of type 2 diabetes in subjects who had participated in the combined lifestyle intervention (diet and exercise) than the control group over the 20 year period (HR 0.57; 95%CI: 0.41-0.81)(Li et al, 2008). This group had a 51% lower incidence of diabetes (HR 0.49; 95%CI 0.33-0.37) during the intervention period.

The follow-up of the Finnish Diabetes Prevention Study assessed the extent to which the originally-achieved lifestyle changes and risk reduction remain after discontinuation of active counselling. After a median of 4 years of active intervention, participants who were still free of diabetes were further followed up for a median of 3 years, with a median total follow-up of 7 years. During the total follow-up, the incidence of type 2 diabetes was 4.3 and 7.4 per 100 person-years in the intervention and control group, respectively (p=0.0001), indicating 43% reduction in relative risk (Lindstrom et al, 2006). Beneficial lifestyle changes achieved by participants in the intervention group were maintained after the discontinuation of the intervention, and the corresponding incidence rates during the post-intervention follow-up were 4.6 and 7.2 (p=0.0401), indicating 36% reduction in relative risk.

Table 2: Studies of lifestyle modification to prevent type 2 diabetes

Author, year	Study type	Population/ risk factors	Intervention	Control	Reduced risk of diabetes (95% Confidence interval)
Abuissa et al (2005a)	Systematic review	IGT; hypertension	Lifestyle; anti-diabetic agents; anti-obesity agent; anti-hypertensive agent.	Placebo or no treatment	Lifestyle: 58%
Burnet et al (2006)	Review	IGT	Lifestyle	No treatment	Lifestyle: DDP: 58% Finnish study: 58% Da-Qing: 31 % Malmo: 63%
Curtis & Wilson (2005)	Systematic review	IGT; obese people; previous GDM; people with hyperlipdemia; or hypertension	Lifestyle Pharmacotherapy Surgery	Placebo or no treatment	Lifestyle: 42% to 58%
Gillies et al (2007)	Systematic review	IGT; obese people; previous GDM.	Diet alone; exercise alone; diet + exercise; acarbose; flumamine; glipizide; metformin; phenformin; orlistat.	Placebo or no treatment	Diet+ exercise: HR 0.51 (95%CI:0.44-0.60) Diet alone: HR 0.67 (95%CI:0.49-0.92) Exercise alone: HR 0.49 (95%CI:0.32-0.74)
Hamman et al (2006)	RCT	BMI of 24 or higher, IGT	Lifestyle	Placebo	58% (95%CI:48-66)
Knowler et al (2002)	RCT	BMI of 24 or higher	Lifestyle or metformin	Placebo or standard lifestyle recommendation	Lifestyle: 58% (95%CI:48-66)

Author, year	Study type	Population/ risk factors	Intervention	Control	Reduced risk of diabetes (95% Confidence interval)
Kosaka et al (2005)	RCT	BMI of 22 or higher	Lifestyle	Standard lifestyle recommendation	67%
Laaksonen et al (2005)	RCT		Lifestyle – specifically leisure time physical activity		63-65%
Li et al (2008)	RCT	IGT	Lifestyle	No treatment	43% (HRR 0.57; 95%CI:0.4-0.8)
Lindstrom et al (2006)	RCT		Lifestyle	No treatment	43%
Norris et al (2005)	Systematic review	Prediabetes	Lifestyle	No treatment	43% to 58%
Liberopoulos et al (2006)	Systematic review	IGT	Lifestyle Anti-obesity drugs Anti-diabetic drugs	Placebo or no treatment	Lifestyle: 67%
Pan et al (1997)	RCT	IGT	Lifestyle	No treatment	Diet: 56% Exercise: 59% Diet + Exercise: 51%
Ramchandran et al (2006)	RCT	IGT	Lifestyle metformin Lifestyle + metformin	Standard healthcare advice	29% (95%CI:20-37)
Tuomilehto et al (2001)	RCT	BMI of 25 or higher, IGT	Lifestyle	General information about diet & exercise	58% (HR,0.4, 95%CI:0.3-0.7)
Yamaoka , Tango (2005)	Meta-analysis	IGT, IFG	Lifestyle	No treatment	50% (RR 0.55; 95%CI:0.44-0.69)

Life style interventions refers to increased physical activity / or dietary changes/ or weight loss.

2. Pharmacotherapy

- **Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals.** (*Evidence Level I)*

Anti-diabetic agents

There is evidence that a number of anti-diabetic agents can prevent the development of type 2 diabetes (Abuissa et al, 2005; Padwal et al, 2005; Salpeter et al, 2008). A recent systematic review by Gillies et al (2007) show that oral diabetes medications (including acarbose; flumamine; glipizide; metformin; phenformin; orlistat) prevent or delay the development of type 2 diabetes in people with IGT (HR 0.70 95% CI 0.62-0.79, P <0.001) (Gillies et al, 2007). The calculated number of people needed to treat to prevent or delay one case of diabetes through the use of these agents was 10.8 (95% credible interval 8.1-15.0) . Similar findings were reported also by a number of other reviews

The Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication (DREAM) study demonstrated the effectiveness of rosiglitazone in preventing the incidence of type 2 diabetes in high risk individuals. In this study, 5269 adults aged 30 years or more with impaired fasting glucose or impaired glucose tolerance, or both, and no previous cardiovascular disease were recruited from 191 sites in 21 countries and randomly assigned to receive rosiglitazone (8 mg daily; n=2365) or placebo (n=2634) and followed for a median of 3 years. The primary outcome was a composite of incident diabetes or death. At the end of study, 306 (11·6%) individuals of those given rosiglitazone and 26·0% of those given placebo developed the composite primary outcome (hazard ratio 0·40, 95% CI 0·35–0·46; p<0·0001); 1330 (50·5%) individuals in the rosiglitazone group and 798 (30·3%) in the placebo group became normoglycaemic (1·71, 1·57–1·87; p<0·0001). The authors concluded that rosiglitazone at 8 mg daily for 3 years substantially reduces incident type 2 diabetes and increases the likelihood of regression to normoglycaemia in adults with impaired fasting glucose or impaired glucose tolerance, or both (DREAM, 2006).

Salpeter and colleagues performed a meta-analysis of randomized controlled trials to assess the effect of metformin on metabolic parameters and the incidence of new-onset diabetes in persons at risk of diabetes. They performed comprehensive English- and non-English-language searches of EMBASE, MEDLINE, and CINAHL databases from 1966 to November of 2006 and scanned selected references and included randomised trials of at least 8 weeks duration that compared metformin with placebo or no treatment in persons without diabetes and evaluated body mass index, fasting glucose, fasting insulin, calculated insulin resistance, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, and the incidence of new-onset diabetes. Four trials in children and adolescents were included. Pooled results of 31 trials with 4,570 participants followed for 8,267 patient-years showed that metformin reduced body mass index (-5.3%, 95% CI -6.7--4.0), fasting glucose (-4.5%, 95% CI -6.0--3.0), fasting insulin (-14.4%, 95% CI -19.9--8.9), and calculated insulin resistance (-22.6%, 95% CI -27.3--18.0) compared with placebo or no treatment. The incidence of new-onset diabetes was reduced by 40% (OR 0.6; 95% CI 0.5-0.8), with an absolute risk reduction of 6% (95% CI 4-8) during a mean trial duration of 1.8 years. Most trials in the meta-analysis provided recommendations for exercise and diet in both the treatment and control groups, so the effect seen was a result of treatment in addition to lifestyle modification. Two trials

evaluated the effect of intensive lifestyle modification alone compared with metformin on diabetes incidence, and pooled data showed that lifestyle modification was significantly more effective than metformin. One trial evaluated the combination of intensive lifestyle measures and metformin on weight, and found that the combination produced the most significant reductions compared with either treatment alone.

Van de Laar and colleagues (2006) conducted a systematic review on the effects of acarbose on diabetes based on a search of the Cochrane Library, PUBMED, EMBASE, Web of Science and LILACS up until February 2006. This search was supplemented by reference to databases of ongoing trials and by consulting expert opinion. Evidence from three studies indicated that acarbose reduces the incidence of diabetes. Evidence from one of these three studies, the STOP-NIDDM which had the lowest risk of bias, suggested that treating 10 people for three years with acarbose would prevent one case of type 2 diabetes.

Padwal et al (2005) systematically reviewed the evidence for the prevention of type 2 diabetes by pharmacological therapies. Randomised controlled trials and cohort studies examining the effect of oral anti-diabetic agents, anti-obesity agents, anti-hypertensive agents, statins, fibrates, and oestrogen on the incidence of type 2 diabetes were identified from MEDLINE, EMBASE, the Cochrane Controlled Trials Registry, and searches of reference lists. Ten studies of anti-diabetic agents and 15 studies of non-oral anti-diabetic agents were found. Anti-diabetic agents and orlistat are the only drugs that have been studied in randomised controlled trials with diabetes incidence as the primary end point. In the largest studies of 2.5–4.0 years' duration, metformin (RR 0.69, 95% CI 0.57–0.83), acarbose (RR 0.75, 95% CI 0.63–0.90), troglitazone (RR 0.45, 95% CI 0.25–0.83), and orlistat (HR 0.63, 95% CI 0.46–0.86) all decreased diabetes incidence compared with placebo. The authors concluded that evidence for statins, fibrates, antihypertensive agents, and estrogen was inconclusive.

Anti-obesity agents

One anti-obesity agent has also been successful in preventing diabetes. Analysis of two trials has shown that orlistat can prevent or delay diabetes in people with IGT (HR 0.44; 95% CI 0.28-0.69) (Gillies et al, 2007). The calculated number of people needed to treat to prevent or delay one case of diabetes with orlistat was 5.4 (95% credible interval 4.1-7.6). This analysis again confirmed earlier findings (Curtis et al, 2005).

Padwal et al (2005) systematic review, as described above, also reported that orlistat (HR 0.63, 95% CI 0.46–0.86) decreases diabetes incidence compared with placebo.

Table 3: Studies of Pharmacotherapy in the prevention of type 2 diabetes

Author, year	Study type	Population/ risk factors	Intervention	Control	Reduced risk of diabetes
Salpeter SR, 2008	Meta-analysis of 31 RCTs, including 4579 patient	obesity, abdominal obesity, metabolic syndrome, polycystic ovary syndrome, impaired glucose tolerance or insulin resistance, family history of diabetes, hypertension, dyslipidemia, and peripheral vascular disease	Metformin	Placebo or no treatment	40%
Abuissa et al (2005a)	Systematic review	IGT; hypertension	Lifestyle Anti-diabetic agents: (metformin; Acarbose; Troglitazone) Anti-obesity drug: orlistat	Placebo or no treatment	Anti-diabetic agents: 31% orlistat: 37%
Curtis & Wilson (2005)	Systematic review	IGT, obese people, previous GDM, people with hyperlipdemia or hypertension	Lifestyle Pharmacotherapy (metformin; Troglitazone; Acarbose; orlistat) Surgery	Placebo or no treatment	Pharmacotherapy: 25% to 56% metformin: 31% Troglitazone: 56% Acarbose: 25-36% orlistat: 33.7%
DREAM Trial (2006)	RCT	IFG or IGT	Rosiglitazone	Placebo	60%
Gillies et al (2007)	Systematic review	IGT, obese, previous GDM.	Diet alone; exercise alone; diet + exercise; acarbose; flumamine; glipizide; metformin;	Placebo	Hazard ratio: Oral diabetes drug: 0.70

Author, year	Study type	Population/ risk factors	Intervention	Control	Reduced risk of diabetes
			phenformin; orlistat		Anti-obesity drug: 0.44
Knowler et al (2002)	RCT	BMI of 24 or higher	Lifestyle or metformin	Placebo + standard lifestyle recommendation	metformin: 31%
Liberopoulos et al (2006)	Systematic review	Non-diabetic obese patients (BMI >30) IGT	Lifestyle Anti-obesity drugs (orlistat) Anti-diabetic drugs (nateglinide; troglitazone; ramipril; acarbose; metformin)	Placebo or no treatment	Anti-obesity drugs: 37.3% Anti-diabetic drugs: 25% - 87.8%
Padwal et al (2005)	Systematic review	IGT; gestational diabetes	Metformin Acarbose Troglitazone Orlistat	Placebo	metformin: RR 0.69 Acarbose: RR 0.75 Troglitazone RR 0.45 Orlistat: Hazard Ratio 0.63
Ramchandran et al (2006)	RCT	IGT	Lifetsyle Metformin Lifestyle & metformin	Standard health care advice	metformin: RR reduction: 26.4% Lifestyle & metformin: RR reduction: 28.2%
Van de Laar et al (2006)	Meta-analysis	IGT or IFG	Acarbose	Placebo	RR: 0.78

3. Surgery

- **Bariatric surgery can prevent/delay progression to type 2 diabetes in people who are morbidly obese.** *(Evidence Level III)*

Another approach to diabetes prevention is through bariatric surgery. Ferchak and Meneghini (2004) searched MEDLINE for relevant studies published between 1990 and 2003 and evaluated the impact of bariatric surgery and lifestyle interventions on the prevention and management of type 2 diabetes. Two pre- and post studies in people with IGT undergoing gastric by-pass (Roux-en-Y procedure) were identified. In the first of these, 98.7 % of subjects (n=165) remained euglycaemic after an average of 7.6 years of follow-up. The second study was a non-randomised controlled study which followed 136 subjects with IGT and morbid obesity (109 underwent gastric by-pass and 27 elected not to have surgery and served as controls). In the later study, only one subject (0.9%) in the surgical group developed diabetes after an average 5.8 years follow-up compared with 6 subjects (22%) in the control group.

There have also been a number of case-control studies that have demonstrated that surgery prevented the development of type 2 diabetes in morbidly obese subjects. The Swedish Obese Subjects (SOS) Study (Sjostrom et al, 2004) was a prospective case-control study involving 1,879 obese patient pairs in which one underwent gastric surgery and the other received non-surgical obesity treatment. The 2-year mean weight loss was 28 kg among obese participants who had undergone surgery compared with 0.5 kg among obese participants who had not. In this study the incidence of diabetes was markedly lower in the surgically treated group than in the control group after 2 years (OR = 0.14, 95% CI: 0.08-0.24, $p<0.001$) and 10 years (OR = 0.25, 95% CI: 0.17-0.38, $p<0.001$).

Another case-controlled study compared laparoscopic gastric banding (LAGB) and conventional diet in the prevention of type 2 diabetes (Pontiroli et al, 2005). Of the 122 subjects in this study, 73 had the LAGB (intervention group) and the control group (No-LAGB) consisted of the 49 subjects who refused surgery but agreed to be followed up. Six of the control group dropped out of the study. At the end of 4-year follow up, five of the control subjects (17.2%) and none of the LAGB subjects (0.0%; $p = 0.0001$) progressed to type 2 diabetes.

A prospective case-control study has investigated the efficacy of minimal invasive gastric banding surgery for reducing caloric intake in morbid obesity, also analysing the effects of weight loss on body composition and metabolic and psychosocial outcomes (Dittmar et al, 2003). This study included 35 morbidly obese adults, of whom 26 underwent laproscopic gastric banding. The nine patients who rejected surgery were treated with metformin and were included as a small control group. The control group failed to exhibit any decrease in body weight, BMI or fat mass, and their metabolic parameters did not improve. Preoperatively, many of the surgical group (14 or 54%) had high fasting blood glucose indicating the presence of type 2 diabetes, while 11 (42%) had IGT. Postoperatively, over mean follow-up time of 17 ± 2.2 months, the surgical group showed a decline in fasting blood glucose values.

A cohort study has assessed the efficacy of the Swedish adjustable gastric band in the treatment of type 2 diabetes, IGT and the metabolic syndrome in 905 morbidly obese patients who had undergone gastric band surgery (Brancatisano et al, 2008). A total of 682 had > 6 months of follow-up, with a median follow-up of 12.5 months. Of these, 78 patients had type 2 diabetes, 64 had IGT, and 100 had the metabolic syndrome. No patient with IGT developed diabetes or progressed to require medication after surgery. Moreover remission and/or improvement in the metabolic syndrome occurred in 88% of patients. Adjustable gastric band surgery was therefore considered to potentially prevent progression to diabetes by morbidly obese patients with IGT.

Summary – Can type 2 diabetes be prevented? how it can be prevented in high risk individuals?

- A large body of evidence demonstrates that type 2 diabetes can be prevented in individuals at high risk of developing diabetes.

- In people with IGT, the evidence clearly demonstrated that lifestyle interventions (ie diet alone, physical activity alone or diet and physical activity combined compared with routine advice) could prevent or delay diabetes in half the subjects.

- 5-7% weight loss can prevent type 2 diabetes in people with IGT, For every kilogram of weight loss, there is a 16% reduction in risk, adjusted for changes in diet and activity.

- Lower percent of calories from fat and increased physical activity predicted weight loss. Increased physical activity was important to help sustain weight loss.

- Moderate-to-vigorous leisure time physical activity or strenuous, structured leisure time physical activity is recommended to reduce the risk of type 2 diabetes.

- Weight loss correlated with decreased progression of IGT to type 2 diabetes, all studies were relatively short term, average follow-up 3 years. It is not known for how many years the weight loss and the effort to sustain it can be maintained.

- Lifestyle modification prevention trials have been conducted among people with IGT because it is the best predictor of future diabetes.

- Pharmacotherapy including metformin and orlistat reduce type 2 diabetes incidence in people with IGT and overweight respectively.

- The studies presented in this section involved individual interventions. The challenge is for policymakers, population health practitioners, researchers, clinicians to implement those proven interventions. Small gains in prevention are likely to have significant population benefits.

- The critical question of whether lifestyle modification and drugs are preventing, or simply delaying, onset of type 2 diabetes remains unresolved.

- Future studies should be designed with diabetes incidence as the primary outcome and should be of sufficient duration to differentiate between genuine diabetes prevention as opposed to simple delay or masking of this condition.

- Further work is needed on the long-term effects of these interventions in diverse community settings.

Evidence Tables: Section 1

a) Can type 2 diabetes be prevented?

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type			
Abuissa et al (2005a)	I	Systematic review	Low	NA	High
Abuissa et al (2005 b)	I	Meta-analysis	High	High	High
Curtis & Wilson (2005)	I	Systematic review	Medium	High	High
Gillies et al (2007)	I	Systematic review	High	High	High
Knowler et al (2002)	II	RCT	High	High	High
Kosaka et al (2005)	II	RCT	High	High	Medium
Li et al (2008)	II	RCT	High	High	High
Lindstrom et al (2006)	II	RCT	High	High	High
Pan et al (1997)	II	RCT	High	High	Medium
Ramchandran et al (2006)	II	RCT	High	High	Medium
Tuomilehto et al (2001)	II	RCT	High	High	High

b) How can type 2 diabetes be prevented in high risk individuals?

1. Lifestyle change

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type			
Abuissa et al (2005a)	I	Systematic review	Low	NA	High
Burnet et al (2006)	I	Systematic review	Low	High	High
Curtis & Wilson (2005)	I	Systematic review	Medium	High	High
de Munter JSL (2007)	I	Systematic review	Medium	High	High
Gillies et al (2007)	I	Systematic review	High	High	High
Hamman et al (2006)	II	RCT	High	High	High
Knowler et al (2002)	II	RCT	High	High	High
Kosaka et al (2005)	II	RCT	High	High	Medium
Laaksonen et al (2005)	II	RCT	High	High	High
Li et al (2008)	II	RCT	High	High	High
Lindstrom et al (2006)	II	RCT	High	High	High
Norris et al (2005)	I	Systematic review	High	High	High
Liberopoulos et al (2006)	I	Systematic review	Low	N/A	High
Pan et al (1997)	II	RCT	High	High	Medium
Ramchandran et al (2006)	II	RCT	High	High	Medium
Tuomilehto et al (2001)	II	RCT	High	High	High
Yamaoka , Tango (2005)	I	Meta-analysis	Medium	High	High

2. Pharmacotherapy

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type			
Abuissa et al (2005a)	I	Systematic review	Low	N/A	High
Curtis & Wilson (2005)	I	Systematic review	Medium	High	High
DREAM Trial (2006)	II	RCT	High	High	High
Gillies et al (2007)	I	Systematic review	High	High	High
Knowler et al (2002)	II	RCT	High	High	High
Liberopoulos et al (2006)	I	Systematic review	Low	N/A	High
Padwal et al (2005)	I	Systematic review	Medium	Medium	High
Ramchandran et al (2006)	II	RCT	High	High	Medium
Salpeter et al (2008)	I	Meta-analysis	High	High	High
Van der Laar et al (2006)	I	Meta-analysis	High	High	High

3. Surgery

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type			
Brancatisano et al (2008)	III-3	Cohort (Prognosis study)	Low	High	High
Dittmar et at (2003)	III-2	Case-Control (Prognosis study)	Medium	Medium	High
Ferchak & Meneghini (2004)	I	Systematic review	Low	High	High
Pontiroli (2005)	III-2	Case-Control (Prognosis study)	Medium	High	Medium
Sjostrom et al (2004)	III-2	Case-Control (Prognosis study)	Medium	High	Medium

Section 2: Identifying individuals at high risk

Question

How can individuals at high risk of type 2 diabetes be identified?

Recommendation

Individuals at high risk of diabetes should be identified through the use of risk assessment tools (Grade C).

Practice Points

- The Australian Risk Assessment Tool (AUSDRISK) should be used to identify people at high risk of developing diabetes
- A risk score of ≥ 15 should be used to categorise high risk
- Risk assessment should begin at age 40 and from age 18 in Aboriginal and Torres Strait Islanders*
- Risk assessment should be repeated every 3 years

* It should be noted that the AUSDRISK may overestimate risk in those under 25 years of age and underestimate risk in Aboriginal and Torres Strait Islanders.

Evidence Statements

- Risk assessment tools using basic clinical information (age, sex, ethnicity, family history of diabetes, hypertension and anthropometric measurements) without laboratory testing identify people at high risk of diabetes.
  Evidence Level II
- The inclusion of laboratory measures (fasting glucose, HDL cholesterol, triglycerides) improve the performance of risk assessment tools in identifying individuals at high risk of diabetes.
  Evidence Level III
- Risk assessment tools for identifying people at increased risk of type 2 diabetes are feasible and effective for use in community settings.
  Evidence Level III

Background – Identifying individuals at high risk

Interventions in people at high risk of developing diabetes can prevent or delay progression to diabetes. Most intervention studies to prevent diabetes have focussed on people with IGT, while some have also included people with IFG. These conditions are prevalent in Australia with the AusDiab Study reporting a prevalence of IGT of 10.6% while the prevalence of IFG was 5.8% (Dunstan , 2002).

The identification of people with IGT requires performing an oral glucose tolerance test (OGTT) which is not practical for community-based diabetes prevention programs. Detecting IFG is easier, but still requires measurement of fasting plasma glucose, which also presents logistic difficulties for community programs.

In recent years attention has focussed on alternate and practical methods which could be applied in a community setting for identifying people at high risk of type 2 diabetes who could be offered preventative interventions (Engelgau et al, 2004).

The most commonly used method has become risk assessment using a risk assessment tool. These are based on the fact there are well documented risk factors which characterise individuals at high risk of the future development of type 2 diabetes.

This section begins with a brief review of these factors and then examines the evidence about risk assessment tools.

Risk factors for developing type 2 diabetes

There are many known risk factors for type 2 diabetes, the difficulty is to determine the ones with the greatest applicability for clinical use (Waugh et al, 2007).

1. Non-modifiable risk factors for developing type 2 diabetes

i. Age / genetic / family history / gender

Prevalence and risk of diabetes increase markedly with increasing age except in those over the age of 75 years. Type 2 diabetes also has a strong genetic component and risk is higher in those with a family history of diabetes (Frayling, 2007). Prevalence rates are higher in men than in women (Dunstan et al, 2001). Risks associated with these non-modifiable factors however, are often only unmasked by the presence of obesity and physical inactivity, indicating the importance of interactions between genetic and lifestyle factors in the development of diabetes (Franks et al, 2007).

ii. Ethnic groups

Diabetes prevalence is high in some of Australia's culturally and linguistically diverse (CALD) communities including people born in Southern Europe, in North Africa and the Middle East or in the Pacific Islands and South Asia (Colagiuri et al, ; Australian Institute of Health and Welfare, 2008). High prevalence of being overweight, physical inactivity and unhealthy diet together with genetic susceptibility and other psychosocial factors related to immigration contribute to the higher incidence and prevalence of diabetes among CALD communities.

iii. Aboriginal and Torres Strait Islander Australians

Aboriginal and Torres Strait Islander Australians are at very high risk of type 2 diabetes. Moreover, diabetes appears earlier in adult life (O'Dea et al, 1993; Hoy et al, 2007). Thus while in European Australians examined in the AusDiab Study, prevalence of diabetes in those aged less than 35 years was only 0.3% (Dunstan et al, 2001), among Aboriginal and Torres Strait Islander people aged below 35 years prevalence rates reached 5.3% (O'Dea et al, 1993).

iv. Low birth weight

A further risk factor for type 2 diabetes that was first recognized by Barker in 1993 (Barker et al, 1993) is low birth weight which may increase the risk of type 2 diabetes through altered programming of muscle and adipose tissue glucose metabolism (Vaag et al, 2006).

II. Modifiable risks factors for developing type 2 diabetes

Many modifiable risks for diabetes have also been identified (Wilson et al, 2007).

i. Overweight and obesity

One of the most important modifiable risks factors is overweight and obesity, not only at current levels but also past obesity and obesity duration (Wilding, 2007). Obesity is most often assessed through use of the body mass index (BMI). A high BMI is well established as a significant predictor of type 2 diabetes (Thomas et al, 2006; Wilson et al, 2007). The AusDiab five-year follow-up study showed that compared with individuals with normal BMI at baseline, overweight people had an almost two-fold increased diabetes risk, whereas in obese individuals the risk increased four-fold. Obese men were at higher risk than obese women (Barry et al, 2006). Not only total fat mass, but fat distribution also has an important influence on diabetes risk. Visceral adipose tissue (adipose tissue deposited within the abdomen around the body organs) and possibly also subcutaneous abdominal adipose tissue, appear to be most detrimental (Wilding, 2007).

ii. Physical inactivity

Physical inactivity induces insulin resistance and can contribute to weight gain (Laaksonen et al, 2005; Hamburg et al, 2007). People who carry out little moderate physical activity are at higher risk of diabetes (Laaksonen et al, 2005). Assessment of physical activity habit and/or sedentary behaviour helps identify those at high diabetes risk

iii. Dietary intake

Diet also affects diabetes risk, mainly through its influence on body weight but other mechanisms such as post-prandial hyperglycaemia and oxidant stress may play a role (O'Keefe et al, 2008). Several dietary factors are associated with alterations in risk. Consumption of salads and cooked vegetables appear protective against development of diabetes (Hodge et al, 2007) as do whole grain cereals (Fung et al, 2002) and adherence to a Mediterranean-style diet (Panagiotakos et al, 2007). Conversely, consumption of high amounts of meat and fatty foods (Hodge et al, 2007) or soft drinks (Dhingra et al, 2007) and also food insecurity (Seligman et al, 2007) can increase risk.

iv. Smoking

An additional factor here is cigarette smoking which can lead to insulin resistance and perturbation of insulin secretion (Facchini et al, 1992; Attvall et al, 1993) so that active smokers are at increased risk of diabetes (Willi et al, 2007).

v. Psychological stress

Stressful events in the family, at work or related to the physical or social environment also appear to contribute to diabetes risk (Golden, 2007). In addition, depression is a risk factor for type 2 diabetes (Knol et al, 2006).

III. Other risk factors

i. Gestational diabetes mellitus (GDM)

GDM is associated with an increased risk of the future development of type 2 diabetes in the mother (Kitzmiller et al, 2007). GDM is common in Australia with prevalence varying with ethnicity, ranging from 3% in women of European background to as high as 17% in women of Indian background (Hunt & Schuller, 2007).

ii. Polycystic ovary syndrome

PCOS is characterized by androgen excess, menstrual irregularity and the appearance of large follicles in one or both ovaries and is linked to insulin resistance, hyperinsulinaemia and frequently to central obesity (Bako et al, 2005). Women with PCOS have an increased risk of abnormalities of glucose intolerance.

iii. The Metabolic Syndrome

The metabolic syndrome describes a cluster of risk factors including central obesity, dyslipidaemia, high blood pressure and hyperglycaemia (Eckel et al, 2005). In Australia approximately 20-30% of people have the syndrome, depending on the definition used (Cameron et al, 2008). The risk of the future development of diabetes in people with the syndrome is increased about 2-4-fold (Eckel et al, 2005).

Using various combinations of the above mentioned risk factors has led to the development of models which have the potential to identify adults at high risk of developing diabetes. As was discussed in the previous section, diabetes can be prevented through lifestyle, pharmacological and surgical interventions. However, as universal population screening is costly and is not recommended, accurate and quick identification of people at high risk of developing diabetes is required to ensure that those who will most benefit from primary prevention interventions are targeted so that these interventions are implemented effectively and efficiently. As detailed further in the report, cohort studies have been conducted and simple identification techniques which are widely and easily applicable to daily clinical practice have been developed.

Evidence- Identifying individuals at high risk

- Risk assessment tools using basic clinical information (age, sex, ethnicity, family history of diabetes, hypertension and anthropometric measurements) without laboratory testing identify people at high risk of diabetes. (*Evidence Level II)*

- The inclusion of laboratory measures (fasting glucose, HDL cholesterol, triglycerides) improve the performance of risk assessment tools in identifying individuals at high risk of diabetes. *(Evidence Level III)*

- Risk assessment tools for identifying people at increased risk of type 2 diabetes are feasible and effective for use in community settings. (*Evidence Level III)*

The traditional way of identifying people at high risk of developing diabetes has used an OGTT. The landmark diabetes prevention studies (eg Finnish and US prevention studies) used one or even two OGTTs to identify people with IGT. While this method is effective because of the high risk of people with IGT developing diabetes, this is not practical for routine clinical practice and community settings.

Risk factor based models
Risk factor based models are an alternate approach and a number of models have been developed for identifying adults at high risk for diabetes. These can use either risk factors alone or in combination with laboratory measurements. Models without laboratory testing are summarised in Table 4. The simplicity of these approaches makes them readily available for use in daily practice.

1. Risk scores without laboratory testing
The most widely used risk tool for characterising individuals according to their future risk of type 2 diabetes is FINDRISK, which was developed in Finland (Lindstrom & Tuomilehto, 2003). A random population sample of 4,746 35-64 year old men and women who were not taking anti-diabetic medications was chosen from the Finnish National Population Register in 1987 and followed for 10 years. A simple diabetes risk scoring system involving only parameters which are considered easy to assess without the need for any laboratory tests or other clinical measurements requiring specialised skills (age, BMI, waist circumference, blood pressure medication, history of high blood glucose levels, diet and physical activity) was produced. Each parameter was assigned an individual score with the Diabetes Risk Score calculated as the sum of these scores varying from 0 (very low risk) to 20 (very high risk). Diabetes Risk Scores were calculated for each participant and a score of 9 was selected as the point defining increased risk of developing diabetes requiring medication treatment, with a sensitivity of 0.78 and specificity of 0.81. The participants were classified into four Diabetes Risk Score categories (0-3; 4-8; 9-12 and 13-20). During the 10 year follow-up, the incidence of medication requiring diabetes was significantly ($p = 0.001$) elevated in the two highest categories for both men (0-3: 0.3%; 4-8: 2.4%; 9-12: 10.5% and 13-20: 32.7%) and women (0-3: 0.6%; 4-8: 1.3%; 9-12: 6.6% and 13-20: 28.2%). This Diabetes Risk Score model was further validated using another random sample of 4,615 from a 1992 survey followed for 5 years. Diabetes Risk Scores were calculated for each participant and they were again classified into the four Diabetes Risk Score categories as above. Similar to the 1987 cohort, the incidence of medication requiring diabetes was significantly ($p = 0.001$) elevated in the

two highest categories for both men (0-3: 0.3%; 4-8: 0.8%; 9-12: 2.6% and 13-20: 23.1%) and women (0-3: 0.1%; 4-8: 0.4%; 9-12: 2.2% and 13-20: 14.1%) in the 1992 cohort. In the 1987 and 1992 cohorts, 25% of both men and women, and 26% of men and 24% of women, respectively were classified in the two highest risk categories.

A similar diabetes risk score has been developed by Pearson and colleagues (2003). Using a large prospective cohort study in the upper Midwestern United States Pearson and colleagues conducted a health risk assessment questionnaire which included specific questions associated with diabetes risk factors (overweight, physical inactivity, age, ethnicity, family history of diabetes and/or hypertension, hypertension, hypercholesterolaemia, gestational diabetes, delivery of a baby > 4.1 kg). Based on available evidence and consensus statements from experts in the field, these 10 risk factors were each assigned a weighted score and the diabetes risk score for each individual was computed as the sum of all risk factor scores. Two thresholds, specifically scores > 5 and scores > 6, were defined as high diabetes risk. The study sample had a mean age of 42.5 years (range 19-91 years), 62.2% of participants were female, 91.5% were white, 71.9% had received some college education, and only 2.7% were older than 65 years. When the high risk score was defined as > 5, 28.2% of the surveyed population were identified at high risk and after an average 2.5 year follow-up, the incidence of diabetes was 3.5% in this high risk group compared with 0.7% in the low risk group whose risk score was < 5 ($p < 0.001$). When the high risk score was defined as > 6, 17.9% of the surveyed population were identified at high risk with the incidence of diabetes at follow-up being 4.6% compared with 0.9% in the low risk group whose risk score was < 6 ($p < 0.001$).

The German Diabetes Risk Score developed by Schulze and colleagues (2007) was based only on anthropometric, dietary and lifestyle factors and estimated the probability of developing diabetes within 5 years. A prospective cohort (EPIC-Potsdam) of 9,729 men and 15,438 women aged 35-65 years was used to derive the risk score for predicting the development of type 2 diabetes. Points were allocated to anthropometry, diet and lifestyle factors and the total German Diabetes Risk Score was calculated to determine the probability of each participant developing diabetes during the follow-up period. Data from a second cohort (EPIC Heidelberg) of 23,398 participants with a similar age range to the EPIC-Potsdam cohort was then used to validate this score. During an average 7 year follow-up, 849 incident cases of type 2 diabetes were observed amongst the EPIC-Potsdam cohort and 658 of the EPIC Heidelberg cohort developed diabetes during the first 5 years of follow-up. These actual incidences of diabetes were comparable to probability estimate of diabetes incidence derived from the risk scores of each of the cohorts [Receiver-Operating Characteristics Area Under the Curve (ROC AUC) 0.84 for the EPIC-Potsdam cohort and 0.82 for the EPIC-Heidelberg cohort] and the observed incidence in both cohorts increased with increasing risk scores.

Risk tools have been developed in other populations. A simple diabetes risk scoring system developed in Thailand based on age, sex, BMI, waist circumference, history of hypertension and family history of diabetes was found to be almost as good as models that included additional laboratory measures such as IFG, IGT, HDL cholesterol and triglycerides (Aekplakorn et al, 2006), with the predictive ability of the model without laboratory tests being only slightly lower than the latter (ROC AUC 0.75 vs 0.79). The diabetes risk scoring system was developed in a cohort of 2,677 non-diabetic Thai individuals aged 35-55 years with a 12 year follow up period and was then validated using a second different cohort of 2,420 Thai individuals with a 5 year follow up.

Table 4: Risk Scores models without laboratory testing to predict diabetes in high risk individuals

Author, year, country	Population	Follow-up (years)	Risk factors included to develop diabetes risk scores	Outcome
Aekplakorn, 2006 , Thailand	2677 non-diabetic Thai individuals aged 35-55 years	12 year	Age, sex, BMI, waist circumference, history of hypertension and family history of diabetes	ROC AUC: 0.747 cf 0.790
Lindstrom. 2003, Finland	4746 men and women age 35-64 years with no anti-diabetic drug treatment	10 years	Age, BMI, waist circumference, blood pressure medication, history of high blood glucose, diet, physical activity	Diabetes Risk Score cut-off point of 9 identified more than 70% of incident cases
Pearson, 2003, US	Mean age of 42.5 years , 62.2% female, 91.5% white, 71.9% received college education, and only 2.7% were older than 65 years.	Average 2.5 years	Overweight, physical inactivity, age, ethnicity, family history of diabetes and/or hypertension, hypertension, hypercholesterolemia, gestational diabetes, delivery of a baby > 9 pounds	A cut-off score of >5 identified 28% of the population and a cut-off score of >6 identified 18% of the population
Schulze 2007, Germany	9729 men and 15438 women, aged 35-65 years	Average 7 years	Anthropometry, diet and lifestyle factors	ROC AUC : 0.84

2. Risk scores with laboratory testing

The following describe risk scores which include laboratory testing. A prospective cohort study in San Antonio, Texas of 1,791 Mexican Americans and 1,112 non-Hispanic whites without diabetes, was used to develop simple multivariable models using readily available clinical variables which are routinely collected to predict the future development of diabetes and compared these to diabetes prediction using an OGTT (Stern et al, 2002). A model based on age, sex, ethnicity, family history, BMI, systolic blood pressure, fasting glucose and HDL cholesterol was superior in predicting future type 2 diabetes compared with a model that relied exclusively on the 2 hour glucose measurement of an OGTT (ROC AUC 84.3 [95% CI: 81.8-86.7]) vs 77.5 [95% CI: 74.3-80.7], p<0.001). Adding the 2 hour glucose measurement of an OGTT to the multivariate model did improve the predictive ability, however this improvement was relatively minor (ROC AUC 85.7 [95% CI: 83.4-88.2], p = 0.015).

In 2005, Schmidt and colleagues (2005) recruited 15,792 men and women aged 45-64 years from four US communities. Following the exclusion of those who were diagnosed with diabetes and those who had incomplete or inconsistent data, 7,915 participants remained in the cohort. A randomly selected half of this sample was used to develop diabetes risk functions. These risk functions were derived from basic clinical information (age, sex,

ethnicity, family history of diabetes, hypertension and anthropometric measurements) alone or combined with simple laboratory measures (fasting glucose, HDL cholesterol, triglycerides). These risk functions were tested on the other random half of the cohort for predicting incident diabetes over a 9 year follow-up period. The predictive ability of a risk function using clinical information only was not significantly different to the predictive ability of fasting glucose levels alone (ROC AUC 0.71 vs 0.74, p=0.2). Predictive ability of the clinical information was improved significantly when it was combined with the fasting glucose levels (ROC AUC 0.78, p<0.001) and slightly further improved when lipid measurements were also included (ROC AUC 0.80, p<0.001).

A screening model reported by Norberg and colleagues (2006) combining HbA_{1c}, BMI and fasting plasma glucose accurately identified individuals at risk of developing diabetes. This study was an incident case-referent study nested within a population-based survey conducted from 1989-2001 in a county in Northern Sweden. Cases were free from diabetes at the beginning of the health survey but were diagnosed with type 2 diabetes during the study period. Two non-diabetic referents were randomly chosen for each diabetes case and after exclusion due to inadequate blood sample, 164 cases and 304 referents were available to assess the predictive ability of the screening model. The model involved using a HbA_{1c} of 4.7%, fasting plasma glucose 6.1-6.9mmol/l and a BMI $\geq$ 27kg/m^2 for men and $\geq$ 30kg/m^2 for women. The sensitivity and specificity of this model was 0.66 and 0.93 respectively for men, and 0.52 and 0.97 respectively for women, with positive predictive values for men and women being 32% and 46% respectively. Substituting data from OGTTs for the fasting plasma glucose levels did not add value to the ability of the model to predict development of diabetes, neither did lowering the fasting glucose criterion to 5.6mmol/l.

The metabolic syndrome has been used to identify people at risk of diabetes. The San Antonio Heart Study (Lorenzo et al, 2003) evaluated the performance of two different definitions of the metabolic syndrome, National Cholesterol Education Program (NCEP) definition and a modified version of the 1999 WHO definition excluding the 2 hour requirement, in predicting incident type 2 diabetes, and compared these to the presence of IGT for predicting diabetes development over a 7-8 year period. Subjects meeting the requirements of the NCEP definition had a six-fold higher risk of developing diabetes compared with those without the syndrome (OR = 6.30, 95% CI: 4.60-8.63). This risk was still 3-fold following adjustment for age, sex, ethnicity, family history of diabetes, IGT and fasting insulin levels (OR = 3.30, 95% CI: 2.27-4.80). IGT and the NCEP definition had comparable sensitivity for predicting diabetes, 51.9 and 52.8 respectively, and were higher than the modified WHO definition (sensitivity = 42.8). IGT however had higher positive predictive value than both the NCEP definition and the modified WHO definition (43.0 vs 30.8 and 30.4 respectively). However this finding is not universal. Cameron et al (2008) did not find that the metabolic syndrome performed well when applied to the AusDiab population.

Australian Diabetes Risk Assessment Tool for Diabetes Prediction (AUSDRISK)

An Australian Diabetes Risk Assessment Tool (AUSDRISK) for the prediction of diabetes has been developed during the course of this guideline development and was introduced on the 1st of July, 2008 (http://www.health.gov.au/internet/main/publishing.nsf/Content/C73A9D4A2E9C684ACA2574730002A31B/$File/Risk_Assessment_Tool.pdf). It attracts a Medicare rebate when applied to people aged 40-49. Individuals in this age range who are at high risk of diabetes are eligible for a subsided lifestyle modification program.

AUSDRISK has been developed from the two AusDiab surveys and predicts the risk of developing diabetes over a 5-year period (Chen et al, 2009). In the original 1999-2000 AusDiab survey, 11,247 individuals participated. In the 2004-5 AusDiab survey, 6,537 of the original cohort presented for re-examination, of whom there were 6,060 participants aged ≥25 years without diagnosed diabetes at baseline. These 6,060 participants, of whom 362 developed diabetes between the two assessments five years apart, were used to derive AUSDRISK. AUSDRISK contains a number of well established risk factors for type 2 diabetes namely: age, gender, ethnicity, family history of diabetes, hypertension, smoking, fruit and vegetable consumption, physical activity, and obesity (Appendix 1).

Using an AUSDRISK score of ≥ 15 has a sensitivity of 54.3% , specificity of 83.1% and PPV of 16.9% respectively for predicting the development of diabetes over the next five years. An AUSDRISK score of ≥ 12 has a sensitivity of 74.0%, specificity of 67.7% and PPV of 12.7% respectively for predicting future diabetes (Chen et al, 2009). An AUSDRISK score of ≥15 identifies ~15% of the total population at high risk of developing diabetes within the next five years.

The performance of AUSDRISK has been assessed when applied to other Australian cohorts. In terms of discriminative ability, AUSDRISK performed only moderately in the Blue Mountains Eye Study (BMES) population (Cugati et al, 2007) but discrimination was very good in the North West Adelaide Health Study (NWAHS) population (Grant et al, 2006). This may be due in part to the limited age range in the BMES which only recruited people older than 49 years. The weighting of age categories is likely to be smaller when a score derived from a wider age group is applied to a population with a limited age range. AUSDRISK calibrated well in the BMES cohort but only reasonably in the NWAHS. The less satisfactory calibration might be related to the lower incidence of diabetes in the NWAHS.

Summary: Identifying individuals at high risk

- Models using basic clinical information (age, sex, ethnicity, family history of diabetes, hypertension and anthropometric measurements) alone or combined with simple laboratory measures (fasting glucose, HDL cholesterol, triglycerides) predict the future development of diabetes.

- Models without the involvement of any laboratory testing have additionally been shown to be useful in identifying people at high risk of diabetes. These are of particular importance as the simplicity of these approaches makes them readily available for use in daily practice.

- In Australia and overseas, diabetes Risk Score tools were developed using a simple, practical and informative scoring system to characterise individuals according to their future risk of type 2 diabetes.

Evidence Tables: Section 2

How can individuals at high risk of diabetes be identified?

1. Risk scores without laboratory testing

Author (year), population	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type*			
Aekplakorn et al (2006), Thailand	II	Cohort	High	High	Medium
Lindström & Tuomilehto (2003), Finland	II	Cohort	High	High	High
Pearson et al (2003), US	III-1	Cohort	Medium	Medium	High
Schulze et al (2007), Germany	II	Cohort	High	High	High

*Prognosis Studies

2. Risk scores with laboratory testing

Author (year), population	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect rating	Relevance Rating
	Level	Study Type*			
Diabetes Prevention Program Research Group (2005), US	III-2	Cohort	Medium	High	High
Stern et al (2002), Mexican American, US	III-2	Cohort	Medium	Medium	Medium
Lorenzo et al (2003), US	III-2	Cohort	Low	Medium	Low
Norberg et al (2006), Sweden	III-2	Cohort	Medium	Medium	High
Schmidt et al(2005), US	III-2	Cohort	Medium	Medium	High

*Prognosis Studies

Section 3: Population strategies to reduce lifestyle risk factors

Question

What population strategies have been shown to be effective in reducing lifestyle risk factors for type 2 diabetes?

Recommendations

Social marketing should be considered as part of a comprehensive approach to reduce risk factors for type 2 diabetes at the population level (Grade C).

Community-based interventions should be used in specific settings and target groups (eg schools, workplace, women's groups) as a strategy for reducing diabetes risk factors (Grade C).

The impact of the built environment on physical activity and food quality and availability should be considered in all aspects of urban planning and design (Grade D).

Practice Point

To be effective, a community-based intervention should:

- have a strong theoretical base
- be designed to send a few clear messages
- use multiple strategies to communicate these messages
- encourage family involvement
- be intensive and sustained over a long period of time.

Evidence Statements

- Sustained, well-executed social marketing can be effective in increasing physical activity, improving nutrition knowledge, attitudes and eating behaviour in a range of target groups, in different settings.
  Evidence Level III

- Mass media campaigns increase awareness, and improve knowledge and attitudes around physical activity and healthy eating and may have a short term effect on physical activity behaviour in some individuals.
  Evidence Level III

- Media-only approaches may be sufficient to encourage a significant proportion of people to alter their dietary habits and contribute to weight control at the population level.
  Evidence Level III

- Mass media campaigns enhance the success of community-based interventions.
  Evidence Level III

- Well-designed community-based intervention programs can improve lifestyle choices and health habits such as increase physical activity and healthy eating.
  Evidence Level III

- Worksite interventions which involve family members can improve dietary habits.
  Evidence Level III

- Worksite health promotion programs that include environmental modifications can influence dietary intake.
  Evidence Level III

- Environmental and policy interventions are effective in reducing chronic disease risk factors including smoking, physical inactivity, and unhealthy eating.
  Evidence Level III

- Policy regulation such as nutrition information on processed foods has the potential to improve food choices and promote healthy eating at a population level.
  Evidence Level III

Background - Population strategies to reduce lifestyle risk factors

A large body of evidence supports the prevention of type 2 diabetes by lifestyle modification. Changes in lifestyle are in general twice as effective as pharmacotherapy in preventing type 2 diabetes. Hence investment of resources in preventing type 2 diabetes is essential to address the current epidemiology and combat the burden of this condition. Colagiuri R et al (2006) suggested that combining a high-risk approach with a population approach is likely to bring health gain across the continuum from preventing the development of risk factors in the general population to reducing or reversing established modifiable risks and preventing the development of diabetes (Figure 1). The complex nature of diabetes means that many organisations and agencies need to be engaged for its effect control.

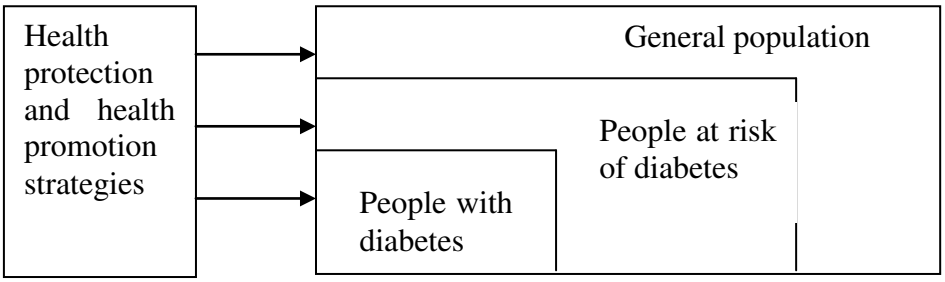

Figure 1: Population health protection and health promotion strategies bring benefit across the diabetes disease continuum (adapted from Colagiuri R, 2006)

A program for the prevention of type 2 diabetes in Finland 2003-2010 (Saaristo et al, 2007) includes three concurrent strategies ie:

- A population strategy aimed at promoting means of nutritional interventions and increased physical activity, so that risk factors of diabetes such as obesity and metabolic syndrome are reduced. This strategy comprises both society-oriented measures and measures targeting individuals. The society-oriented measures include measures relating to sports policy, food policy, educational policy, social development and environmental policy
- A high risk strategy - individual oriented strategy targeting individuals at high risk of developing type 2 diabetes
- A strategy of early diagnosis and management.

Framework of health promotion strategy to address diabetes risk factors

The WHO provided a guide on important elements of successful policies and plans for a population based approach to physical activity (WHO, 2007). The suggested elements included high level political commitment, integration in national policies, identification of national goals and objectives, funding, cultural sensitivity, multiple interventions and implementation at different levels.

Adapting the WHO framework, the objectives of health promotion strategies to address diabetes risk factors such as physical inactivity and unhealthy eating would be:

1. **Increase community awareness** of healthy lifestyle behaviours including benefits, health risks associated with unhealthy behaviours, and how to adopt a healthy lifestyle.

Intervention that increase awareness includes but is not limited to social marketing campaigns and mass media campaigns.

2. **Increase community skills to change behaviours and adopt a healthy lifestyle** through community-based interventions in a variety of settings such as schools, worksites, churches, community centres.

3. **Develop policies and create environments that support healthy lifestyle** by ensuring that public and social policy, and the built environment are designed to encourage health promoting behaviour on a population scale.

1. Increase community awareness

Social marketing

In recent years there has been growing interest in social marketing interventions to promote healthy behaviour such as quitting smoking, improving diet, increasing physical activity, and tackling the misuse of substances like alcohol and illicit drugs and sexual health (Brown, 2002; Farrelly et al, 2003; Gordon et al, 2006). Moreover, there is emerging evidence to support the effectiveness of social marketing interventions in changing behaviour in a range of target groups in different settings (Grier & Bryant, 2005; Gordon et al, 2006).

Social marketing provides a promising framework for improving health both at the individual level and at wider environmental and policy-levels. Since late 1980, health promotion campaigns in Australia and overseas began applying social marketing practice. For example, the Victoria Cancer Council developed its anti-tobacco campaign 'Quit' (1988), and 'SunSmart' (1988) against skin cancer which had the slogan *Slip! Slap! Slop! (Dixon et al, 2008) (VIChealth website)* and the 'VERB^{tm}' campaign in the US (Wong et al, 2004).

What is social marketing?

Several definitions of social marketing exist. For the purpose of this guideline the following definition which is most commonly used by researchers (Wong et al, 2004; Grier & Bryant, 2005; Gordon et al, 2006) has been adopted as follows:

'Social marketing is the application of commercial marketing technologies to the analysis, planning, implementation and evaluation of programs designed to influence voluntary behaviour' (Andreasen, 1995), cited by (Grier & Bryant, 2005; Gordon et al, 2006).

Theories and models of social marketing

Social marketing frameworks and the method used to derive them have considerable potential application in health promotion and can also guide aspects of evaluation of initiatives (Grier & Bryant, 2005). Anderson's six key principles for benchmarking of social marketing are: behaviour change, consumer research, segmentation and targeting, marketing mix, exchange, competition (Grier & Bryant, 2005).

Social marketing interventions

Gordon et al (2006) have argued that social marketing interventions can work upstream by changing the behaviour of organisations, professionals, retailers, or policy makers as well as with individuals. However, due to difficulties in measuring policy and environmental change, meaningful measurable outcome data was not reported (Gordon et al, 2006).

Mass media campaigns
Mass media campaigns to promote healthy behaviours and discourage unhealthy ones have become major tools to improve the public health (Randolph & Viswanath, 2004). There is evidence that comprehensive tobacco control programs which include mass media campaigns can be effective in changing behaviour in adults (Bala et al, 2008). Similarly, campaigns to promote physical activity and healthy eating show evidence in increasing awareness and changing attitude and beliefs (Bauman et al, 2001; Bauman et al, 2003). The evidence of mass media effectiveness in sustainable behaviour change is not conclusive (Bauman et al, 2001; Bauman et al, 2003).

Many types of media are used for social marketing purposes including broadcast, print, electronic media and the internet (Marcus et al, 1998).

Public education
Earlier public education programs demonstrated change in behaviour. For example change in smoking rates, use of seat belts and child safety seats, cancer screening rates, and incidence of sudden infant death syndrome. However, public education tends to work slowly and may take decades to achieve change in behaviour.

2. Increase community skills to change behaviour and adopt a healthy lifestyle.

Community-based interventions
Community context has been identified as an important determinant of health outcomes. Community has been defined as a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings (MacQueen et al, 2001).

Worksites have been a popular and useful setting for a wide range of chronic disease prevention programs. Their appeal includes reaching a large number of people at a relatively low cost, the social structure of workplaces can be used to provide support and positive reinforcement for appropriate change such as eating and physical activity behaviour, environmental changes can be achieved at worksites eg food services, workplace layout, building design and physical activity facilities, and health promotion activities may have economic appeal to employers who also stand to benefit from increased productivity through improved employer health, less illness and absenteeism and reduced disability cost (Gill et al, 2005).

3. Develop policies and create environments that support healthy lifestyle

Growing attention is focussing on how environmental and policy interventions can affect chronic disease burden (Engbers et al, 2005; Gebel et al, 2005; Brownson et al, 2006). Although, due to the dynamics of every day life, the diffuse nature and multiplicity of variables involved, this is a difficult area in which to attribute cause and effect, there has been an acceleration of interest and experimentation in this area in recent years. As a result there is an emerging body of promising models for mitigating the negative effect of the food and physical activity environment on health and, notably on diabetes and other chronic diseases risks such inappropriate and over nutrition, and physical inactivity.

Creating supportive environments that help people to make healthy choices is an important underlying principle of health promotion. Effective strategies strengthen the skills and

capabilities of people to take action to improve their health. The provision of nutritional information at point-of-purchase (for example, with on pack nutrition labelling) can raise the awareness of consumers about the composition of foods they habitually consume and aid them in making a healthy choice. The content and format of nutrition labelling on foods has primarily been the result of a legislative requirement to provide information *per se*, and it is not specifically designed to promote healthier food choices. Several studies demonstrate the difficulty consumers face in understanding and using nutrition labelling in its current standard format. Consumers and public health groups and some governments have called for labelling that is comprehensive, clearer and easier to use. (Cowburn, 2003).

Evidence- Population strategies to change behaviours

1. Social marketing, and mass media interventions

- **Sustained, well-executed social marketing can be effective in increasing physical activity, improving nutrition knowledge, attitudes and eating behaviour in a range of target groups, in different settings.** (*Evidence Level III)*

- **Mass media campaigns increase awareness, and improve knowledge and attitudes around physical activity and healthy eating and may have a short term effect on physical activity behaviour in some individuals.** (*Evidence Level III)*

- **Media-only approaches may be sufficient to encourage a significant proportion of people to alter their dietary habits and contribute to weight control at the population level.** (*Evidence Level III)*

- **Mass media campaigns enhance the success of community-based interventions.** (*Evidence Level III)*

Social marketing, including mass media interventions, to promote physical activity
Mass media campaigns can raise awareness for community change. Two systematic reviews have examined the impact of national media campaigns in promoting physical activity (Cavill, 1998; Cavill & Bauman, 2004). The first discusses included three studies which helped to change attitudes and levels of knowledge towards physical activity, but had limited short-term impact on participation in physical activity (Cavill, 1998). The second, more comprehensive review (Cavill & Bauman, 2004) searched Medline, Current Contents, CINAHL, PsychLit, Eric and Sports Discus for studies written in English since 1970. Fifteen campaigns were identified targeting whole populations or defined sub-groups. These were based on diverse mass media strategies, including paid TV commercials, public service announcements, radio and newspaper advertising plus many unpaid media publicity techniques. As these campaigns were each linked to other community activities it proved difficult to separate out the effect of the media component. Nevertheless these campaigns appeared to achieve a high level of recall, with a median of 70% of the target group aware of the campaign. Increased knowledge or attitudes to physical activity were found among half the campaigns reporting this measure. Few campaigns however, reported other related variables, such as saliency, beliefs, self-efficacy or behavioural intention. Although increased physical activity was reported among motivated sub-groups, few campaigns reported increased physical activity across a population. It was concluded that while campaigns increase awareness of the issue of physical activity, they may not have a population-level effect on behaviour. It was suggested that campaigns should focus more on social norms, to bring about long-term behaviour change as part of a broader strategy that included policy and environmental change (Cavill & Bauman, 2004).

As part of a National Social Marketing Strategy (NSMS) for health improvement in the UK, a series of literature reviews investigated the effectiveness of social marketing (Gordon et al,

2006). Three reviews were evaluated. All used pre-defined search and inclusion criteria and defined social marketing interventions by six key principles. This evaluation indicated that social marketing interventions can be effective in improving diet, increasing physical activity, and tackling substance abuse. Moreover, it can work with a range of target groups, in different settings.

Social marketing may improve physical activity behaviour (Gordon et al, 2006). This review identified 22 social marketing studies focussing on improving physical activity (14 community-based, 6 school based, one using the media, and one implemented in a workplace setting). Eight of the 21 that sought to change behavioural outcomes, had positive effects overall. Seven studies reported mixed results and six had no effect. Of the effective studies, one workplace intervention reported that participants became significantly more likely to participate in moderate physical activity and less likely to undertake mild physical activity. The Wheeling Walks intervention, a community-based campaign to promote walking amongst sedentary 50-65 year olds reported an improvement in physical activity levels. Fourteen studies were identified that reported physiological outcomes including BMI, CVD rates, cholesterol levels and blood pressure. One of these, an American study directed towards low income earners, reported lower CVD rates in the intervention group than the control group.

Kahn et al (2002) used the Guide to Community Preventive Service's methods to evaluate the effectiveness of various approaches to increasing physical activity. Approaches included mass media campaigns addressing messages about physical activity to large audiences via newspapers, radio, television and/or billboards. Effectiveness measures were: change in the percentage of people doing a specified physical activity; change in energy expenditure; or change in the percentage of the population categorized as sedentary. Three relevant studies were identified and these reported only a modest trend toward increasing physical activity, although two reported significant and substantial improvements in knowledge and beliefs. It was concluded that insufficient evidence was available to assess the effectiveness of mass media campaigns to increase physical activity (Kahn et al, 2002).

Marcus et al. (1998) also conducted a systematic review of physical activity interventions using mass media, print media, and information technology. Studies were located by searching Medline, Psychlit, and Eric databases for the years 1983-1987. Twenty-eight studies were identified (7 national mass media campaigns and 21 campaigns delivered through health care, the workplace, or in the local community). These were based on a variety of print, graphic, audiovisual and broadcast media. In the seven mass media studies, recall of messages generally was high (around 70%), but the campaigns had very little impact on behaviour. Community interventions using print and/or telephone changed behaviour in the short term. Interventions that were well-tailored to the target audience and that provided multiple contacts were the most effective.

Finlay and Faulkner (2005) conducted another systematic search of the literature which was assessed from two perspectives. Studies since 1998 were reviewed for their success in impacting message recall and behaviour change and then were assessed for a more sophisticated understanding of the media processes of inception, transmission and reception. This review found that mass media interventions influenced short-term recall of the physical activity message and to a lesser extent its associated knowledge. However, most studies gave little in-depth consideration to the design of media messages.

Mass media campaigns targeting physical inactivity

A number of media campaigns have been conducted in Australia. A state-based mass-media campaign to promote regular moderate-intensity activity was undertaken in NSW in February 1998 (Bauman et al, 2001) targeting adults aged 25 to 60 years who were motivated but insufficiently active. States other than NSW comprised the unexposed control group. The campaign included paid and unpaid television and print-media advertising, physician mail-outs and community-level support programs and strategies. The campaign was evaluated by examining pre- and post campaign differences in physical activity campaign message recall, knowledge, motivational readiness, and reported behaviour, employing both within and between-state comparisons. Unprompted recall of the activity messages increased substantially in NSW (2.1% to 20.9%, $P<0.01$), with only small changes observed elsewhere (1.2% to 2.6%). Prompted awareness also rose significantly in NSW (12.9% to 50.7%, P<0.0001) with only a trend elsewhere (14.1% to 16%, P=0.06). Knowledge of appropriate moderate-intensity activity and physical activity self-efficacy also increased significantly in the campaign state. Compared with all others, those in the target group who recalled the media message were 2.08 times more likely to increase their activity by at least an hour per week (95% CI:1.51-2.86).

Merom and co-workers (2005) conducted a population-based cohort study to determine whether Australia's 'Walk to Work Day' media campaign resulted in behavioural change. This annual short campaign which aims to encourage walking, among working adults in Australian cities, comprised newspaper advertisements and community service announcements relayed nationally through radio and free-to-air television. A cohort of people (18 to 65 years, n = 1,100, 55% response rate) were randomly sampled from metropolitan areas before and after the campaign. A significant decrease in "car only" use and an increase in walking with use of public transport was noted among participants. Moreover, employed people spent significantly more time walking (+ 16 min/wk; P< 0.05) and in other moderate physical activity (+120 min/wk; P< 0.005). There was correspondingly a significant decrease in the proportion of workers who were "inactive" (P <0.05).

Mass media campaigns have also been conducted overseas. Increased awareness and intention to change were reported by Bauman et al (2003) from a mass media and community wide intervention (the 'Push-Play' Campaign) aimed at increasing physical activity in New Zealand. This campaign recommended 30 minutes of moderate-intensity physical activity daily. Activities were promoted as fun, part of community life and easy to achieve for New Zealand adults and were supported by community and primary care programs and events. Annual cross-sectional population surveys (1999-2002) monitored the impact of the campaign. Substantial increases were found in awareness of the 'Push Play' message (30% in 1999 to 57% in 2002, P<0.001), and of the 'Push Play' logo (14% to 52%, P<0.001). Although the numbers of adults who intended to be more active increased (1.8% in 1999 to 9.4% in 2002), no sustained change in physical activity was evident, 38.6% of the 1999 sample reporting 5+ days activity per week, increasing to 44.5% in 2000, but declining to 38.0% in 2002. The only significant difference in physical activity levels occurred from 1999 to 2000 (difference 5.8%, 95% CI 0.1%-11.6%).

Beaudoin et al (2007) conducted a mass media campaign in New Orleans to promote walking and fruit and vegetable consumption in a low-income, predominantly African-American urban population. The campaign included high-frequency paid television and radio advertising, as well as bus and streetcar signage tailored for African-Americans. The impact

was evaluated by random-digit-dial telephone surveys conducted at baseline in 2004 and following the onset of the campaign in 2005. Survey items included campaign message recall, and attitudes and behaviours associated with walking, snack foods and fruit and vegetable consumption. After 5 months, there were significant increases in message recall measures, positive attitudes toward fruit and vegetable consumption, and positive attitudes toward walking. Behaviours however did not change significantly.
Hillsdon et al (2001) assessed *'England's ACTIVE for LIFE campaign'* by conducting a 3-year prospective longitudinal survey. A multi-stage, cluster random probability design was used to select a nationally representative sample of 3,189 adults aged 16-74 years. Six to eight months after the campaign began, 38% of those sampled were aware of the main advertising images used by *'ACTIVE for LIFE'*. The proportion knowledgeable about moderate physical activity recommendations increased by 3.7% (95% CI 2.1%, 5.3%) between years 1 and 3. The change in proportion of active people however between baseline and years 1 and 2 was -0.02 (95% CI -2.0 to +1.7) and between years 1 and 3 was -9.8 (-7.9 to -11.7). There was no evidence that *ACTIVE for LIFE* improved physical activity, overall or in any subgroup.

Miles et al. (2001) evaluated a large UK health education mass media campaign *'Fighting Fat, Fighting Fit'* (FFFF) targeted at groups with high prevalence of obesity. A postal questionnaire survey was sent to a random sample of 6,000 adults registered with FFFF at the start of the campaign and again 5 months later. Sixty-one percent of those sampled completed the baseline questionnaire while 58% completed the follow-up 5 months later. Overall, 74% of respondents reported that their activity levels had increased. An additional 94 min per week was now spent being active ($P < 0.001$). The proportion classified as sedentary declined from 34 to 25%, ($P < 0.001$) while the proportion engaged in regular moderate exercise increased from 29 to 45%, ($P < 0.001$) and those doing vigorous exercise increased from 3 to 6% ($P < 0.001$). Overall 19% shifted from inactive to active with similar changes seen in men and women. Mean body weight was also 2.3 kg lower than before the campaign ($P < 0.001$) with 44% reporting that they had lost weight. The proportion of `obese' people declined by 6% ($P < 0.001$), although 52% overall remained within this category. At the same time, satisfaction with body weight also improved ($P < 0.001$) and a significant reduction was reported in fat and snack consumption, together with an increased fruit, vegetable and starch intake.

Promotion of walking as a form of physical activity holds considerable potential, both in terms of health benefits and its wide appeal to inactive groups. Wimbush et al. (1998) evaluated a national Scottish mass media walking campaign targeted at people aged 30-55 who did not regularly exercise. They were reached through a television advertisement and a telephone helpline. Campaign impact was assessed by population surveys and surveys of the helpline callers at baseline and follow-up. These evaluated change in awareness, change in knowledge and beliefs about walking, motivational change and change in intentions regarding walking/exercise as well as in actual walking/exercise behaviour. Awareness of the television advertisement peaked at 70% during the first 4-week burst, falling to 54% during the non-broadcast period. At a population level, the campaign had a notable positive impact on knowledge about walking as a form of exercise but no impact on actual walking behaviour. The proportion of adults aware of the telephone helpline rose from 5% at the start of the campaign to 16% four months later, although only 5% of respondents then used the helpline service. Of those who called the helpline, however, 48% claimed to be more physically active when contacted one year later (Wimbush et al, 1998).

Sogaard and Fonnebo (1992) evaluated a short fund-raising campaign, launched in 1987 by a charity organisation in cooperation with the sole Norwegian national TV-channel. The

campaign which involved a large proportion of the Norwegian population, concluded with a six hour TV-show. Twenty-two per cent of the population reported changes in one or more health-related habits (one third took more exercise, while one quarter reduced/quit smoking). New knowledge about health issues and health concern created by the campaign, were the factors most clearly associated with self-reported behaviour change.

An interesting community based campaign targeting physical inactivity in the US was assessed by Renger et al (2002). The goal of this study was to develop, implement, and evaluate a community-based effort using Prochaska's Transtheoretical Model as a guide. Community members developed television and worksite media messages focusing on the benefits and barriers of physical activity and on increased self-efficacy. The campaign proved effective not only in changing perceptions on the barriers and benefits of exercise and in raising self-efficacy but also in changing behaviour. The success of the campaign was considered to relate to its unique local nature. Seeing local community members participate in physical activity may motivate people to comply with the media messages.

Table 5: Summary of study characteristics for social marketing/mass media and physical activity

Author, year, country, Campaign name	Study Type	Mass media approach	Evaluation	Outcome measure/s	Results
Bauman, (2001), NSW, Australia	Quasi experimental design & Cohort study	Paid and unpaid television and print-media advertising	Cross-sectional representative population surveys, before and after the campaign	Physical activity; media message awareness; physical activity knowledge; self-efficacy & intention	Message recall increased; Knowledge and physical activity self-efficacy increased.
Bauman et al (2003), New Zealand, 'Push-Play'	Before-and-after study	Television commercials	Cross-sectional surveys	Increase physical activity at a population level	Substantial increases were found in awareness of the message; Although the number of adults who intended to be more physically active increased, no sustained increase in physical activity was evident.
Beaudoin et al. (2007), New Orleans, US	Before-and-after study	High frequency paid television & radio advertising, as well as bus and streetcar signage	Random-digit-dial telephone surveys	Message recall; attitudes and behaviours associated with walking	Significant increase in message recall; positive attitudes towards walking.
Cavill, (2004)	Systematic review	Paid TV commercials; public service announcements; radio & newspaper advertising; plus many unpaid media publicity	15 campaigns	Campaign awareness; knowledge and attitude to physical activity; increased physical activity	Increased knowledge to physical activity; It was therefore concluded that while campaigns increase awareness of the issue of physical activity, they may not have a population-level effect on behaviour.

Author, year, country, Campaign name	Study Type	Mass media approach	Evaluation	Outcome measure/s	Results
Finaly, (2005)	Systematic review	TV, radio and print media	8 studies	Message recall; behaviour change	Found mass media interventions influenced recall. No changes in behaviour.
Gordon, (2006)	Systematic review	One intervention in this review used the media	22 social marketing campaigns (14 Community-based; 6 school based; 1 used the media; 1 workplace setting)	Increasing exercise	Eight of the 21studies that sought to change behavioural outcomes, had positive effects overall. Seven studies reported mixed results and six had no effect.
Hillsdon et al (2001), UK, *'England's ACTIVE for LIFE*	Prospective longitudinal survey	Television advertisements and print media (newspapers, magazines)	Prospective longitudinal survey	Awareness of the campaign; knowledge about physical activity; increase physical activity	The proportion knowledgeable about moderate physical activity recommendations increased; There was no evidence that ACTIVE for LIFE improved physical activity, overall or in any subgroup.
Kahn,. (2000)	Systematic review	Newspapers, radio, television, and/or billboards	3 studies identified	Change in physical activity behaviour; change in energy expenditure; change in % of pop. categorized as sedentary	Three studies reported a modest trend towards physical activity.
Marcus, (1998)	Systematic review	Mass media, print media & information technology	28 studies (7 mass media campaigns; 21 were delivered through health care, the workplace, or in the community	Recall of campaign; physical activity behaviour	Recall of messages generally high, but he campaigns had very little impact on behaviour.

Author, year, country, Campaign name	Study Type	Mass media approach	Evaluation	Outcome measure/s	Results
Merom, (2005), Australia, 'Walk to Work Day'	Cohort study	Newspaper advertisements & community service announcements relayed nationally through radio and TV	cohort study to evaluate mass media campaign	Behaviour change	A significant decrease in "car only" use and an increase in walking with use of public transport was noted among participants.
Miles et al. (2001), UK, *'Fighting Fat Fighting Fit' (FFFF)*	Before-and-after study	Television and radio campaign	Postal questionnaire survey	Increase activity levels	The proportion classified as sedentary declined from 34 to 25%; while the proportion engaged in regular moderate exercise increased from 29 to 45%. Overall 19% shifted from inactive to active with similar changes seen in men and women.
Renger et al (2002), US	Before-and-after study	Community members developed television & worksite media messages	Random Telephone interview and written survey	Changes in knowledge, beliefs, and attitudes about physical activity and lifestyle changes	The campaign proved to be effective not only changing perceptions of the barriers of physical activity and on increased self-efficacy.
Sogaard and Fonnebo (1992), Norway	Before-and-after study	National television/radio campaign	Random sample questionnaire	Changes in health related behaviours	Twenty-two percent of the population reported changes in one or more health-related behaviours (one third took more exercise).

Author, year, country, Campaign name	Study Type	Mass media approach	Evaluation	Outcome measure/s	Results
Wimbush et al. (1998), Scotland	Pre-test/post-test	Television advertisement	Population surveys	Changes in awareness, change in knowledge about walking , motivational change and change in intentions regarding walking/exercise as well as in actual walking/exercise behaviour	At a population level, the campaign had a notable positive impact on knowledge about walking as a form of exercise but no impact on actual walking behaviour. Of those who called the helpline, 48% claimed to be more physically active when contacted one year later.

Social marketing, including mass media interventions, to promote healthy eating and nutrition

Mass media campaigns in Australia and elsewhere have been conducted to promote healthy eating and nutrition. Many of these campaigns have focused on promoting the consumption of more fruits and vegetables (Foerster et al, 1995; Dixon et al, 1998; Ashfield-Watt, 2006; Pollard et al, 2008). One multi-strategy fruit and vegetable social marketing campaign was conducted from 2002 to 2005 in Western Australia (Pollard et al, 2008). This included mass media advertising (television, radio, press and point-of-sale), public relations events, publications, and a website (www.gofor2and5), plus school and community activities. The aim was to increase awareness among adults of the need to eat more fruit and vegetables and over a five-year period to increase consumption by one serving per day. The impact was evaluated through two independent telephone surveys. One conducted with 5,032 adults monitored attitudes towards fruit and vegetables, and beliefs and consumption prior to, during and 12 months after the campaign. The second surveyed 17,993 adults between 2001 and 2006 to continuously monitor consumption. Over three years, the mean number of servings of fruit and vegetables consumed per day rose by 0.8 (+0.2 serves per day for fruit and +0.6 serves per day for vegetables, $P<0.05$).

A similar campaign has been evaluated in Victoria (Dixon et al, 1998). The *2 Fruit 'n' 5 Veg Every Day* campaign ran from 1992-1995 based around television advertising. It was evaluated by annual surveys examining public awareness, beliefs about desirable eating habits for fruit and vegetables, and reported consumption. Over the years, patterns of public awareness, reported consumption, and beliefs about appropriate levels of consumption tended to parallel changes in the level of mass media advertising. During the most intense period of promotion, significant increases in all these variables occurred. These findings are consistent with those of (Pollard et al, 2008) who concluded that mass media campaigns are effective but need to be sustained to achieve the desired behaviour changes

The *5+ a day,* a social marketing campaign in New Zealand aimed at increasing fruit and vegetable intake has been evaluated based on responses to two questionnaires (Ashfield-Watt, 2006). One focused on awareness and understanding of the *5+ a day* campaign while the other focused on attitudes to health and on consumption of fruit and vegetables. It was found that 71% of respondents identified the '5 servings a day' message with the *5+ a day* logo regardless of whether they had seen the logo before. It was also found that the association of positive relationships between fruit and vegetables and health as well as daily fruit and vegetable intake were significantly influenced by gender, ethnicity, education and occupation (all $P\leq0.05$).

A similar campaign has been conducted in California (Foerster et al, 1995). *The 5 a Day – for Better Health!* campaign promoted a message to eat five servings of fruit and vegetables every day as part of a low-fat diet. Outcome evaluation included measured change in reported daily fruit and vegetable consumption and in awareness, knowledge, and belief variables among the target population. Fruit and vegetable consumption was increased by this campaign.

The Stanford *Five-City Study* was a six-year mass media and community cardiovascular risk reduction intervention evaluated by comparing two treatment cities (n = 122,800) with two control cities (n = 197,500). Measures included change in knowledge of cardiovascular risk factors and change in mean blood pressure, plasma cholesterol, smoking rate, BMI and resting pulse rate after 5.3 years (Taylor et al). People in the treatment communities were found to have

gained significantly less weight than subjects in the control communities over 6 years (0.57 kg versus 1.25kg, P< 0.05).

Mass-media campaigns have also been used in the US to reduce the intake of foods high in saturated fat, including campaigns aimed at getting consumers to switch from whole milk to low-fat milk. A mass media campaign run in West Virginia and known as *1% or Less* has been evaluated (Reger et al, 1999). This campaign used paid advertising and public relations to encourage people in a given city to switch from whole milk or 2% fat milk (high-fat milk) to 1% fat or fat-free milk (low-fat milk). Effectiveness was assessed by change in supermarket milk sales and pre- and post- telephone surveys conducted in the intervention and a comparison city. In the targeted city, sale of low-fat milk increased from an initial 29% of total milk sales to 46% of milk sales in the month following the campaign, an increase maintained after 6-months. As reported from telephone surveys, 34% of high-fat-milk drinkers exposed to the campaign switched to low-fat milk compared with 3.6% in the comparison city (P < 0.0001). A subsequent survey (Reger et al, 2000) examined the effectiveness of the educational approaches used in this campaign. After community-based educational programs and public relations activities the 20% of high-fat milk drinkers reported switching to low-fat milk compared with 7% for the comparison city (P<0.0001). This approach was therefore more effective than the advertising-only campaign, which resulted in 13% of high-fat milk drinkers switching to drinking low-fat milk (P<0.01).

The *1% or Less* campaign was also trialled in the multi-ethnic population of the state of Hawaii as a 6-week intervention (Maddock et al, 2007). Campaign effectiveness was measured with sales data and cross-sectional telephone surveys. The proportion of people drinking low-fat milk rose after the campaign from 30% to 41% (P<.001), the response remaining although diminished at 3-months. This translates to approximately 65,000 people switching to low-fat milk during the campaign with approximately 32,000 people still making this choice three months later.

Mass-media campaigns have also been used to combat obesity, for example the British *Fighting Fat, Fighting Fit* (FFFF)" campaign. This campaign created high awareness in all socio-economic groups, although memory for the healthy lifestyle message was poor in those with little education and/or from ethnic minority groups (Wardle et al, 2001). Awareness was also no higher in overweight than normal weight respondents (Wardle et al, 2001). The campaign was evaluated by a before and after study of 6,000 adults registered with FFFF (Miles et al, 2001). The majority of these were 'overweight' or obese' women. These respondents reported significant weight reduction, decreased fat and snack intake, and significant increase in physical activity, and in fruit, vegetable and starch intake during the six months of the campaign.

A 3-year media campaign aimed at preventing weight gain among Dutch adults was evaluated with 11 population-based surveys (Wammes et al, 2007). Campaign awareness increased from 61% after the first campaign wave to 88% after the final messages were given. Message recall ranged from 42% to 68% and small positive differences was found in attitudes, perceived social support, and intention to prevent weight gain.

The New Zealand Health Sponsorship Council has recently prepared a systematic review on nutrition-related social marketing. This focuses on factors identified by the World Health Organization (WHO) as causally related to obesity including a high intake of energy-dense,

micronutrient-poor foods, a high intake of sugar-sweetened soft drinks and fruit juices and high levels of television viewing. In selecting interventions for inclusion, three of the six categories given in Andreasen's criteria of social marketing were required to be present. In total, 83 social marketing papers were selected from 238 initially identified. Studies aimed at children were included. Evidence for the effectiveness of nutrition-related social marketing appeared moderate for energy-dense, micronutrient-poor foods while evidence was limited or weak for sugar-sweetened beverages and television viewing although very few papers addressed these last two issues. It was found that effective nutrition-related social marketing can occur with nearly any target group (whole population, ethnic groups, children, low income) and in nearly any setting (schools, home, workplaces, churches, and the wider community) (Thornley et al, 2007).

A number of process factors were identified as important for effective social marketing of nutrition messages. Simple messages are required, well-tailored to the target group, culturally appropriate, and widely acceptable to stakeholders and service providers. Communication needs a comprehensive approach with multiple intervention strategies and communication channels. Interventions must be of sustained duration. They should be supported by strong partnerships between government, industry, non-government organisations (NGOs), and communities. Moreover, local programs need to be coordinated with, and supported by national approaches although they also need to be culturally specific and to promote community control, participation and leadership. Successful programs require continual monitoring and evaluation. They should focus on foods rather than nutrients. Environmental barriers also need to be identified such as the patterns of marketing unhealthy foods (Thornley et al, 2007).

Table 6: Summary of study characteristics for social marketing / mass media and nutrition

Author, year, Country	Study Type	Risk factors	Intervention	Control	Duration	Outcome measure	Results
Ashfield-Watt et al (2006), New Zealand	Before-and-after study	Reduce chronic diseases	Media campaign	None	5 yrs	Media message awareness; intake of fruit & vegetables	Increased awareness of 5+day message; increased consumption of fruit & vegetables.
Dixon et al (1998), Victoria, Australia	Time-series analysis, longitudinal study	Reduce chronic disease such as cardiovascular disease, type 2 diabetes, and certain forms of cancer.	Mass media campaign	None	3 yrs	Awareness of the campaign; beliefs about desirable eating habits (Fruit & vegetables); and consumption of these foods	Significant increases in public awareness; reported consumption; & beliefs about appropriate levels of consumption.
Foerster et al (1995), Californian Population	Before and After study	Chronic diseases such as cardiovascular disease & some cancers due to high-fat low-fibre diet. As well as hypertension, obesity & diabetes.	Mass media campaign	None	3 yrs	Changes in reported daily fruit & vegetable consumption; changes in awareness, knowledge and belief variables among the population	
Maddok et al (2007), Hawaii , US	Before and After study	High saturated fat diets linked to high blood cholesterol, obesity, heart disease.	Multi component campaign – paid radio & TV advertising, a press conference, taste tests, web site etc	None	6 weeks	Reduction in saturated fat intake through increased consumption of low-fat milk	Significant increase in low-fat milk consumption from 30.2% to 40.8% of milk drinkers. Sales data shows an increase in low fat milk sales from 32.7% to 39.9%.

Author, year, Country	Study Type	Risk factors	Intervention	Control	Duration	Outcome measure	Results
Miles et al (2001), UK	Before and After study	Obesity	Mass-media campaign	None	7 weeks	Weight, eating behaviour and activity patterns were assessed.	Participants reported significant reductions in weight, and in fat and snack intake, and significant increases in exercise levels, and in fruit & vegetable intake during the 6mth of the campaign.
Pollard et al (2008), Western Australia	Before and After study	Reduce chronic diseases – cardiovascular disease, some cancers	Multi-strategy social marketing campaign	None	3 yrs	Awareness of the recommended servings of fruit & vegetables; increase in the servings of fruit & vegetables per day	Increased awareness of the recommended servings of fruit & vegetables; Population net increase in the mean number of servings of fruit & vegetables per day over the 3 yrs.
Reger et al (1999), West Virgina, US	Quasi-experimental research design – one intervention city & one comparison city	High saturated fat diets linked to high blood cholesterol, obesity, heart disease.	Mass media campaign – paid advertising and public relations	Yes, Comparison city	6 weeks	Reduction in saturated fat intake through increased consumption of low-fat milk	In the intervention city, low fat milk sales increased from 29% of overall milk sales before the campaign to 46% of sales in the month following the campaign. The increase was maintained at the 6mth follow up. 34.1% of high-fat-milk drinkers reported switching to low-fat milk in the intervention community

Author, year, Country	Study Type	Risk factors	Intervention	Control	Duration	Outcome measure	Results
							compared with 3.6% in the comparison community.
Reger et al (2000), West Virginia , US	Comparative study	High saturated fat diets linked to high blood cholesterol, obesity, heart disease	One intervention used public relations and community-based educational activities & the other used paid advertising	A comparison city	6-8 weeks	Reduction in saturated fat intake through increased consumption of low-fat milk	After the community based education intervention the proportion of high-fat milk drinkers who reported drinking low-fat milk was 19.6% compared with 6.8% for the comparison city ($p<0.0001$). After the advertising-only campaign, 12.8% of high-fat milk drinkers reported drinking low-fat milk ($p<0.01$).
Taylor et al (1991), Stanford, US	Quasi-experimental design. Both cohort and cross-sectional (independent) samples were used in the study	Reduction of cardiovascular risk factors – including overweight	Mass media campaign & community health education	Two control cities	6 years	Reduction in weight	Subjects in treatment communities gained significantly less weight than subjects in control communities (0.57kg compared with 1.25kg) over 6 yrs.

Author, year, Country	Study Type	Risk factors	Intervention	Control	Duration	Outcome measure	Results
Wammes et al (2007), Netherlands	Before and After study	Weight-gain prevention.	Mass media campaign	None	3 yr	Campaign awareness; perceived body weight status; overweight-related risk perceptions; attitudes; & motivation for preventing weight gain.	Campaign awareness ranged from 61% after the 1st campaign wave to 88.4% after the final wave. Small positive differences were found in attitudes, perceived social support, and intentions for preventing weight gain.
Wardle et al (2001), UK	Before and After study	obesity	Mass media campaign	None	7 weeks	Awareness of obesity prevention message	Awareness of the campaign was high in all socio-economic groups, but memory for the healthy lifestyle message was significantly poorer in those with lower levels of education and for ethnic minority groups.

2. Community-based interventions for behaviour change

- **Well-designed community-based intervention programs can improve lifestyle choices and health habits such as increase physical activity and healthy eating.** *(Evidence Level. III)*

- **Worksite interventions which involve family members can improve dietary habits Worksite interventions which involve family members can improve dietary habits.** (*Evidence Level III)*

- **Worksite health promotion programs that include environmental modifications can influence dietary intake . (***Evidence Level III)*

Community-based intervention to reduce physical inactivity

Satterfield et al undertook a literature review (1990-2001) of community-based interventions intended to prevent or delay type 2 diabetes (Satterfield et al, 2003). The search revealed 16 published interventions, eight conducted in the US. Among studies in adults, most reported improvements in knowledge or adoption of regular physical activity. Several investigators offered reflections about the process of engaging communities and the effectiveness of participatory research, while others gave insights about the expectations and limitations of community-based diabetes prevention research. Many studies reported limitations in design, including lack of control or comparison groups, low response rates or poor information on non-responders and use of quite brief intervention periods. More research was called for.

Ogilvie et al (2007) conducted a comprehensive systematic review to assess the effects of interventions promoting walking among individuals and populations. Relevant reports in any language were identified by searching 25 electronic databases, as well as websites, reference lists, existing systematic reviews, and by contacting experts. Papers selected included all controlled before/after studies intending to change how much people walk, papers comparing effects between social groups and/or effects on physical activity, fitness, risk factors for disease, and on health and wellbeing. Forty-eight studies (19 randomised controlled trials and 29 other studies) were included, of which 27 were concerned with walking in general and 21 studies were concerned with walking as a mode of transport. It was concluded that interventions tailored to people's needs, and targeted at the most sedentary or at those most motivated to change, can encourage people to walk more. It was found that successful interventions can be delivered at an individual level through brief advice, pedometer use, or telephone support or at households (individualised marketing) or via groups although the sustainability, generalisability, and clinical benefit of many of these approaches remained ill-defined. Evidence for the effectiveness of interventions applied to workplaces, schools, communities, or local government areas often depended on isolated studies or subgroup analyses. Five non-randomised studies of interventions were found that measured effects in whole populations. All of these involved combined approaches eg: mass media campaigns augmented by community events and other local supportive measures (modest environmental improvements, formation of walking groups, and written materials or brief advice given to individuals). An intervention with a substantial mass media component proved most effective (Ogilvie et al, 2007). Walking in a successful intervention was seen to increase by up to 30-60 minutes a week on average, at least in the short term. Although much of the research

provided evidence of efficacy rather than effectiveness, this survey concluded that interventions to promote walking could contribute substantially towards increasing the activity levels for the most sedentary people.

Fogelholm et al (2002) reviewed community interventions for prevention of cardiovascular disease. A Medline search and reference lists of two comprehensive systematic reviews was used to identify studies published during or after 1990. Only five interventions were identified, each with a duration of 4-7 years. All promoted dietary change, increased physical activity and measured obesity prevalence. Two of four studies found no significant intervention effects on physical activity. The residents of the intervention communities of the *Minnesota Heart Health Study* became somewhat more physically active while the *Stanford Five-City Study* also had a positive effect on physical activity. Most studies found interventions had no effect on BMI although in the *Stanford Five-City Study*, BMI increased less in the treatment than in control communities.

Hillsdon et al (1996). carried out a systematic review of 11 randomised controlled trials promoting physical activity in apparently healthy American adults. Studies were identified by searches of Medline, Excerpta Medica, Sport, and SCI Search from 1966-1996. Interventions ranged from 5 weeks to two years and included walking, jogging or swimming for at least 30 minutes three times per week. Those that resulted in increased activity involved exercise that was home based, of moderate intensity, involved walking, and had regular follow up. Walking from home was more successful than exercise which relied on attendance at structured exercise sessions. Only two facility-based trials compared with six home-based trials reported increased exercise by participants. All trials prescribing walking reported increased activity. Moderate intensity activity was also associated with higher compliance rates. Regular follow-up was found to increase the proportion of people able to maintain an initial improvement. The reviewers concluded that brisk walking has the greatest potential for increasing overall activity levels in a sedentary population. They also point out that walking is an exercise most likely to be adopted by people of any age, any socioeconomic background or ethnicity and is accepted by both sexes.

Ogilvie et al. (2004) conducted a systematic review identifying interventions that promoted replacement of car travel by walking and cycling. A search of electronic databases, bibliographies, websites, and reference lists identified 22 studies. Evidence suggested that targeted behaviour change programs can change the behaviour of motivated subgroups, resulting (in the largest study) in a shift of around 5% of all trips at a population level. Single studies of commuter subsidies and a new railway station also showed positive effects.

A number of Australian community-based interventions have been evaluated. An impact evaluation of the *WellingTonne Challenge* (*WC*) was recently undertaken (Lyle et al, 2008). *WC* was a whole-of-community project designed to help a small rural community in NSW lose weight. The program included: a community-wide effort to lose 1000kg, the promotion of healthy lifestyle behaviours such as increased consumption of fruit and vegetables, increasing participation in physical and incidental activity, and stronger community participation. For each objective, a range of strategies was developed and incorporated into a 12-week schedule of activities. Local media and public support from several well-known community members were used to engage and motivate the community. Local supportive partnerships were established with other health groups and health staff, service clubs, local food businesses, sporting bodies, local media and other community groups. Before-after data analysis revealed that the project successfully engaged the community with around 10% of the

target group formally participating. Participants achieved a weight reduction of around 3 kg as well as positive changes in diet and physical activity.

Another community-based multi-strategic health promotion intervention, *'Concord, A Great Place to be Active'*, was a social marketing campaign implemented from 1997 to 1999 among women aged 20-50 years living in the Concord, an inner-western region of Sydney (Wen et al, 2002). A key feature of this campaign was the partnership between Concord Council (the local government) and the Central Sydney Health Promotion Unit (CSHPU). Increased opportunities were created to participate in physical activity through community walking events, walking groups and community physical activity classes, all of which were heavily promoted through the media. The intervention was evaluated by qualitative and quantitative methods and by using key informant interviews, focus groups and pre- and post-intervention telephone surveys. The proportion of sedentary women fell significantly from 21.6% (95% CI 19.2-23.1) to 15.2% (95% CI 13.8-17.6) while the number of women who intended to walk more increased from 65.8% to 71.8% ($P<0.05$).

A recent study (Cochrane & Davey, 2008) evaluated strategies to increase physical activity in an urban community. Two deprived inner-city electoral ward areas of Sheffield, UK, with similar socio-demographic and health profiles were selected. A study was carried out over a 21 month period that consisted of five phases: preparation/piloting, initial survey estimates, a community awareness campaign and physical activity intervention (given to the intervention area only) and lastly, evaluation. The awareness campaign included focus group meetings, household leaflets, poster displays, events and competitions. The physical activity intervention included walking, exercise referral, sports and water sports activities. Impact was evaluated by recording uptake and attendance at all sessions, and with a post-intervention postal survey. At follow-up, questionnaires were sent to 2,500 randomly selected addresses in both areas. At baseline similar proportions in control and intervention areas were undertaking physical activity (intervention 36%, control 33%). At follow-up, 38 different activity groups were in place in the intervention area and 1,275 individuals had attended at least one activity. Responses were received from 55% of people in the intervention area and 45% in the control area. After one year, compared with controls, the intervention sample demonstrated trends towards being more physically active with greater readiness to take up physical activity, better general health and improved health ($P<0.001$). Further, 30.6% (intervention) versus 18.3% (control) reported an increase in physical activity, while 13.7% (intervention) versus 24.5% (control) reported no intention to exercise. These differences in proportions translate to an overall effect size estimate of 0.23. Residents in the intervention area were more likely to report being active (OR= 1.79; 95% CI 1.38-2.32; $P<0.001$).

Another study in Belgium assessed the effectiveness of the "*10,000 Steps Ghent*" campaign (De Cocker et al, 2007) one year after intervention. This multi-strategy community-based intervention promoted physical activity to adults via local media campaign, environmental approaches, the sale and loan of pedometers and several physical activity projects. In 2005, baseline data were collected from 872 randomly selected subjects aged 25 to 75, from Ghent (the intervention community) plus 810 from a similar comparison community. Of these, 76% and 78%, respectively completed the follow-up in 2006. During this one year interval there was an increase of 8% in the number of people reaching the "10,000 steps" per day target in Ghent, while no increase occurred in the comparison community. In Ghent, mean steps increased by 896 per day (95% CI: 599-1192) with no increase evident in the comparison community (mean change -135 [95% CI: -432 to 162; F time x community=22.8, $P<0.001$].

Wray et al (2005) have evaluated a community-wide *Walk Missouri* media campaign to promote walking undertaken in a small American town. This campaign promoted walking and local community-sponsored wellness initiatives through four types of media (billboard, newspaper, radio, and poster advertisements) over a five-month period in the summer of 2003. The campaign was conducted in four phases: formative research; program design and pre-testing; implementation; and impact assessment. A telephone survey (n = 297) conducted after and not before the campaign, assessed the campaign impact. One in three respondents reported seeing or hearing campaign messages on one or more types of media. Reported exposure to the campaign was then found to be significantly associated with two of four pro-walking belief scales (social and pleasure benefits) and with one of three community-sponsored activities (participation in a community-sponsored walk).

Community-based intervention to promote healthy eating

A systematic review was conducted to assess the effectiveness of community-based interventions in increasing fruit and vegetable consumption (Ciliska et al, 2000). A search was conducted through electronic databases, hand-searching, and retrieval from reference lists. Sixty articles from the one hundred and eighty-nine that were retrieved were rated as relevant. The researchers found that the most effective interventions gave clear messages about increasing fruit and vegetable consumption, incorporated multiple strategies that reinforced the messages, involved the family, were more intensive, were provided over a longer period of time, rather than one or two contacts, and were based on a theoretical framework.

Engbers et al (2005) conducted a systematic review to assess the effectiveness of worksite health promotion programs with environmental modifications on physical activity, dietary intake, and health risk indicators. Environmental modifications are thought to be an important addition to health promotion programs if significant behavioural changes among the target population are to be achieved. The researchers conducted online searches for articles published up to January 2004 using the following inclusion criteria: randomized controlled trial, intervention which included environmental modifications, main outcome included physical activity, dietary intake, and health risk indicators, and healthy working population. Thirteen relevant, mostly multi-centre, trials were included. All studies aimed to stimulate healthy dietary intake, and three trials focused on physical activity. Follow-up measurements of most studies took place after an average 1-year period. The authors concluded that it was difficult to draw general conclusions based on the small number of studies included in the review. However, evidence exists that worksite health promotion programs that include environmental modifications can influence dietary intake.

A report by Gill et al (2005) found extensive evidence that community nutrition interventions can be effective in changing attitudes, knowledge and eating practices (Contento et al, 1995). They also reported that a major systematic review of behavioural dietary interventions (AHRQ, 2000) found considerable evidence regarding the effectiveness of interventions to help people modify their dietary intake of fats and fruit and vegetables.

The *Coronary Health Improvement Project* (CHIP) was a community-based lifestyle intervention program that aimed to reduce coronary risk, especially in high risk groups (Englert et al, 2007). The project involved a 40 hour education curriculum delivered over a 30-day period with clinical and nutritional assessments before and after. The participants were instructed to optimize their diet, quit smoking and exercise daily (walking 30 min/day). Of 1,569 subjects enrolled between 2000 and 2002 in 5 CHIP community projects, 1,517

participants graduated and delivered complete clinical data sets for evaluation. At the end of the 30-day intervention period, stratified analyses of total cholesterol, LDL, triglycerides, bloods glucose, blood pressure and weight showed highly significant reductions with the greatest improvement among those at highest risk. Englert et al concluded that well-designed community-based intervention programs can improve lifestyle choices and health habits. They can also markedly reduce the level of coronary risk factors in a non-randomised population.

Eat Better & Move More (EBMM) was a community-based program designed to improve the diets and increase physical activity among the elderly in the US (Wellman et al, 2007). A 10-site intervention study was conducted. Sites included dining centres, neighbourhood recreation centres, and housing complexes in urban inner-city, suburban and rural locations. Pre-intervention and post-intervention assessments focused on nutrition and physical activity stages of change, self-reported health status, dietary intakes, physical activity, and program satisfaction. Of 999 participants enrolled, 620 completed the program. The EBMM Guidebook included 12 weekly sessions incorporating mini-talks and activities for group nutrition and physical activity sessions. "Tips & Task" sheets encouraged individuals to attain personal goals. Check boxes served as visual reminders of daily goals. Short lists of healthful options within a featured food message enabled participants to personalize choices to improve their diets. Weekly mini-sessions included interactive activities based on actual food items, food labels, and program meals. Sessions were led by registered dietitians at 8 of the 10 sites. Results showed that 73% and 75% of participants, respectively, made a significant advance of 1 or more nutrition and physical activity stages of change; 24% reported improved health status. Daily intake of fruit increased 1 or more servings among 31% of participants, vegetables, 37%, and fibre, 33%. Daily steps increased 35%, blocks walked, 45%, and stairs climbed, 24%. The authors' concluded that this easy-to-implement program improves diet and activity levels.

As discussed earlier, worksites have been a popular and useful setting for a wide range of chronic disease prevention programs. The *Treatwell 5-a-Day* study was a worksite intervention aimed at increasing consumption of fruits and vegetables (Sorensen et al, 1999). Twenty-two worksites were randomly assigned to 3 groups: a minimal intervention control group, a worksite intervention, and a worksite-plus-family intervention. The interventions used community organising strategies and were structured to target multiple levels of influence. Data were collected by self-administered employee surveys before and after the intervention. The response rate was 87% (n=1,359) at baseline and 76% (n=1,306) at follow-up. Results showed that total fruit and vegetable intake increased by 19% in the worksite-plus-family group, 7% in the worksite intervention group and 0% in the control group (P=.05) (Sorensen et al, 1999). The worksite-plus-family intervention was more successful in increasing fruit and vegetable consumption than was the worksite intervention. The authors' concluded that worksite interventions involving family members appear to be a promising strategy for influencing dietary habits.

A study by Verall et al (2000) examined the impact of the *Working Well Trial,* a worksite health promotion intervention, on the worksite smoking and nutrition environment. The study was a randomised, un-blinded, controlled trial with 3 years of follow-up in 114 worksites (n=20,801 employees) in the US. Fifty seven worksites (n=10,071) participants were allocated to the nutrition and smoking intervention group and 57 (n=10,730) were allocated to the control group. Interventions aimed to achieve changes in both social norms and the physical environment. Employees at intervention worksites formed employee advisory boards, which collaborated with an interventionist from the study (eg, proposed ways of increasing

accessibility to healthy foods, and developed and implemented company policies to support healthy eating and smoking cessation). Employees at control worksites received baseline survey data and used optional distribution of printed materials and self help programs. Changes in worksite physical environment and social norms related to nutrition and smoking were assessed by surveys of employees and key organisational informants. Compared with employees at control worksites, those at intervention worksites perceived a change in both the physical environment (access to health food and nutrition information, $P<0.001$) and social environment (co-worker support for low fat dietary choices and management concern about employees nutrition, $P<0.001$). The researchers found that a worksite health promotion intervention improved the physical and social environment related to health behaviours.

Another low-intensity worksite-based nutrition intervention was conducted in Belgium and focussed on promoting low-fat dietary habits (Braeckman et al, 1999). Employees from four local worksites were recruited to participate in the intervention. The sites were randomised to control conditions or to the intervention programme that consisted of an individualized health risk appraisal, group sessions, mass media activities and environmental changes. Participants were seen before and three months after intervention to measure blood lipids, nutrition knowledge and dietary changes. Eighty-three per cent of all eligible subjects were screened (n=770) and follow-up measures were obtained for 82%. The score for nutrition knowledge improved significantly in the intervention group. There was also a net reduction in the intake of total calories and in the percentage of energy from total fat ($P<0.05$). For all employees assessed, there were no changes in mean total cholesterol level or fatty acid composition. The intervention programme achieved dietary changes and was successful in obtaining a more short-term beneficial cholesterol level in employees at higher cardiovascular risk.

The Dutch Heart Health community intervention (Ronda et al, 2004) was a cardiovascular disease prevention program with a community component that aimed to reduce fat intake as well as increase physical activity. In order to implement the intervention, nine local health committees were set up, each organising activities that facilitated and encouraged people to adopt healthier lifestyles. A pre-test-post-test control group design with two post-tests was used to evaluate the intervention. At baseline, representative random cohort research samples were selected in the study region and in a control region. Data on fat intake and physical activity, and on the psychosocial determinants of these behaviours, were gathered by mail surveys. The community intervention involved 293 activities. One hundred and sixty-six of these activities concerned nutrition, 84 physical activity and 15 smoking, and 28 activities were more general and targeted more than one risk behaviour. Examples of such activities include computer-tailored nutrition education, nutrition tours in supermarkets, a regional daily television program “Heartbeat on the Move” to promote physical activity, and walking and cycling months. In addition, there were ongoing activities trying to draw attention to the project and its specific activities, such as commercials on local television and radio, newspaper articles, and posters and pamphlets. The authors found that the intervention had a significant effect on fat reduction, especially among respondents aged ≤ 48 years ($P=0.003$). Respondents who were familiar with a health project in their community reported more social support towards decreasing their fat intake than those who were not familiar with such a health project [odds ratio (OR) = 1.463; $P = 0.037$).

In 2001 the UK Department of Health funded pilot community-based interventions to improve fruit and vegetable intakes in five economically deprived areas of England. The interventions involved building community networks to achieve and sustain increased fruit and vegetable intakes through collaboration between retailers, educators, primary care teams,

employers and local media. Ashfield-Watt et al (2007) evaluated the interventions. Data on intakes of and beliefs about fruit and vegetables were collected by a short postal questionnaire from 810 individuals living in the pilot communities and 270 individuals who were participating in an unrelated observational study (controls). Data was collected before and after a 12-month intervention period. The results showed that compared with controls, the intervention group significantly increased knowledge of the 5-a-day optimum (P=0.01) and reported increased access to fruits and vegetables (P=0.001). Smoking habit strongly predicted change in fruit and vegetable intakes (P=0.01) in the intervention group. Ashfield-Watt et al. concluded that community-based interventions can produce important changes in knowledge of and access to fruit and vegetables. However, in this study change in fruit and vegetable intake was strongly influenced by smoking habit.

Maddock et al (2006) evaluated the *Healthy Hawaii Initiative* which was a state-wide program designed to reduce chronic disease risk factors. The program commenced in the year 2000 and implemented interventions in schools and communities and through public and professional education to improve physical activity and nutrition. Evaluation of these programs included long-term objectives focusing on health outcomes and shorter-term objectives focusing on health behaviours. Results showed positive trends in adults for increased fruit and vegetable consumption and a reduction in no leisure time physical activity. No leisure time physical activity in adults decreased by 7.2% from 25.5% in 1999 to 18.3% in 2003. Over the same time period, the percentage of adults eating five or more servings a day also increased by 5.2% from 22.4% to 27.6%. The researchers concluded that the *Healthy Hawaii Initiative* appears to have some impact on short-term indicators but more years of data collection will be necessary before true trends can be detected to assess the overall impact of the initiative.

3. Develop policies and create environments that support healthy lifestyle

- **Environmental and policy interventions are effective in reducing chronic disease risk factors including smoking, physical inactivity, and unhealthy eating.** (*Evidence Level III)*

- **Policy regulation such as nutrition information on processed foods has the potential to improve food choices and promote healthy eating at a population level.** (*Evidence Level III)*

The physical environments

An emerging body of evidence suggests that polices and environmental interventions that support the adoption of healthy behaviours are promising in reducing the burden of chronic diseases such as diabetes and cardiovascular disease. In this section, we present selected reviews to highlight the potential of policy and environmental interventions to mitigate unhealthy behaviour. A comprehensive review by Brownsen et al (2006) described effective and promising environmental and policy interventions to address tobacco use, physical activity, and healthy eating. A total of 17 interventions were reviewed, organized across 3 domains affecting the physical environment/access, economic environment, and communication environment. Many of these interventions are effective. There are several important lessons to consider such as the need to start with environmental and policy approaches, intervene comprehensively and across multiple levels; make use of economic evaluations; make better use of existing analytic tools; understand the politics and local context; address health disparities, and conduct sound policy research (Brownson et al, 2006).

A systematic review was conducted by Hider (2001) to assess the effectiveness of environmental changes in reducing calorie intake or calorie density (Hider, 2001). One thousand one hundred and sixty five articles were identified by the search, 439 studies were considered against the inclusion criteria and 13 studies were located that had examined the effectiveness of environmental interventions to change calorie intake or calorie density. The most common environmental interventions were changes in the recipes, menus or prices of items available at food service areas. Point-of-choice information was also frequently used. Environmental interventions were often combined with other types of interventions in workplace, educational or community settings. However, the review concluded that conclusions about the effectiveness of environmental interventions is limited by the deficiencies in the research, their frequent use in conjunction with a variety of other interventions, and the heterogeneous nature of the outcome variables that have been used.

Gebel and co-workers (2005) reviewed evidence on the links between physical environments and physical activity, nutrition and obesity and reported that their findings are consistent with reports from earlier published reviews (Gebel et al, 2005). This review also highlighted that while there is an accumulating body of evidence on how physical environments affect physical activity, there is very little published or available research on influences of the environment on nutrition and obesity. This report discussed that there are several urban form characteristics (natural and built environment) that tend to be associated with physical activity, and possibly nutrition-related obesity behaviours. These include mixed land use and density, footpaths and cycle ways and facilities for physical activity, street connectivity and design, transport infrastructure and systems, and linking residential, commercial and business areas. However, the authors' acknowledge a key limitation in interpreting the available

research is that even where there are reasonably consistent associations between environmental variables and health behaviours, the evidence cannot be interpreted as definitively 'causal'. Drawing on theory, a social ecological model has been used to acknowledge the complexity of the links, and point to the necessity of more comprehensive approaches to research that integrate psychological, organisational, cultural, community planning, and regulatory perspectives.

Auchincloss et al (2008) used linear regression to estimate associations between area features and insulin resistance in data from 3 sites of The Multi-Ethnic Study of Atherosclerosis, a study of adults aged 45-84 years who did not have diabetes. This study showed greater neighbourhood physical activity resources were consistently associated with lower insulin resistance. Adjusted for age, sex, family history of diabetes, race/ethnicity, income and education, insulin resistance was reduced by 17% (95% CI -31% to -1%) for an increase from the 10th to 90th percentiles of resources. Greater healthy food resources were also inversely related to insulin resistance, although the association was not robust to adjustment for race/ethnicity. Analyses including diet, physical activity, and body mass index suggested that these variables partly mediated observed associations. Results were similar when impaired fasting glucose/diabetes was considered as the outcome variable. The authors conclude that diabetes prevention efforts may need to consider features of residential environment.

Policy action and regulation

The evidential basis of environmental approaches to reducing population obesity has recently been examined in a narrative review (Faith et al, 2007). Applying National Heart, Lung, and Blood Institute criteria, the effects of: (a) taxing or subsidising foods, (b) manipulating the ease of food access, and (c) restricting access to certain foods were examined. It was concluded that although food price manipulations may alter point-of-purchase food acquisition, there is little evidence to show that this changes dietary intake or impacts on long-term energy balance and weight control. Ease of food access however, can influence food purchases, and may affect food intake and body weight. In an ecological observational study (Cutler et al, 2003), international comparisons were made on economic effects of legal strategies to alter food consumption and obesity prevalence. It was predicted that countries with more restrictive policies (limiting access to certain foods) would have lower obesity prevalence. In a regression analysis of 10 countries (Australia, Belgium, Canada, Denmark, France, Germany, Italy, Poland, the UK and the United States), each additional food statute was found to be associated with a 4.5% reduction in the percentage of the adult population that was obese. As this study was ecological in nature; it can not be assumed that a single type of legislation will have the same effect in all countries. Moreover, limiting access to certain foods may not completely restrict access to other energy-dense foods that could, potentially, compensate for the restricted items.

Another review (Sacks et al, 2008) has set out a structure for systematically identifying areas for obesity prevention policy action. Such areas can be systematically identified by considering policy opportunities for each level of governance (local, state, national, international and organisational); for each sector of the food system (primary production, food processing, distribution, marketing, retail, catering and food service) and in each sector that influences physical activity environments (infrastructure and planning, education, employment, transport, sport and recreation). Potential regulatory policy intervention areas are widespread throughout the food system, e.g., land-use zoning (primary production within

local government), food safety (food processing within state government), food labelling (retail within national government). Policy areas for influencing physical activity fall predominantly within local and state government responsibility for example, walking and cycling environments (infrastructure and planning sector) and physical activity education in schools (education sector).

In the Australian context, fruitful areas for policy change include area where existing laws and regulations:

- are obesogenic e.g. land-use laws that allow large concentration of fast-food outlets selling energy-dense foods.
- serve as barriers to efforts to prevent obesity e.g. public liability laws as a barrier to opening school grounds after hours.
- serve as facilitators to obesity prevention e.g., mandatory physical education in schools, car-free areas of cities.

Policy areas likely to impact on obesity prevalence may also include those where there are regulatory gaps or weaknesses which, if addressed, would enhance obesity prevention efforts, for example, restricting food marketing to children, implementing front of pack nutrition signposting systems (Sacks et al, 2008). The reviewers concluded that a coordinated approach to policy development and implementation across all levels of government is necessary to deliver complementary policy action. Similarly, a collaborative 'whole of government' approach, spanning multiple sectors, is required to avoid fragmented, overlapping or contradictory policies. The process requires an initial consultation with stakeholders to prioritise policy areas for potential intervention. This would be followed by full analysis of selected policy areas, including an examination of constraints and historical influences. Specific interventions should then be defined and modelled for health and environmental impact, using best available evidence to assess effectiveness and cost-effectiveness (Sacks et al, 2008).

A systematic review (Magnusson, 2008) has examined legal strategies that could help prevent population weight gain. Review of the evidence suggested that considerable work remains to be done in identifying the institutional features that could best deliver policy improvements for obesity and chronic diseases across sectors and levels of government. This review indicated that the Law can serve obesity prevention by altering the information environment by generating information resources for use by governments and individuals. Nutrition surveillance data are important for galvanising political commitment for public health policies, evaluating interventions taken at a population level, and mandating the provision of information to consumers to facilitate healthier choices. Reform in this area could make a substantial contribution to public health nutrition by protecting against deceptive and misleading claims and assisting consumers to choose foods that will contribute to a healthier diet and restricting advertising to consumers. Food marketing, including television advertising can shape food preferences and purchase. Many public health advocates therefore support regulatory constraints on the advertising of foods high in sugar, salt and fat as part of a broader policy response to obesity prevention.

Magnusson's review (2008) states that obesity is an economic issue as well as a health issue. Economic policies aim to improve patterns of diet and physical activity not by dictating behaviour, but by changing costs of behaviour. Key roles for economic policy could include the use of taxes and subsidies to promote the production and distribution of healthier foods; greater use government oversight to improve standards of catering in schools, hospitals and

all government departments; and the creation of local area targets for obesity reduction and improved nutrition. The review also suggested that in Australia, both private and public sector employers need to become "health policy entrepreneurs", taking greater responsibility for health in the workplace. Although improved productivity, reduced absenteeism, and better profile as an "employer of choice" provide return on such investment, tax incentives might also encourage introduction of "health and wellbeing" programs in the workplace.

Magnusson (2008) argues that the clinical health care system can also be an important setting for assessing obesity and making "lifestyle prescriptions". The *Lifescripts* program is a recent Australian initiative in this area. Funded by the Commonwealth government, and implemented through local divisions of general practice, *Lifescripts* encourages doctors to assess their patients for lifestyle risk factors and make written lifestyle prescriptions. Incentives are required to support this program. A new Medicare Benefits Schedule item thus encourages general practitioners to undertake a comprehensive health check on middle-aged patients presenting with identifiable risk factors for chronic disease. Recent legislative changes also make it easier for private health insurers to cover similar services. In this review, Magnusson argues that a regulatory approach can make a substantial contribution to addressing the economic, social and environmental determinants of modern "obesogenic environments". This will require governments to adopt a clear theoretical approach to the problem, to exhibit a degree of bravery and demonstrate a commitment to outcomes that extend beyond the usual timeframes that operate in politics. Magnusson concludes that the challenge remains to act cooperatively across sectors and levels of government and to realise the potential of law as a policy tool, together with other strategies, to wind back the impact of overweight and obesity on chronic disease in Australia.

While there are numerous examples of policy actions that could be highlighted, the current literature around food labelling has been selected as an example given the recent interest in reform in this area as outlined below.

Several systematic reviews have explored consumers understanding and use of nutrition labelling. Cowburn and coworkers (2005) identified 103 relevant papers most from North America or Northern Europe and only a minority (9%) judged of medium to high quality. Although reported use of nutrition labels was high, more objective measures suggested consumers may not actually use nutrition labelling during food purchase. Consumers who do examine labels appear to understand some of the terms used but are confused by others. Most consumers can retrieve simple information and make simple calculations and comparisons between products, but their ability to accurately interpret the nutrition label reduces as the complexity of the task increases. The addition of interpretational aids such as verbal descriptors and Nutritional Reference Values (NRV) helps consumers compare products and assess the nutrient contribution made by specific foods to their overall diet. The reviewers concluded that improved nutrition labelling could make a small but important contribution at point-of-purchase to promote selection of healthy food choices.

Grunert and co-workers(Grunert, 2006) have reviewed research conducted between 2003–2006 in 15 countries of the European Union on how consumers perceive, and use nutrition information on food labels. In a total of 58 studies, widespread consumer interest in nutrition information on food packaging was identified. Consumers liked simplified front-of-pack information but responded differently to different formats. The review did not provide insight into how labelling information was used in real-world situations, or how it might affect consumers' dietary patterns.

Drichoutis and co-workers (2006), however, have examined the determinants of label use more thoroughly. They found that the label with the most positive dietary benefits displayed percentage nutrient content relative to the Recommended Daily Intake (RDI). Consumers performed poorly when required to manipulate quantitative nutrient information displayed on a pack. Most preferred bold text and coloured nutrition panels. Consumers mainly sought to avoid negative nutrients in food products and were more successful in achieving this when supported by an information campaign. The reviewers found that most empirical research surveyed, indicated that provision and use of information can significantly change dietary patterns, leading to a better dietary intake or to reduced consumption of 'unhealthy' foods.

The European Heart Network (2003) has carried out a systematic review on nutrition labelling. The search identified 307 papers of which 130 studies were reviewed. From these, it appeared that although consumers reported a high use of nutrition labels, actual use during food purchase may be much lower. This may be due to lack of time, problems with the way information is presented, lack of understanding of terms or concerns about the accuracy of the information given. Consumers do not understand all of the terms used on labels. They make simple comparisons between similar products but their ability to accurately interpret the nutrition label reduces as the complexity of the task increases.

Apart from nutrition information food packets often display health claims. An Australian review (Williams, 2005) has examined consumer understanding of such claims. This search (conducted from 1984 to 2004) found that consumers find health claims useful, considering a product with a health claim as healthier than others and one that they were more likely to purchase. Consumers however, thought health claims should be approved by government and were more skeptical of health claims from food companies. They were unable to make clear distinctions between nutrition content claims, structure-function claims, and health claims; and disliked long and complex, scientifically worded claims. Most preferred split claims with a succinct statement of the claim displayed on the front of the package.

Present requirements for mandatory nutrition labelling have been in force in Australia since late 2002. A study (Fabiansson, 2006) was conducted to ascertain whether consumers are provided with sufficient information to make an informed choice. The NSW Food Authority bought quintuplicate samples of 70 different food products from supermarkets in NSW during October 2004 to May 2005. 'Low-claim' as well as conventional products were sampled to check if extra attention was given to low claim labelling. Low claim products are foods that carry claims that they are "low" in a particular undesirable nutrient such as sodium or fat. All nutrients declared on the nutrition information panel (ie protein, total fat, total sugar, sodium, energy and total carbohydrate) were analysed for 350 samples. A significant discrepancy was noted between actual and declared values. Precision varied from -13% to +61% for individual nutrients. Australian food legislation does not stipulate tolerance limits. In some countries a ±20% discrepancy is allowed while others specify upper and lower limits and allow a maximum discrepancy of -20% for beneficial nutritional compounds and +20% for unfavourable compounds. In the Australian study, food labelling was shown to be somewhat inaccurate. Only 16% of the 70 products fully complied when a leeway of ±20% for any nutritional compound on the label was set. With separate upper and lower limits, only 51% of products fully complied. Compliance improved to 27% and 70% of products, respectively, by excluding variations in minor nutrients of less relevance to consumers.

A survey (Williams, 2005) of 1,200 Australian adults has sought to identify the factors of greatest concern to consumers in relation to the safety and quality of food. Confirming earlier

findings made by an ANZFA consumer survey made in 1996, respondents indicated that they were most concerned to check labels for food additives, and more consumers were concerned about these than about added salt or sugar (p<0.001). Consumer concerns about food additives thus contrast strongly with the views of health professionals such as dietitians and GPs, who regard nutritional information and allergy warnings as the most useful information on food labels.

A study has specifically examined (Reid & Hendricks, 1994) consumer understanding and use of label information about dietary fat and cholesterol. Mall intercept interviews of 149 food shoppers (80% female), revealed that most (60%) believed it is very important to reduce dietary fat intake. However, the claims "low in saturated fat" and "no cholesterol" and the term "non-hydrogenated" were often misunderstood. Many respondents (50-66%) correctly interpreted "% B.F./M.F.", "low fat" versus "reduced in fat" claims, and the fat content of margarines. Only 18% used % B.F. information to choose cheese and yoghurt. Depending on the claim, only 34-56% of respondents reported consulting other label information; with the lowest rate of "additional consultation", (34%) reported for the "no cholesterol" claim.

A more recent study (Higginson et al, 2002) aimed to identify the nutrition label information accessed by a small number of consumers (n=14) while shopping for food. Information on fat content was predominantly accessed followed by energy information. The type of product influenced label examination. Fat information was looked at more in foods likely to be high in fat (biscuits, butter/margarine, crisps and sandwich filling). Consumers particularly claimed to read nutrition labels for complete (ready made) meals and dairy products.

Wansink and co-workers (2004) interviewed 118 shoppers at a grocery store in Illinois, USA. As assessed by one-tail t test, short claims generated more favourable ratings as to how beneficial for health (p<.05), how appealing (p<.05), and how low in saturated fat (p<0.05) the product was perceived. It was concluded that short claims on the front-label generated stronger, more favourable beliefs than longer claims.

Feunekes et al. (2008) reviewed two studies that looked at the impact of eight front-of-pack nutrition labelling formats on consumers from four European countries. In total 1,630 people (18-55 yrs) were recruited from Internet panels in the UK, Germany, Italy and the Netherlands for study 1 while a further 776 were recruited in Italy and the UK for study 2. Participants evaluated several products (including healthier and less healthy variants of the same product category) with a front-of-pack nutrition labelling format. Study 1 evaluated different labelling formats on consumer friendliness (comprehension, liking and credibility) while study 2 measured the effect of the different labelling formats on decision-making (usage intention and process time). The results indicated minor differences in consumer friendliness and usage intention between simpler (such as Healthier Choice Tick, Smileys and Stars) and more complex front-of-pack nutrition labelling formats (such as Multiple Traffic Light, Wheel of Health and GDA scores). Endorsement by national and international health organisations strongly increased credibility. Participants also needed significantly less time to evaluate simpler front-of-pack labelling compared to more complex labelling formats.

Rayner et al (2001) conducted a small cross-sectional study examining how consumers use health-related food endorsements on food labels. Three endorsement programs were assessed via protocol analysis: those of the two major UK retailers, Tesco and Sainsbury's, plus the "Pick the Tick" program of the National Heart Foundation of Australia. Protocol analysis involves the subject "thinking aloud" while performing a task either (a) shopping normally or

(b) shopping "healthily" for foods on a predetermined list to generate a protocol. Each subject was also interviewed to investigate reported use of endorsements. Subjects were a quota sample (N = 44) of shoppers representative of the UK and Australian populations. Information about the subjects, the protocols, and interview data were analysed quantitatively; the protocols were also analysed qualitatively. Sainsbury's and Australian shoppers never used the endorsements when shopping. Although Tesco shoppers claimed to use endorsements and the explicit nature of the symbol used appeared helpful, protocol analysis revealed no actual use. The reviewers suggest that health-related food endorsements, in particular the Australian "Pick the Tick" program, are less frequently used by shoppers than the advocates of such programs suggest. They called for more research to establish the impact of health-related food endorsement programs on food purchasing behaviour.

A report by Kelly et al (2008) has recently reported the results of consumer research study to determine which front-of-pack labelling system would be most appropriate for use in Australia. Four different front-of-pack labelling systems were tested, based on variations of the two major systems, traffic light labelling (where total fat, saturated fat, sugar and sodium are ranked and colour coded as either high (red), medium (amber) or low (green) based on nutrient cut-points; and the Percentage Daily Intake (%DI) system (which shows the contribution of energy, protein, total fat, saturated fat, total carbohydrate, sugar, fibre and sodium provided by a serve of a food as a percentage of daily requirements for each nutrient). In June 2008, 790 consumers living in NSW were surveyed. All participants were the main grocery buyer or shared the responsibility for grocery purchases in their households. Participants were recruited from shopping centres across Sydney and Newcastle, with representation from high, medium and low socio-economic areas, and from metropolitan and regional areas. Around 200 consumers were asked about each of the four systems. Each person was shown two products, each labelled in two different ways. Questions examined consumers' label preference and also objectively tested how well each system allowed consumers to identify healthier food products (Kelly et al, 2008).

The study by Kelly et al (2008) found that consumers largely supported the introduction of front-of-pack food labelling, preferring a single system to be used across all food packages. This would then require mandatory labelling regulations. While consumers preferred the colour-coded %DI food labelling system, consumers using the traffic light system were five times more likely to correctly identify healthier food products compared to the monochrome %DI system, and three times more likely to correctly identify the healthier products compared to the colour-coded %DI system. While consumer preferences are important, the critical issue when considering the introduction of front-of-pack food labelling into the Australian grocery market, is whether consumers can use the information on the label to make healthier food choices The monochrome %DI system proved less useful for consumers from lower socio-economic groups, with people from lowest socio-economic group *six times less likely* to correctly identify the healthier food products using the monochrome %DI labelling than people from the highest socio-economic group. This difference between socioeconomic groups was statistically significant ($p<0.05$). Across all socio-economic groups, consumers displayed a similar ability to use the Traffic Light systems to identify healthier foods. The researchers concluded that to maximise the ease and accuracy with which consumers make healthy food choices, regulations should be introduced to mandate the display of Traffic Light front-of-pack labelling on all Australian food products.

Summary – Population strategies

- Social marketing is effective in increasing physical activity, improving nutrition knowledge, attitudes and eating behaviour in a range of target groups in different settings.

- Mass media campaigns help change attitudes and levels of knowledge towards physical activity, but have limited short-term impact on participation in physical activity.

- Mass media campaigns enhance the success of community-based educational programs and public relations activities.

- Effective community-based interventions gave clear messages, incorporated multiple strategies, involved the family, were more intensive, were provided over a longer period of time, and were based on a theoretical framework.

- Worksites are an effective setting for community-based interventions aimed at promoting healthy eating, especially worksite programs that include environmental modifications and involve family members.

- Well-designed community-based intervention programs can improve lifestyle choices and healthy habits.

- Environmental interventions show promise but evidence about their effectiveness is limited by the deficiencies in research.

- Policy action, including regulation and legislation, has a distinct role shaping a health promoting environment. Effective policy action requires coordination across all levels of government and all sectors. The mechanisms and impact of policy actions are still not fully understood and so efforts to observe and measure changes should be prioritised.

Evidence Tables: Section 3

Population strategies effective in reducing risk factors for type 2 diabetes

Social marketing and mass media – physical inactivity

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Bauman et al[a] (2001)	III-2	Comparative Before and After study	Medium	High	High
Bauman et al[a] (2003)	III-3	Time series analysis, longitudinal study	Medium	High	High
Beaudoin et al[a] (2007)	III-3	Cross-sectional Before and After study	Medium	High	High
Cavill et al[a] (2004)	III-3	Systematic review of comparative studies (Before & After)	Medium	High	High
Finlay et al[a] (2005)	III-3	Systematic review of comparative studies (Before & After)	Medium	N/A	High
Gordon et al (2006)	III-3	Systematic review of comparative studies (Before & After)	Medium	N/A	High
Hillsdon et al[b] (2001)	III-3	Prospective longitudinal study	Low	High	High
Kahn et al (2000)	III-3	Systematic review of comparative studies (Before & After)	Medium	N/A	High
Marcus et al[a] (1998)	III-3	Systematic review of comparative studies (Before & After)	Medium	N/A	High
Merom et al (2005)	III-3	Non-experimental cohort study	Medium	High	High
Miles et al (2001)	III-3	Before and After study	Medium	High	High
Sogaard et al (1992)	III-3	Before and After study	Medium	N/A	High
Wimbush et al[a] (1998)	III-3	Before and After study	Medium	N/A	High

[a] increase in awareness and intention to be more active/healthy diet but little or no effect on changing behaviour.
[b] Significant increase in number knowledgeable about physical activity recommendations but no evidence of improved physical activity.

Social marketing and mass media – healthy eating

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Ashfield-Watt (2006)	III-3	Before and After study	Medium	High	High
Dixon et al (1998)	III-3	Time series analysis, longitudinal study	Medium	High	High
Foerster et al (1995)	III-3	Before and After study	Low	N/A	High
Maddock et al (2007)	III-3	Before and After study	Low	High	High
Miles et al (2001)	III-3	Before and After study	Low	High	High
Pollard et al (2008)	III-3	Before and After study	Low	High	High
Reger et al (1999)	III-2	Non-randomised experimental trial	Medium	High	High
Reger et al (2000)	III-2	Non-randomised experimental trial	Medium	High	High
Taylor et al (1991)	III-2	Non-randomised experimental trial	Medium	High	High
Wammes et al (2007)	III-3	Before and After study	Low	N/A	High
Wardle et al (2001)	III-3	Before and After study	Low	N/A	High

Community-based interventions – physical inactivity

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Cochrane et al (2008)	III-2	Non-randomised experimental trial	Medium	High	High
De Cocker et al (2007)	III-2	Comparative Before and After study	Medium	High	High
Fogelhom et al (2002)	III-2	Systematic review of comparative studies with concurrent control	Low	N/A	High
Hillsdon et al (1996)	I	Systematic review of RCTs	Medium	N/A	High
Lyle et al (2008)	III-3	Before & After study	Low	N/A	High
Ogilvie et al (2004)	III-3	Systematic review prospective & retrospective studies	Low	N/A	High
Ogilvie et al (2007)	III-3	Systematic review of Before & After studies	Medium	N/A	High
Satterfield et al (2003)	III-3	Systematic review of comparative studies (Before & After studies)	Low	N/A	High
Wen et al (2002)	III-3	Before & After study	Low	High	High
Wray et al (2005)	III-3	Cross-sectional study	Low	N/A	High

Community-based interventions - healthy eating

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Ashfield-Watt et al [a] (2007)	III-3	Before and After study	Medium	High	High
Braeckman et al (1999)	III-2	Controlled before and after study	Low	High	High
Ciliska et al (2000)	III-3	Systematic review of comparative studies (Before & After)	Medium	N/A	High
Engbers et al (2005)	I	Systematic review of RCTs	Medium	N/A	High
Englert et al (2007)	III-3	Before and After study	Low	High	High
Maddock et al (2006)	III-3	Before and After study	Low	N/A	High
Ronda et al (2004)	III-2	Controlled before and after study	Medium	High	High
Sorensen et al (1999)	III-2	Controlled before and after study	Medium	High	High
Verrall (2000)	III-1	Randomised (allocation not concealed) controlled trial	Medium	High	High
Wellman et al (2007)	III-3	Before and After study	Low	High	High

[a] Significant increase in knowledge of message of 5 a day message but no demonstrable effect on total fruit & vegetable intake.

Policy action and regulation

a) Policies to reduce population obesity

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Faith et al (2007)	III-3	Systematic Review of Observational & Quasi-experimental studies	Medium	N/A	N/A
Cutler et al (2003)	III-3	Ecological observational study	N/A	N/A	N/A
Sacks et al (2008)	III-3	Systematic Review of policy interventions	Medium	N/A	N/A
Magnusson (2008)	III-3	Review	Low	N/A	N/A

b) Food labelling

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Cowburn et al (2005)	III-3	Systematic Review of cross-sectional studies	Medium	N/A	Low
Grunert et al (2006)	III-3	Systematic Review of cross-sectional studies	Medium	N/A	Medium
Drichoutis et al (2006)	III-3	Systematic Review of cross –sectional studies	Low	N/A	Medium
European Heart Network (2003)	III-3	Systematic Review of cross-sectional studies	Medium	N/A	Low
Williams (2005)	III-3	Systematic Review of cross-sectional studies	Medium	N/A	Medium
Fabiansson (2006)	III-2	Diagnostic test		N/A	N/A
Williams (2004)	III-3	Cross-sectional study	Medium	Medium	Low
Reid & Hendricks (1994)	III-3	Cross-sectional study	Low	Low	Low
Higginson et al (2002)	III-3	Cross-sectional study	Low	Low	Low
Wansink et al (2004)	III-2	Comparative Study with concurrent controls	Medium	High	Low
Feunekes et al (2008)	III-3	Cross-sectional study	Medium	Medium	Medium
Rayner et al (2001)	III-3	Cross-sectional study	Medium	Low	Low
Kelly et al (2008)	III-3	Cross-sectional study	Medium	High	Low

Section 4: Cost effectiveness and socio-economic implications

Questions

a) Is prevention of type 2 diabetes cost-effective?

b) What are the socio-economic implications of prevention of type 2 diabetes?

Recommendation

To be optimally cost-effective and cost saving in the long term, interventions to prevent diabetes should focus on lifestyle modification.

Practice Points

- Lifestyle modification interventions for high risk individuals should be implemented at the level of routine clinical practice.
- In absence of specific strategies targeting low socio economic people, strategies aimed at the general population are recommended.
- Culturally appropriate lifestyle interventions should be provided in accessible settings.

Evidence Statements

- Lifestyle modification can prevent or delay the development of diabetes at costs acceptable to society.
- Lifestyle modification interventions are cost-effective and cost saving in people at high risk of developing diabetes.
- Metformin and acarbose are cost-effective pharmacological interventions in people at high risk of developing diabetes.
- Lifestyle modification interventions are often more cost-effective than pharmacological interventions.

- Cost-effectiveness of life style modification interventions and metformin improves when the interventions are implemented in routine clinical practice
- Interventions for preventing diabetes are equally effective in culturally specific and low socio economic high-risk groups

  Evidence Level II

Background – Cost effectiveness and socio-economic implications

The prevalence of type 2 diabetes has become epidemic in Australia and worldwide. The direct and indirect costs of caring for people with type 2 diabetes and its complications are considerable and will continue to rise. In 2004-05 the direct health care expenditure on diabetes was $907 million (of which type 2 diabetes accounted for 81% at $733 million), accounting for 1.7% of the total allocatable recurrent health expenditure for that year (Australian Institute of Health and Welfare, 2008). These figures almost certainly underestimate the true cost of diabetes. The DiabCo$t study reported that the average total (direct plus indirect) health costs for an individual with type 2 diabetes was $5360 per year (Colagiuri et al, 2003). The costs per year for individuals with both macrovascular and microvascular complications was on average 2.4 times higher than for those with no complications ($9625 vs. $4020). Based on a diabetes prevalence of 7.4%, the total annual cost for people with type 2 diabetes in Australia was estimated to be $2.2 billion, and if the cost of carers is included this figure rises to $3.1 billion. In addition, people with type 2 diabetes receive $5540 per year on average in Commonwealth benefits, increasing the total annual cost of diabetes to $6 billion .

There is compelling evidence from well designed randomised trials, as discussed in the previous sections, demonstrating that preventive measures such as lifestyle changes and pharmacotherapy have the potential to reduce the risk of type 2 diabetes and hence reduce the costs associated with the disease. Progression to diabetes was reduced in the Da Qing study by 40%, in the Finnish and US Diabetes Prevention Programs by 58%.

Cost effective models are widely used to help policy makers to guide decisions about interventions (Hutubessy et al, 2003). However, cost effectiveness models do not address issues of implementation such as feasibility and acceptability (Briggs et al, 1994). To determine the cost-effectiveness of interventions, this section includes evidence from studies that reported economic analysis of interventions that investigated diabetes prevention as a primary outcome.

Socio economic implications

The prevalence of diabetes varies with socio-economic position and increases with increasing disadvantage (Carter et al, 1996; Fisher et al, 2002; Candib, 2007). In 2001, the prevalence of self-reported diabetes was almost twice as high in the most disadvantaged areas than in the least disadvantaged in Australia (Australian Institute of Health and Welfare, 2008). Across Australia, Aboriginal people have a significantly higher prevalence of diabetes than the general population (O'Dea et al, 1993; Hoy et al, 2007) and certain overseas-born Australians have a higher prevalence of diabetes than people born in Australia (Colagiuri et al, 2007; Australian Institute of Health and Welfare, 2008).

Evidence – Cost effectiveness and socio economic implications

Cost of prevention of type 2 diabetes

- **Lifestyle modification can prevent or delay the development of diabetes at costs acceptable to society.**

The DPP demonstrated that intensive lifestyle and metformin interventions reduced the incidence of type 2 diabetes compared with a placebo intervention. Herman et al. (2005) described the direct medical costs, direct non-medical costs, and indirect costs of the placebo, metformin, and intensive lifestyle interventions over the 3-year study period of the DPP interventions to prevent or delay type 2 diabetes. Research costs were excluded. The direct medical cost of laboratory tests to identify one subject with IGT was US$139. Over 3 years, the direct medical costs of the interventions were US$79 per participant in the placebo group, US$2,542 in the metformin group, and US$2,780 in the lifestyle group. The direct medical costs of care outside the DPP were US$272 less per participant in the metformin group and US$432 less in the lifestyle group compared with the placebo group. Direct non-medical costs were US$9 less per participant in the metformin group and US$1,445 greater in the lifestyle group compared with the placebo group. Indirect costs were US$230 greater per participant in the metformin group and US$174 less in the lifestyle group compared with the placebo group. From the perspective of a health system, the cost of the metformin intervention relative to the placebo intervention was US$2,191 per participant and the cost of the lifestyle intervention was $2,269 per participant over 3 years. From the perspective of society, the cost of the metformin intervention relative to the placebo intervention was US$2,412 per participant and the cost of the lifestyle intervention was US$3,540 per participant over 3 years. This study demonstrated that the metformin and lifestyle interventions are associated with modest incremental costs compared with the placebo intervention.

Cost effectiveness of prevention of type 2 diabetes

- **Lifestyle modification interventions are cost-effective and cost saving in people at high risk of developing diabetes.**

- **Metformin and acarbose are cost-effective pharmacological interventions in people at high risk of developing diabetes**

- **Lifestyle modification interventions are often more cost-effective than pharmacological interventions**

- **Cost-effectiveness of life style modification interventions and metformin improves when the interventions are implemented in routine clinical practice**

Several studies have assessed the cost-effectiveness of the interventions used in the US DPP on health and economic outcomes (DPP Research Group, 2003; Palmer et al, 2004; Eddy et al, 2005;

Herman et al, 2005; Ackermann et al, 2006). The DPP group (2003) performed cost utility analyses with the interventions as implemented in the DPP and as they might be implemented in clinical practice from a health system perspective that considered direct medical costs only and a societal perspective that considered direct medical costs, direct non-medical costs, and indirect costs. This study demonstrated that the lifestyle and metformin interventions required more resources than the placebo intervention from a health system perspective, and over 3 years they cost approximately US $2,250 more per participant. As implemented in the DPP and from a societal perspective, the lifestyle and metformin interventions cost US $ 24,400 and US $ 34,500, respectively, per case of diabetes delayed or prevented and US $51,600 and US $ 99,200 per quality-adjusted life-year (QALY) gained. As the interventions might be implemented in routine clinical practice and from a societal perspective, the lifestyle and metformin interventions cost US $ 13,200 and US $14,300, respectively, per case of diabetes delayed or prevented and US $27,100 and US $ 35,000 per QALY gained. From a health system perspective, costs per case of diabetes delayed or prevented and costs per QALY gained tended to be lower. These findings suggest that over 3 years, the lifestyle and metformin interventions were effective and were cost-effective from the perspective of a health system and society. Both interventions are likely to be affordable in routine clinical practice, especially if implemented in a group format and with generic medication pricing.

More recently, Herman et al (2005) estimated the lifetime cost-utility of the US DPP interventions using a Markov simulation model to estimate progression of disease, costs, and quality of life. The target population were DPP participants 25 years of age. Outcome measures were cumulative incidence of diabetes, microvascular and neuropathic complications, cardiovascular complications, survival, direct medical and direct non-medical costs, QALYs, and cost per QALY. The base-case analysis show that compared with the placebo intervention, the lifestyle and metformin interventions were estimated to delay the development of type 2 diabetes by 11 and 3 years, respectively, and to reduce the absolute incidence of diabetes by 20% and 8%, respectively. The cumulative incidence of microvascular, neuropathic, and cardiovascular complications were reduced and survival was improved by 0.5 and 0.2 years. Compared with the placebo intervention, the cost per QALY was approximately US$1,100 for the lifestyle intervention and US$31,300 for the metformin intervention. From a societal perspective, the interventions cost approximately US$8,800 and US$29,900 per QALY, respectively. From both perspectives, the lifestyle intervention dominated the metformin intervention. The sensitivity analysis demonstrated that the cost-effectiveness improved when the interventions were implemented as they might be in routine clinical practice, the lifestyle intervention was cost-effective in all age groups, and the metformin intervention did not represent good use of resources for persons older than 65 years of age. However the authors acknowledged the limitation of analysis including simulation results depend on the accuracy of the underlying assumptions, including participant adherence.

Ackermann and co-workers (2006) explored whether the US DPP lifestyle intervention could be offered in a way that allows return on investment for private health insurers while remaining attractive for consumers, employers, and US Medicare (Ackermann et al, 2006). They used the DPP and other published reports to build a Markov simulation model to estimate the lifetime progression of disease, costs, and quality of life for adults with impaired glucose tolerance. The model assumed a health-payer perspective and compared DPP lifestyle and placebo interventions. Primary outcomes included cumulative incidence of diabetes, direct medical costs, quality-

adjusted life-years (QALYs), and cost per QALY gained. This study shows that compared with placebo, providing the lifestyle intervention at age 50 years could prevent 37% of new cases of diabetes before age 65, at a cost of $1,288 per QALY gained. A private payer could reimburse US$655 (24%) of the US$2,715 in total discounted intervention costs during the first 3 intervention years and still recover all of these costs in the form of medical costs avoided. If Medicare paid up to US$2,136 in intervention costs over the 15-year period before participants reached age 65, it could recover those costs in the form of future medical costs avoided beginning at age 65. The authors concluded that cost-sharing strategies to offer the DPP lifestyle intervention for eligible people between ages 50 and 64 could provide financial return on investment for private payers and long-term benefits for Medicare.

Another cost-effectiveness analysis using the Archimedes model was conducted by Eddy et al (2005) and compared no prevention, the DPP lifestyle modification program, lifestyle modification begun after a person develops diabetes, and metformin and reached a different conclusion. They used data from published basic and epidemiologic studies, clinical trials, and Kaiser Permanente administrative data. They included adults at high risk for diabetes, specifically, BMI >24 kg/m2, fasting plasma glucose level of 5.3 to 6.9 mmol/L and 2-hour glucose tolerance test result of 7.8 to 11.0 mmol/L. Compared with no prevention program, the DPP lifestyle program would reduce a high-risk person's 30-year chances of developing diabetes from about 72% to 61%, the chances of a serious complication from about 38% to 30%, and the chances of dying of a complication of diabetes from about 13.5% to 11.2%. Metformin would deliver about one third the long-term health benefits achievable by immediate lifestyle modification. Compared with not implementing any prevention program, the expected 30-year cost/QALY of the DPP lifestyle intervention from the health plan's perspective would be about US$143,000. From a societal perspective, the cost/QALY of the lifestyle intervention compared with doing nothing would be about US$62,600. Either using metformin or delaying the lifestyle intervention until after a person develops diabetes would be more cost-effective, costing about US$35,400 or US$24,500 per QALY gained, respectively, compared with no program. Compared with delaying the lifestyle program until after diabetes is diagnosed, the marginal cost-effectiveness of beginning the DPP lifestyle program immediately would be about US$201,800. Compared with no program, lifestyle modification for high-risk people can be made cost-saving over 30 years if the annual cost of the intervention can be reduced to about US$100. However, the authors suggested that the program used in the DPP study may be too expensive for health plans or a national program to implement and recommended less expensive methods are needed to achieve the degree of weight loss seen in the DPP.

To establish whether implementing the active treatments used in the US DPP would be cost-effective in Australia, France, Germany, Switzerland, and the UK, Palmer et al. (2004) used a Markov model and simulated 3 states - IGT, type 2 diabetes, and deceased. They used probabilities from the DPP and published data. Country-specific direct costs were used throughout. Assuming only within-trial effects and costs of interventions, both metformin and intensive lifestyle changes improved life expectancy versus control. Mean improvements in non-discounted life expectancy were 0.11 and 0.22 years for metformin and intensive lifestyle changes, respectively. Both interventions were associated with cost savings versus control in all countries except the UK, where a small increase in costs was observed in both intervention arms. When a lifetime effect of interventions was assumed, incremental improvements in life expectancy were 0.35 and 0.90 years for metformin and intensive lifestyle changes, respectively.

Results were sensitive to probabilities of developing type 2 diabetes, the projected long-term duration of effect of interventions after the 3-year trial period, the relative risk of mortality for type 2 diabetes compared with IGT, and the costs of implementing the interventions. The authors concluded that incorporation of the DPP interventions into clinical practice in 5 developed countries was projected to lead to an increase in diabetes free years of life, improvements in life expectancy, and either cost savings or minor increases in costs compared with standard lifestyle advice in a population with IGT (Palmer et al, 2004). However this study did not include the costs of screening to detect people with IGT.

The health benefits and costs of a national diabetes screening and prevention scenario were estimated among Australians ages 45-74 (Colagiuri & Walker, 2008). The Australian Diabetes Cost-Benefit Model was used to compare baseline and scenario outcomes from 2000 to 2010. People at high risk of developing diabetes (IGT or IFG) were offered lifestyle intervention, reducing the numbers developing diabetes. Among those at high risk, 53,000 avoided developing diabetes by 2010. Average yearly intervention and incremental treatment cost was AU$179 million, with a cost per disability-adjusted life-year of AU$50,000.

Icks et al (2007) assessed the cost-effectiveness of the primary prevention of type 2 diabetes using population-based data (KORA Survey in Augsburg, Germany, total population approximately 600,000). The researchers used a decision analytic model, time horizon 3 years to compare staff education, targeted screening and lifestyle modification or metformin in people aged 60-74 years with a BMI $\geq$ 24 kg/m2 and pre-diabetic status (fasting glucose 5.3-6.9 mmol/l and 2-h post load glucose 7.8-11.0 mmol/l) according to the US DPP trial. The main outcome measures were cases of type 2 diabetes prevented, cost (Euro), and incremental cost-effectiveness ratios (ICERs). Under model assumptions, 14,908 people in the target population would develop diabetes if there was no intervention, 184 cases would be avoided with lifestyle intervention and 42 cases with metformin intervention. From the perspective of statutory health insurance and society, costs for lifestyle modification were 856,507 euro and 4,961,340 euro, respectively, and for metformin 797,539 euro and 1,335,204 euro. Up to 5% of the costs were due to staff education and up to 36% to screening. Lifestyle was more cost effective than metformin. ICERs for lifestyle vs. 'no intervention' were 4664 euro and 27,015 euro per case prevented from the statutory health insurance and societal perspective. This study suggests that the total cost and cost per case of diabetes avoided is high.

Jacobs-van der Bruggen et al (2007) explored the long-term health benefits and cost-effectiveness of both a community-based lifestyle program for the general population (community intervention) and an intensive lifestyle intervention for obese adults, implemented in a health care setting (health care intervention). Researchers estimated short-term intervention effects on BMI and physical activity from the international literature. The National Institute for Public Health and the Environment Chronic Diseases Model was used to project lifetime health effects and effects on health care costs for minimum and maximum estimates of short-term intervention effects. Cost-effectiveness was evaluated from a health care perspective and included intervention costs and related and unrelated medical costs. Effects and costs were discounted at 1.5 and 4.0% annually. The analysis highlighted that one new case of diabetes per 20 years was prevented for every 7-30 participants in the health care intervention and for every 300-1,500 adults in the community intervention. Intervention costs needed to prevent one new case of diabetes (per 20 years) were lower for the community intervention (euro 2,000-9,000) than for

the health care intervention (euro 5,000-21,000). The cost-effectiveness ratios were euro 3,100-3,900 per QALY for the community intervention and euro 3,900-5,500 per QALY for the health care intervention. The authors concluded that health care interventions for high-risk groups and community-based lifestyle interventions targeted to the general population (low risk) are both cost-effective ways of curbing the growing burden of diabetes.

Lindgren et al (2007) developed a simulation model to assess the economic consequences of an intervention like the one studied in the Finnish Diabetes Prevention Study (DPS) in a Swedish setting. The model used data from the trial itself to assess the effect of intervention on the risk of diabetes and on risk factors for cardiovascular disease. Results from the UKPDS were used to estimate the risk of cardiovascular disease and stroke. Cost data were derived from Swedish studies. The intervention was assumed to be applied to eligible people from a population-based screening program of 60-year-olds in the County of Stockholm from which the baseline characteristics of the subjects were used. The model predicted that implementing the program would be cost-saving from the healthcare payers' perspective. Furthermore, it was associated with an increase in estimated survival of 18 years. Taking into consideration the increased health resource utilisation by subjects due to their longer survival, the predicted cost-effectiveness ratio was 2,363 euro per QALY gained.

Cost-effectiveness of the interventions in the Indian Diabetes Prevention Programme (IDPP) was reported by Ramachandran et al (2007). Relative effectiveness and costs of interventions (Life Style Modification [LSM], metformin, and LSM and metformin) in the IDPP were estimated from the health care system perspective. Costs of intervention considered were only the direct medical costs. Direct non-medical, indirect, and research costs were excluded. The cost-effectiveness of interventions was measured as the amount spent to prevent one case of diabetes within the 3-year trial period. The results of this study show that the direct medical cost to identify one subject with IGT was US$117. Direct medical costs of interventions over the 3-year trial period were US$61 per subject in the control group, US$225 with LSM, US$220 with metformin, and US$270 with LSM and metformin. The number of individuals needed to treat to prevent a case of diabetes was 6.4 with LSM, 6.9 with metformin, and 6.5 with LSM and metformin. Cost-effectiveness to prevent one case of diabetes with LSM was US$1,052, with metformin US$1,095, and with LSM and metformin US$1,359. Similar to other cost-effectiveness studies in Western societies, LSM and metformin were cost-effective interventions for preventing diabetes among high risk-individuals in India.

To compare the health and economic outcomes of using acarbose, an intensive lifestyle modification programme, metformin or no intervention to prevent progression to diabetes in Canadian individuals with IGT, Caro et al (2004) developed a model to simulate the course of individuals with IGT under each treatment strategy. Subjects remain in the IGT state or transition from IGT to diabetes, to normal glucose tolerance (NGT) or to death. Effectiveness and resource use data were derived from published intervention trials. A comprehensive health-care payer perspective incorporating all major direct costs, reported in 2000 Canadian dollars, was adopted. Caro et al estimated that over a decade, 70 of the 1000 untreated subjects are expected to die and 542 develop diabetes. Intensive lifestyle modification is estimated to prevent 117 cases of diabetes, while metformin would prevent 52 and acarbose 74 cases. The proportion of those who return to NGT also increases with any treatment. They also suggested that though lifestyle modification is more effective, it can increase overall costs depending on how it is implemented,

whereas acarbose and metformin reduce costs by nearly Ca$1000 per subject. Lifestyle modification was cost effective, varying from $749/life year gained (LYG) vs. no treatment to about Ca$10,000/LYG vs. acarbose. Acarbose costs somewhat more than metformin, but is more effective: Ca$1798/LYG. The results of this model suggest that the treatment of IGT in Canada is a cost-effective way to prevent diabetes and may generate savings. Moreover, intensive lifestyle modification, though more costly than pharmacological treatments, led to the greatest health benefits at reasonable incremental costs.

The economic evidence for acarbose in the prevention of diabetes and cardiovascular events in individuals with IGT have been reviewed by Josse et al (2006) and Quilici et al (Quilici et al, 2005). The economic analyses have been conducted for Spain, Germany, Sweden and Canada. In Spain, acarbose was more effective and less costly (dominant) compared with placebo. In Germany, the cost per subject free of diabetes was under 800 pounds; acarbose was dominant for those at high risk for type 2 diabetes, CVD or both, and a similar outcome in the Swedish study (Quilici et al, 2005). In Canada, acarbose was dominant compared with no intervention and very cost-effective compared with metformin (C Dollars 1798/ LYG). The particularly cost-effective outcomes or cost savings delivered by acarbose for IGT subjects at high risk for type 2 diabetes and/or CVD suggest that acarbose is an economically attractive strategy for high-risk individuals.

Socio economic implications

- **Interventions for preventing diabetes are equally effective in culturally specific and low socio economic high-risk groups** (*Evidence Level II).*

In the major diabetes prevention studies, the effectiveness of interventions has been shown to apply across a wide range of cultural groups including China (Pan et al, 1997; Li et al, 2008) , India (Ramachandran et al, 2006) and Japan (Kosaka et al, 2005). Also in the US DPP, the largest trial of primary prevention of diabetes, approximately half of the participants were African American, Hispanic American, Asian American, or Native American. Over the 3 year study period, the magnitude of risk reduction for developing diabetes in the lifestyle intervention group was similar across all ethnic groups (Knowler et al, 2002).

Results from a recent systematic review of community based nutrition and physical activity interventions targeting low income populations illustrated that interventions aimed at low income groups tend to be delivered in an interactive visual format, to be culturally appropriate, to be administered in accessible primary care settings and to provide incentives (Chaudhary & Kreiger, 2007).

McArthur et al (2001) conducted an exploratory study in the US on the socio-economic implications of food labelling. Participants in federal food assistance programs (n=130) and low-income non-participants (n=51) were interviewed about nutrition labels. Regarding label use, 35.4 % of participants and 45.1% of non-participants reported that they seldom/never read labels while 33.1 % of participants and 35.3% of non-participants always/frequently read labels in the grocery store. There were no significant differences between mean scores of participants and non-participants on how to use the nutrition label. Nutritionists working with low-income individuals need to provide more learning opportunities that teach how to use nutrition labels.

Sullivan (2003) conducted a similar but smaller qualitative study in Canada. The study used a facilitated group approach and involved semi-structured open-ended questions which provided flexibility and insight into how participants regarded the food label. The author found that low-income consumers need assistance in understanding the total label and in overcoming distrust and a suspicion that labels are deceptive. The author states that the food-buying challenge is greater for low-income consumers due to a restricted food budget compounded by knowledge gaps and food-label misunderstanding.

Summary - Cost effectiveness and socio-economic implications

- Lifestyle interventions, metformin and acarbose are cost-effective in people at high risk of developing diabetes.
- RCTs have shown that lifestyle changes can prevent or delay the development of diabetes at costs acceptable to society.
- These models are based on assumptions regarding long term health outcomes.
- Future lifestyle modification programs for low socio economic people at high risk of diabetes are needed to generate evidence of its effectiveness and to inform implementation of such interventions.
- In absence of specific strategies targeting low socio economic people, strategies aimed at general populations are recommended.

Evidence Tables: Section 4

Cost-effectiveness of prevention of type 2 diabetes

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Ackermann et al (2006)	N/A	Modelling (Markov Model)	N/A	N/A	N/A
Caro et al (2004)	N/A	Modelling (simulation model)	N/A	N/A	N/A
Colagiuri & Walker (2008)	N/A	Modelling (Cost-Benefit Model)	N/A	N/A	N/A
DPP Research Group (2003)	II	RCT	High	High	High
Eddy et al (2005)	N/A	Modelling (Archimedes Model)	N/A	N/A	N/A
Herman et al (2005)	N/A	Modelling (Markov Model)	N/A	N/A	N/A
Icks et al (2007)	N/A	Modelling (Decision Analytic Model)	N/A	N/A	N/A
Jacobs-van der Bruggen et al * (2007)	N/A	Modelling	N/A	N/A	N/A
Josse et al (2006)	N/A	Review	Low	Medium	Medium
Lindgren et al (2007)	N/A	Modelling (simulation model)	N/A	N/A	N/A
Palmer et al (2004)	N/A	Modelling (Markov Model)	N/A	N/A	N/A
Quilici et al (2005)	II	RCT	High	High	High
Ramachandran et al (2007)	II	RCT	High	High	Medium

* The National Institute for Public Health and the Environment Chronic Diseases

Socio-economic implications of prevention of type 2 diabetes

Author (year)	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Chaudhary & Kreiger (2007)	III-2	Systematic Review of observational studies	Low	N/A	High
MaArthur et al (2001)	III-3	Cross-sectional study	Medium	Low	Medium
Sullivan (2003)	III-3	Cross-sectional study	Low	Low	Medium

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Appendices

Appendix 1: The Australian Type 2 Diabetes Risk Assessment Tool

The Australian Type 2 Diabetes Risk Assessment Tool (AUSDRISK)

1. Your age group?

Under 35 years	0 points
35 – 44 years	2 points
45 – 54 years	4 points
55 – 64 years	6 points
65 years or over	8 points

2. Your gender?

Female	0 points
Male	3 points

3. Ethnicity/Country of birth:

3a. Are you of Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent?

No	0 points
Yes	2 points

3b. Where were you born?

Asia (including the Indian sub-continent), Middle East, North Africa, Southern Europe	2 points
Other	0 points

4. Have either of your parents, or any of your brothers or sisters been diagnosed with diabetes (type 1 or type 2)?

No	0 points
Yes	3 points

5. Have you ever been found to have high blood glucose (sugar) (for example, in a health examination, during an illness, during pregnancy)?

No	0 points
Yes	6 points

6. Are you currently taking medication for high blood pressure?

No	0 points
Yes	2 points

7. Do you currently smoke cigarettes or any other tobacco products on a daily basis?

No	0 points
Yes	2 points

8. How often do you eat vegetables or fruit?

Everyday	0 points
Not everyday	1 point

9. On average, would you say you do at least 2.5 hours of physical activity per week (for example, 30 minutes a day on 5 or more days a week)?

Yes	0 points
No	2 points

10. Your waist measurement taken below the ribs (usually at the level of the navel)?

For those of Asian or Aboriginal or Torres Strait Islander descent:

Men	Women	
Less than 90 cm	Less than 80 cm	0 points
90 – 100 cm	80 – 90 cm	4 points
More than 100 cm	More than 90 cm	7 points

For all others:

Men	Women	
Less than 102 cm	Less than 88 cm	0 points
102 – 110 cm	88 – 100 cm	4 points
More than 110 cm	More than 100 cm	7 points

Add up your score

Your risk of developing type 2 diabetes within 5 years*:

Less than 5: Low risk

Approximately one person in every 100 will develop diabetes.

6-14: Intermediate risk

For scores of 6-8, approximately one person in every 50 will develop diabetes.

For scores of 9-14, approximately one person in every 20 will develop diabetes.

15 or more: High risk

For scores of 15-19, approximately one person in every seven will develop diabetes.

For scores of 20 and above, approximately one person in every three will develop diabetes.

If you scored 15 or more points, it is important that you discuss your score with your doctor.

*The overall score may overestimate the risk of diabetes in those aged less than 25 years and underestimate the risk of diabetes in people of Aboriginal and Torres Strait Islander descent.

The Australian Type 2 Diabetes Risk Assessment Tool was originally developed by the International Diabetes Institute on behalf of the Australian, State and Territory Governments as part of the COAG Diabetes reducing the risk of type 2 diabetes initiative.

Appendix 2

Guideline Search Strategy and Yield

Electronic databases searched:

- Medline
- EMBASE
- Cochrane Library
- CINAHL
- NHS Economic Evaluation Database 3rd Quarter 2008, for question 4 (cost effectiveness)

Other:

- Report/publications that did not appear in the search but were suggested by members of the Expert Advisory Group

Terms used to search the databases:

Detailed in search strategy tables (Appendix 4). The tables include search terms used for Medline search. These search terms have been modified as appropriate for other databases.

Search inclusion criteria:

See general and specific inclusion and exclusion criteria (Appendix 3). This guideline was an update of the Evidence Based Guideline for the Primary Prevention of Type 2 Diabetes that was published in 2001 (searches were ceased in 1999). Searches for the current guideline were limited by the publication years as follows:

- Question 1: 1st January 1999 to 20 March 2008
- Question 2: 1st January 1999 to 14 April 2008
- Question 3: when the database started to 2nd September 2008
- Question 4: when the database started to 21st of July 2008

Abbreviations and explanation of table headings

Identified = number of articles which matched the mesh terms listed or contained the text terms in each particular database

Relevant = those articles considered relevant to the questions being asked after viewing titles or abstracts

Articles identified by other strategies = including articles or reports suggested by the Expert Advisory Group or other experts or public submissions

Total for Review = those articles considered relevant to the question after viewing titles and abstracts, contained original data or were systematic reviews of original articles and met the inclusion/exclusion criteria

Total no. reviewed and graded = articles used to generate the evidence for the identified question . These articles have been summarised and graded

Questions		No. articles identified (all databases combined)	No. relevant articles	Articles identified by other strategies	Total for review	Total no. reviewed and graded	Level I	Level II	Level III	Level IV	Highest level of evidence
1a	Can type 2 diabetes be prevented?	3,637	309		123	11	4	7			I
1b	How can type 2 diabetes be prevented in high risk individuals?	242	72	2*	63	26	12	10	4		I
2	How can individuals at high risk of type 2 diabetes be identified?	1,748	209		38	11		4	7		II
3	What population strategies have been shown to be effective in reducing risk factors for type 2 diabetes?										
	Social marketing (healthy eating)	603	356		14	11			11		III
	Social marketing (physical inactivity)	1,736	748		33	13			13		III
	Community interventions (healthy eating)	6,680	1,780		13	10	1		9		I
	Community interventions (physical inactivity)	6,928	2,430		16	10	1		9		I
	Policy and regulation			10*	10	4			4		III
	Food labelling	627	30	4*	28	13			13		III
4	Is prevention cost-effective? What are the socio-economic implications?	49 13	31 7		13 7	13 7					N/A

* Reports/publications that did not appear in the search but were suggested by members of the Expert Advisory Group.

Appendix 3: Generic Inclusion Criteria used to determine the suitability of articles for review

Inclusion criteria

The following are the criteria of articles to be included in the literature review:

- Present original data or reviews of original data
- Focus on type 2 diabetes or include a cohort with type 2 diabetes
- Address one or more of the specified research question
- Applicable to diabetes care or prevention in Australia
- Conducted in humans
- Conducted in appropriate population for the question being addressed
- Other specific inclusion criteria for each guideline

Exclusion criteria

- Studies of inappropriate patient population
- Articles and reviews which present the author's opinion rather than evidence
- Small review articles where the material is covered more adequately by more recent/or more comprehensive reviews
- In vitro and animal studies
- Genetic studies that are not clinically applicable

Specific criteria used to determine the suitability of articles for review (Primary Prevention guideline)

- Interventions that focus on primary prevention of type 2 diabetes
- Where two or more articles appear to report data from the same group of subjects, only the most complete article should be used to generate data for the analyses
- The sample size should be 100 or more
- The duration of the study – 12 months or more (intervention or follow-up)
- Exclude studies of inappropriate populations (small studies in populations not relevant to the Australian population)
- Post hoc analyses unless they provide significant additional information not already covered in the original study report
- For question 3 (population strategies), due to limited number of studies and that issue have not been addressed in previous guideline, the following criteria were applied:
    - search years: when the database started until July 2008
    - all study types were included – whether systematic reviews, pre-post studies, cohort studies, population studies, etc.
    - intervention – social marketing; mass media campaign, community-wide intervention or policy change.
    - outcome – enhanced/ improved health risk behaviours, specifically, physical activity/ and or nutrition
    - interventions that were individually based (not community based) or those targeting children (school based) were excluded.

Appendix 4: Search Strategies and Terms

Question 1:

Can type 2 diabetes be prevented? If yes,
How can type 2 diabetes be prevented in high risk individuals?

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	120874
2	Primary Prevention/	10282
3	and/1-2	390
4	prevent$.tw.	621678
5	1 and (2 or 4)	8413
6	randomized controlled trial.pt.	263468
7	5 and 6	459
8	animals/ not (animals/ and humans/)	3247594
9	7 not 8	459
10	limit 9 to yr=1999-2007	329

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	120874
2	Primary Prevention/	10282
3	and/1-2	390
4	prevent$.tw.	621678
5	1 and (2 or 4)	8413
6	meta-analysis.pt.	19286
7	meta-anal$.tw.	21932
8	metaanal$.tw.	783
9	quantitativ$ review$.mp. or quantitative$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	406
10	systematic$ review$.mp. or systmatic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	15902
11	methodologic$ review$.mp. or methodologic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	196
12	review.pt. and medline.tw.	19685
13	6 or 7 or 8 or 9 or 10 or 11 or 12	53738
14	5 and 13	211
15	limit 14 to yr=1999-2007	180
16	limit 15 to english language	164

Prevention – lifestyle interventions

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	120874
2	Primary Prevention/	10282
3	and/1-2	390
4	prevent$.tw.	621678
5	1 and (2 or 4)	8413
6	meta-analysis.pt.	19286
7	meta-anal$.tw.	21932
8	metaanal$.tw.	783
9	quantitativ$ review$.mp. or quantitative$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	406
10	systematic$ review$.mp. or systmatic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	15902
11	methodologic$ review$.mp. or methodologic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	196
12	review.pt. and medline.tw.	19685
13	6 or 7 or 8 or 9 or 10 or 11 or 12	53738
14	5 and 13	211
15	limit 14 to yr=1999-2007	180
16	limit 15 to english language	164
17	exp Obesity/dh [diet therapy]	4281
18	limit 17 to yr="1999 - 2008"	1783
19	exp Diet, fat-restricted/	1971
20	limit 19 to yr="1999 - 2008"	1356
21	exp diet, reducing/	7882
22	limit 21 to yr="1999 - 2008"	2412
23	exp diet therapy/	32692
24	limit 23 to yr="1999 - 2008"	9956
25	exp fasting/	23795
26	limit 25 to yr="1999 - 2008"	6620
27	(diet or diets or dieting).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	234583
28	limit 27 to yr="1999 - 2008"	85191
29	(diet$ adj (modif$ or therapy or intervention$ or strateg$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	15343
30	limit 29 to yr="1999 - 2008"	3863
31	(low calorie or calorie control$ or healthy eating).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	2603
32	limit 31 to yr="1999 - 2008"	1456
33	exp dietary fats/	57096
34	limit 33 to yr="1999 - 2008"	20038
35	(fruit$ or vegtable$).mp. [mp=title, original title, abstract, name	37794

	of substance word, subject heading word]	
36	limit 35 to yr="1999 - 2008"	23408
37	(high fat$ or low fat$ or fatty food$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	13851
38	limit 37 to yr="1999 - 2008"	7537
39	food, formulated/ or formula diet.mp.	4999
40	limit 39 to yr="1999 - 2008"	1308
41	exp exercise/	61673
42	limit 41 to yr="1999 - 2008"	34469
43	exp exercise therapy/	18536
44	limit 43 to yr="1999 - 2008"	7520
45	(aerobics or physical therapy or physical activity or physical inactivity).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	53555
46	limit 45 to yr="1999 - 2008"	28091
47	(fitness adj (class$ or regime$ or program$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	497
48	limit 47 to yr="1999 - 2008"	163
49	(aerobics or physical therapy or physical training or physical education).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	38547
50	limit 49 to yr="1999 - 2008"	13077
51	sedentary behavio$r reduction.mp.	1
52	limit 51 to yr="1999 - 2008"	1
53	sedentary behavio$r.mp.	234
54	limit 53 to yr="1999 - 2008"	213
55	or/17-54	420412
56	16 and 55	37

Prevention – pharmacological interventions

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	121035
2	Primary Prevention/	10289
3	and/1-2	390
4	prevent$.tw.	622504
5	1 and (2 or 4)	8425
6	meta-analysis.pt.	19327
7	meta-anal$.tw.	21993
8	metaanal$.tw.	784
9	quantitativ$ review$.mp. or quantitative$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	406
10	systematic$ review$.mp. or systmatic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	15963
11	methodologic$ review$.mp. or methodologic$ overview$.tw. [mp=title, original title, abstract, name of substance word, subject heading word]	196
12	review.pt. and medline.tw.	19733
13	6 or 7 or 8 or 9 or 10 or 11 or 12	53880
14	5 and 13	212
15	limit 14 to yr=1999-2007	180
16	limit 15 to english language	164
17	exp Drug Therapy/	418999
18	pharmacotherapy.tw.	11442
19	pharmaco$.tw.	273186
20	((drug$ or medication) adj5 (therap$ or treatment$ or administration)).tw.	153282
21	17 or 18 or 19 or 20	783140
22	5 and 16 and 21	36

Prevention – Surgical interventions

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	121035
2	Primary Prevention/	10289
3	and/1-2	390
4	prevent$.tw.	622504
5	1 and (2 or 4)	8425
6	randomized controlled trial.pt.	263783
7	5 and 6	461
8	animals/ not (animals/ and humans/)	3250104
9	7 not 8	461
10	limit 9 to yr=1999-2007	329
11	exp Gastroplasty/	2787
12	limit 11 to yr="1999 - 2008"	2198
13	gastrectomy/ or gastric surgery.mp.	22766
14	limit 13 to yr="1999 - 2008"	4181
15	exp Gastric Bypass/ or gastric band$.mp.	4532
16	limit 15 to yr="1999 - 2008"	4069
17	lap-band.mp.	272
18	limit 17 to yr="1999 - 2008"	252
19	roux-en-y.mp. or exp Anastomosis, Roux-en-Y/	4418
20	limit 19 to yr="1999 - 2008"	2700
21	exp Biliopancreatic Diversion/	656
22	limit 21 to yr="1999 - 2008"	503
23	biliopancreatic bypass.mp.	47
24	limit 23 to yr="1999 - 2008"	10
25	gastro$gastrostomy.mp.	22
26	limit 25 to yr="1999 - 2008"	3
27	restrictive surgery.mp.	88
28	limit 27 to yr="1999 - 2008"	70
29	malabsorptive surgery.mp.	8
30	limit 29 to yr="1999 - 2008"	8
31	bariatric surgery.mp.	2877
32	limit 31 to yr="1999 - 2008"	2719
33	(jejuonoileal bypass or jejuno-ileal bypass).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	201
34	limit 33 to yr="1999 - 2008"	19
35	or/11-34	32007
36	10 and 35	0
37	5 and 35	32

Question 2:

How can individuals at high risk of type 2 diabetes be identified?

	Searches	Result
1	diabetes mellitus/ or diabetes mellitus, type 2/	120874
2	Mass Screening/	61921
3	screen$.tw.	282678
4	Risk Assessment/	94571
5	risk score$.tw.	2620
6	high risk.tw.	99690
7	or/2-6	476944
8	1 and 6 and 7	2358
9	limit 8 to (yr="1999 - 2008" and "all adult (19 plus years)")	1175

Question 3:

What population strategies have been shown to be effective in reducing risk factors for type 2 diabetes?

Social Marketing – Nutrition and Diet

	Searches	Result
1	exp Obesity/	89386
2	exp Diet, Fat-Restricted/	1968
3	exp Diet, Reducing/	7877
4	(diet or diets or dieting).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	234395
5	(diet$ adj (modif$ or therapy or intervention$ or strateg$)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	15341
6	(low calorie or calorie control$ or healthy eating).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	2597
7	exp Dietary Fats/	57050
8	(fruit$ or vegetable$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	53457
9	(high fat$ or low fat$ or fatty food$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	13831
10	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9	378385
11	exp Social Marketing/	827
12	exp "Marketing of Health Services"/	13286
13	Mass Media/	6701
14	campaign$.tw.	15927
15	11 or 12 or 13 or 14	34410
16	10 and 15	733
17	limit 16 to "all adult (19 plus years)"	319

Social Marketing Physical activity

	Searches	Result
1	exp exercise/	61590
2	exp leisure activities/	103704
3	Physical Fitness/	16308
4	exp motor activity/	78430
5	physical activit$.tw.	28548
6	exercis$.tw.	137514
7	1 or 2 or 3 or 4 or 5 or 6	305695
8	exp health promotion/	34689
9	exp "marketing of health services"/	13286
10	Community Health Services/	22935
11	Consumer Participation/	11219
12	Health Education/	44766
13	Mass Media/	6701
14	Health Behavior/	19181
15	campaign$.tw.	15927
16	consumer health education.mp.	43
17	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16	148283
18	7 and 17	10584
19	limit 18 to "all adult (19 plus years)"	5804
20	9 or 13 or 15	34410
21	7 and 20	850

Community intervention – Nutrition & Diet

	Searches	Result
1	exp diet therapy/	32669
2	(diet or diets or dieting).tw.	168072
3	(low calorie or calorie control$ or healthy eating).tw.	2597
4	fat intake.tw.	3974
5	exp dietary fats/	57050
6	(fruit$ or vegetable$).tw.	40530
7	(high fat$ or low fat$ or fatty food$).tw.	13831
8	exp health promotion/	34689
9	((community or consumer) and (education or program$ or campaign$ or promotion)).tw.	44494
10	Community Health Services/	22935
11	(consumer participation or consumer education).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	11432
12	(health education or education).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	409024
13	1 or 2 or 3 or 4 or 5 or 6 or 7	254406
14	8 or 9 or 10 or 11 or 12	480105
15	13 and 14	10171
16	limit 15 to "all adult (19 plus years)"	5178

Community intervention – Physical activity

	Searches	Result
1	exp exercise/	61590
2	exp leisure activities/	103704
3	Physical Fitness/	16308
4	exp motor activity/	78430
5	physical activit$.tw.	28548
6	exercis$.tw.	137514
7	1 or 2 or 3 or 4 or 5 or 6	305695
8	exp health promotion/	34689
9	Community Health Services/	22935
10	Consumer Participation/	11219
11	Health Education/	44766
12	consumer health education.mp.	43
13	8 or 9 or 10 or 11 or 12	105019
14	7 and 13	6556
15	limit 14 to "all adult (19 plus years)"	3143

Food Labelling

	Searches	Result
1	Food/ or Food Labelling/	20114
2	Limit 1 to English language	16757
3	Nutrient.mp. or Food/	52300
4	Limit 3 to English language	46223
5	Nutrition.mp.	109899
6	Limit 5 to English language	86047
7	Ingrident.mp.	6049
8	Limit 7 to English language	5555
9	Label.mp.	47456
10	Limit 9 to English language	45807
11	Panel.mp.	51102
12	Limit 11 to English language	49131
13	Information.mp.	518302
14	Limit 13 to English language	470149
15	Pack.mp.	5463
16	Limit 15 to English language	5061
17	Consumer.mp.	46744
18	Limit 17 to English language	43726
19	Purchaser.mp.	472
20	Limit 19 to English language	459
21	Point-of-purchase.mp.	92
22	Limit 23 to English language	92
23	Point of choice.mp.	30
24	Limit 23 to English language	30
25	Choice.mp.	154102
26	Limit 25 to English language	126341
27	8 or 6 or 4 or 2	132224
28	16 or 10 or 12 or 14	564286
29	22 or 18 or 24 or 26 or 20	168606
30	27 and 28 and 29	627

Question 4:
Is prevention cost-effective?
(NHS Economic Evaluation Database 3rd Quarter 2008)

#	Searches	Results
1	exp "Costs and Cost Analysis"/	19762
2	primary prevention/	99
3	prevent$.tw.	2933
4	exp diabetes mellitus , type 2/	341
5	2 or 3	2933
6	1 and 4 and 5	59
7	limit 6 to English language	49
8	from 7 keep 15, 23, 25-27, 30, 32-33, 36-37...	12

Appendix 5: NHMRC Evidence Statement Grading Forms

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q 1a. Can type 2 diabetes be prevented? If Yes, 1b. How can type 2 diabetes be prevented in high risk individuals?		**Evidence table ref: Section 1**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Progression to type 2 diabetes in high risk individuals can be prevented or delayed. (4 systematic reviews, 7 RCTs) (Level A). Lifestyle modification including increasing physical activity, improving diet, and weight loss are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals. (8 systematic reviews, 5 RCTs) (Level A) Weight loss, physical activity and dietary modification contribute to reducing the risk of developing type 2 diabetes. (8 systematic reviews, 5 RCTs) (Level A). Lifestyle interventions in people with impaired glucose tolerance (IGT) reduce progression to type 2 diabetes beyond the intervention period. (2 RCTs) (Level B)	**A**	**Several Level I or II studies with low risk of bias**
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	~~C~~	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	A	**All studies consistent**
	~~B~~	**Most studies consistent and inconsistency can be explained**
	~~C~~	**Some inconsistency, reflecting genuine uncertainty around question**
	~~D~~	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	A	**Very large**
	~~B~~	**Moderate**
	~~C~~	**Slight**

	~~D~~	**Restricted**
4. Generalisability		
	A	**Evidence directly generalisable to target population**
	~~B~~	**Evidence directly generalisable to target population with some caveats**
	~~C~~	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	~~C~~	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	A	
2. Consistency	A	
3. Clinical impact	A	
4. Generalisability	A	
5. Applicability	A	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade A**	

Lifestyle modification that focus on increased physical activity, dietary change and weight loss should be offered to all individuals at high risk of developing type 2 diabetes.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	**YES**
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	**YES**
Are the guideline development group aware of any barriers to the implementation of this recommendation?	
	NO

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q 1a. Can type 2 diabetes be prevented? If Yes, 1b. How can type 2 diabetes be prevented in high risk individuals?			**Evidence table ref: Section 1**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*			
Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) are effective in preventing/delaying the onset of type 2 diabetes in high risk individuals. (7 Systematic reviews, 3 RCTs) (Level A)	**A**	**Several Level I or II studies with low risk of bias**	
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**	
	~~C~~	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**	
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**	
2. Consistency *(if only one study was available, rank this component as 'not applicable')*			
	~~A~~	**All studies consistent**	
	B	**Most studies consistent and inconsistency can be explained**	
	~~C~~	**Some inconsistency, reflecting genuine uncertainty around question**	
	~~D~~	**Evidence is inconsistent**	
	NA	**Not applicable (one study only)**	
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*			
	~~A~~	**Very large**	
	B	**Moderate**	
	~~C~~	**Slight**	

	~~D~~	**Restricted**
4. Generalisability		
	~~A~~	**Evidence directly generalisable to target population**
	B	**Evidence directly generalisable to target population with some caveats**
	~~C~~	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	~~A~~	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	C	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	A	
2. Consistency	B	
3. Clinical impact	B	
4. Generalisability	B	
5. Applicability	C	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade B**	

Pharmacological interventions (including metformin, acarbose, rosiglitazone and orlistat) could be considered in people at high risk of developing type 2 diabetes

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	**YES**
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q 1a. Can type 2 diabetes be prevented? If Yes, 1b. How can type 2 diabetes be prevented in high risk individuals?		**Evidence table ref: Section 1**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Bariatric surgery can prevent/delay progression to type 2 diabetes in people who are morbidly obese. (1 Systematic review, 4 case-control / cohort prognosis studies) (Level III)	A	**Several Level I or II studies with low risk of bias**
	B	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	C	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	D	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	A	**All studies consistent**
	B	**Most studies consistent and inconsistency can be explained**
	C	**Some inconsistency, reflecting genuine uncertainty around question**
	D	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some unknown factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	A	**Very large**
	B	**Moderate**
	C	**Slight**

	~~D~~	**Restricted**
4. Generalisability		
	~~A~~	**Evidence directly generalisable to target population**
	~~B~~	**Evidence directly generalisable to target population with some caveats**
	C	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	~~A~~	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	C	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	C	
2. Consistency	A	
3. Clinical impact	A	
4. Generalisability	C	
5. Applicability	C	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade C**	

Bariatric surgery can be considered in selected morbidly obese individuals (based on weight alone or the presence of co-morbidities) at high risk of type 2 diabetes.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	**YES**
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	**YES**
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q2. How can individuals at high risk of type 2 diabetes be identified?		**Evidence table ref: Section 2**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Risk assessment tools using basic clinical information (age, sex, ethnicity, family history of diabetes, hypertension and anthropometric measurements) without laboratory testing identify people at high risk of diabetes. (4 Cohort Prognostic studies level II) The inclusion of laboratory measures (fasting glucose, HDL cholesterol, triglycerides) improve the performance of risk assessment tools in identifying individuals at high risk of diabetes. (5 Cohort Prognostic studies level III) Risk assessment tools for identifying people at increased risk of type 2 diabetes are feasible and effective for use in community settings. (Cohort Prognostic studies level III)	~~A~~	**Several Level I or II studies with low risk of bias**
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	C	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	A	**All studies consistent**
	~~B~~	**Most studies consistent and inconsistency can be explained**
	~~C~~	**Some inconsistency, reflecting genuine uncertainty around question**
	~~D~~	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	A	**Very large**
	~~B~~	**Moderate**
	~~C~~	**Slight**

	~~D~~	**Restricted**
4. Generalisability		
	A	**Evidence directly generalisable to target population**
	~~B~~	**Evidence directly generalisable to target population with some caveats**
	~~C~~	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	~~C~~	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	C	
2. Consistency	A	
3. Clinical impact	A	
4. Generalisability	A	
5. Applicability	A	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade C**	

Individuals at high risk of diabetes should be identified through the use of risk assessment tools.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	**YES**
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	
	NO

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q3. What population strategies have been shown to be effective in reducing lifestyle risk factors for type 2 diabetes?		**Evidence table ref: Section 3**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Sustained, well-executed social marketing can be effective in increasing physical activity, improving nutrition knowledge, attitudes and eating behaviour in a range of target groups, in different settings. (Level III) Mass media campaigns increase awareness, and improve knowledge and attitudes around physical activity and healthy eating and may have a short term effect on physical activity behaviour in some individuals. (Level III) Media-only approaches may be sufficient to encourage a significant proportion of people to alter their dietary habits and contribute to weight control at the population level. (Level III) Mass media campaigns enhance the success of community-based interventions. (Level III)	~~A~~	**Several Level I or II studies with low risk of bias**
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	C	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	~~A~~	**All studies consistent**
	~~B~~	**Most studies consistent and inconsistency can be explained**
	~~C~~	**Some inconsistency, reflecting genuine uncertainty around question**
	D	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	~~A~~	**Very large**
	~~B~~	**Moderate**

	~~C~~	**Slight**
	D	**Restricted**
4. Generalisability		
	~~A~~	**Evidence directly generalisable to target population**
	B	**Evidence directly generalisable to target population with some caveats**
	~~C~~	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	~~C~~	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	C	
2. Consistency	D	
3. Clinical impact	D	
4. Generalisability	B	
5. Applicability	A	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade C**	

Social marketing should be considered as part of a comprehensive approach to reduce risk factors for type 2 diabetes at the population level.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	
	NO
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q3. What population strategies have been shown to be effective in reducing lifestyle risk factors for type 2 diabetes?		**Evidence table ref: Section 3**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Well-designed community-based intervention programs can improve lifestyle choices and health habits such as increase physical activity and healthy eating. (Level III) Worksite interventions which involve family members can improve dietary habits. (Level III) Worksite health promotion programs that include environmental modifications can influence dietary intake. (Level III)	~~A~~	**Several Level I or II studies with low risk of bias**
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	C	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	~~A~~	**All studies consistent**
	~~B~~	**Most studies consistent and inconsistency can be explained**
	C	**Some inconsistency, reflecting genuine uncertainty around question**
	~~D~~	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	~~A~~	**Very large**
	~~B~~	**Moderate**
	C	**Slight**

	~~D~~	**Restricted**
4. Generalisability		
	~~A~~	**Evidence directly generalisable to target population**
	~~B~~	**Evidence directly generalisable to target population with some caveats**
	C	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	~~C~~	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	C	
2. Consistency	C	
3. Clinical impact	C	
4. Generalisability	C	
5. Applicability	A	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade C**	

Community-based interventions should be used in specific settings and target groups (eg schools, workplace, women's groups) as a strategy for reducing diabetes risk factors.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	
	NO
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): Q3. What population strategies have been shown to be effective in reducing lifestyle risk factors for type 2 diabetes?		**Evidence table ref: Section 3**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
Environmental and policy interventions are effective in reducing chronic disease risk factors including smoking, physical inactivity, and unhealthy eating. (*Level III)* Policy regulation such as nutrition information on processed foods has the potential to improve food choices and promote healthy eating at a population level. (*Level III)*	~~A~~	**Several Level I or II studies with low risk of bias**
	~~B~~	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	~~C~~	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	D	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	~~A~~	**All studies consistent**
	~~B~~	**Most studies consistent and inconsistency can be explained**
	C	**Some inconsistency, reflecting genuine uncertainty around question**
	~~D~~	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
N/A	A	**Very large**
	B	**Moderate**
	C	**Slight**
	D	**Restricted**
4. Generalisability		
	~~A~~	**Evidence directly generalisable to target population**
	~~B~~	**Evidence directly generalisable to target population with some caveats**

	C	**Evidence not directly generalisable to the target population but could be sensibly applied**
	~~D~~	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	~~C~~	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	D	
2. Consistency	C	
3. Clinical impact	N/A	
4. Generalisability	C	
5. Applicability	A	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.	**Grade D**	

The impact of the built environment on physical activity and food quality and availability should be considered in all aspects of urban planning and design.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	
	NO
Are there any resource implications associated with implementing this recommendation?	**YES**
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**

NHMRC Evidence Statement
(If rating is not completely clear, use the space next to each criteria to note how the group came to a judgment.)

Key question(s): a) Is prevention of type 2 diabetes cost-effective? b) What are the socio-economic implications of prevention of type 2 diabetes?		**Evidence table ref: Section 4**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
(Based on 10 modelling studies and 3 RCTs) Lifestyle modification can prevent or delay the development of diabetes at costs acceptable to society. Lifestyle modification interventions are cost-effective and cost saving in people at high risk of developing diabetes. Metformin and acarbose are cost-effective pharmacological interventions in people at high risk of developing diabetes. Lifestyle modification interventions are often more cost-effective than pharmacological interventions. Cost-effectiveness of lifestyle modification interventions and mefformin improves when the interventions are implemented in routine clinical practice.	~~A~~	**Several Level I or II studies with low risk of bias**
	B	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	~~C~~	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	~~D~~	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	~~A~~	**All studies consistent**
	B	**Most studies consistent and inconsistency can be explained**
	~~C~~	**Some inconsistency, reflecting genuine uncertainty around question**
	~~D~~	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
N/A	A	**Very large**
	B	**Moderate**
	C	**Slight**

	D	**Restricted**
4. Generalisability		
No Australian economic evaluation.	A	**Evidence directly generalisable to target population**
	B	**Evidence directly generalisable to target population with some caveats**
	C	**Evidence not directly generalisable to the target population but could be sensibly applied**
	D	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	~~A~~	**Evidence directly applicable to Australian healthcare context**
	~~B~~	**Evidence applicable to Australian healthcare context with few caveats**
	C	**Evidence probably applicable to Australian healthcare context with some caveats**
	~~D~~	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
1. Evidence base	B	
2. Consistency	B	
3. Clinical impact	N/A	
4. Generalisability	D	
5. Applicability	C	

Indicate any dissenting opinions

RECOMMENDATION	GRADE OF RECOMMENDATION	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.		
To be optimally cost-effective and cost saving in the long term, interventions to prevent diabetes should focus on lifestyle modification.*		

* NHMRC Evidence Hierarchy does not assign a level of evidence to economic evaluation studies that are based on modelling. Grading could not be determined using the NHMRC matrix.

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	
	NO
Are there any resource implications associated with implementing this recommendation?	
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	
	NO

Appendix 6: Overview of Guideline Development Process and Methods

National Evidence Based Guidelines for the Prevention and Management of Type 2 Diabetes

Overview of Guideline Development Process

and

Methods

Prepared by
The Diabetes Unit
Menzies Centre for Health Policy
The University of Sydney

for the
Diabetes Australia Guideline Development Consortium

Last updated 5 May 2009

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Purpose and Structure of the Document

Purpose

This 2008-9 series of guidelines for type 2 diabetes updates and builds on the original suite of evidence based diabetes guidelines which were initiated in 1999 under funding from the Department of Health and Ageing (DoHA) to the Diabetes Australia (DA) Guideline Development Consortium. Under the initial diabetes guideline project, six evidence based guidelines for type 2 diabetes were endorsed by the NHMRC. The purpose of the initial guidelines and the current guidelines is to provide systematically derived, objective guidance to:

1. Improve quality and consistency of care and reduce inappropriate variations in practice by assisting clinicians' and consumers' understanding of and decisions about treatment and management options
2. Inform fund holders and health service planners about the effectiveness and feasibility of the various options
3. Assist researchers and research authorities to highlight i) areas of diabetes prevention and care for which there is inconclusive evidence and ii) areas of deficiency in the evidence which require further or definitive research.

The specific purpose of this current project which commenced in early 2008 was to update two of the previous guidelines - Primary Prevention, and Case Detection and Diagnosis – and to develop three new guidelines, one for Blood Glucose Control, one for Chronic Kidney Disease and one for Patient Education.

Structure

This *Overview of the Guideline Development Process and Methods* outlines the rationale for the guidelines and the organisational structure, methods and processes adopted for the Type 2 Diabetes Guideline project, including the Blood Glucose Control Guideline. The guidelines are structured to present the recommendations, practice points, evidence statements, documentation of search strategies and search yield and a textual account of the evidence underpinning each recommendation.

Final format and implementation

The contract between the DoHA and the DA Guideline Development Consortium makes provision for locating and synthesising the available evidence on the five index areas into guideline recommendations and describing the objective justification for the recommendations. Thus, the contract covers the development of the guidelines up to and including endorsement by the NHMRC but does not include implementation of the guidelines.

However, following endorsement by the NHMRC there will need to be an independent process of consultation with potential guideline users to determine the final format of the guidelines for wide dissemination to clinicians and consumers. Once this format has been agreed, an implementation strategy to encourage and facilitate the widespread uptake of the guidelines in everyday practice will need to be developed and actioned at national and state

and territory level. It is our understanding that the DoHA has developed an implementation plan and strategies and is currently obtaining internal sign-off on these before enacting them.

1.0 Introduction and Overview

1.1 Diabetes as a health burden

Results of the national diabetes prevalence survey, AusDiab (Dunstan et al, 2002), which was conducted on representative sample of some 11,000 people across Australia, found a prevalence of diabetes of 7.4% in people aged 25 years or older. Another 16.4% of the study population had either impaired glucose tolerance or impaired fasting glucose. AusDiab also confirmed that there is one person with undiagnosed diabetes for every person with diagnosed diabetes. Findings from the second phase of AusDiab, a 5-year follow-up survey of people who participated in the baseline study, have indicated that every year eight out of every 1,000 people in Australia developed diabetes (Barry et al, 2006). This, together with the increasing number of new cases of pre-diabetes, obesity, the metabolic syndrome, and kidney disease, has demonstrated that abnormal glucose metabolism is exerting a major impact on the health of Australians (Magliano et al, 2008).

Diabetes has a demonstrably high health and cost burden (Colagiuri et al, 2003; AIHW, 2008) resulting from its long term complications which include:

- heart disease and stroke
- foot ulceration, gangrene and lower limb amputation
- kidney failure
- visual impairment up to and including blindness
- erectile dysfunction

The health burden of diabetes is described in more detail throughout the guideline series but to put these complications in perspective, it is worth noting here that, in Australia, diabetes is the most common cause of:

- blindness in people under the age of 60 years
- end stage kidney disease
- non-traumatic amputation

Diabetes is heavily implicated in deaths from cardiovascular disease (CVD) but, due to death certificate documentation deficiencies; this link is believed to be substantially under reported. At a global level, diabetes is predicted to increase dramatically in the next decade or two (IDF, 2006). With an ageing and increasingly overweight and physically inactive population, and a cultural mix comprising numerous groups known to be at high risk of type 2 diabetes, Australia is a prime candidate for realising the projected increases.

Due to sheer numbers, the major proportion of the total diabetes burden is attributable to type 2 diabetes which is the most common form of diabetes and accounts for approximately 85% of all diabetes in Australia. Type 2 diabetes occurs predominantly in mature adults with the prevalence increasing in older age groups. However, in high risk populations such as Aboriginal and Torres Strait Islander people it may become manifest much earlier.

These guidelines focus exclusively on type 2 diabetes in non-pregnant adults. Like type 1 diabetes, type 2 diabetes is characterised by high blood glucose levels. However, unlike type 1 diabetes, the key feature of type 2 diabetes is insulin resistance rather than insulin deficiency. Consequently, its treatment does not necessarily require insulin and in many people, particularly in the initial years following diagnosis, type 2 diabetes can be successfully

managed with dietary and general lifestyle modification alone or in combination with oral anti-diabetic medications. Insulin therapy may be required if and when oral medication becomes ineffective in lowering and maintaining the blood glucose within an acceptable range. Assiduous attention to the management of elevated blood pressure, lipid problems and overweight is also required as these common features of type 2 diabetes markedly increase the risk of long term complications.

1.2 Key components and principles of diabetes care

Key components of care
In 1995, the NSW Health Department identified three key components of diabetes care, stating that …. 'there is consensus supported by published literature that diabetes care and outcomes can be improved by providing access for all people with diabetes to:

- information about their condition and self care education
- ongoing clinical care to provide optimal metabolic control
- screening for and appropriate treatment of complications' (Colagiuri R et al, 1995).

These and the principles of care below were included in the initial suite of guidelines for type 2 diabetes and remain as valid now as they were then.

Principles of care
The particular expression of the universally accepted diabetes care principles set out below was abbreviated from those developed by the UK Clinical Advisory Group (CSAG, 1994) and later summarised by the NSW Health Expert Panel on Diabetes (New South Wales (NSW) Department of Health, 1996) and was further adapted for this project:

- People with diabetes should have access to timely and ongoing care from a diabetes team. This should ideally include a doctor, nurse and dietitian with specific training and experience in the management of diabetes. Additional expertise, for example in podiatry, social work, behavioural psychology and counselling, should be available as required as should referral access to specialist services for the management of identified complications

- People with diabetes are entitled to access to opportunities for information, education and skills acquisition to enable them to participate optimally in their diabetes management

- People with diabetes are entitled to access high quality health services regardless of their financial status, cultural background, or place of residence

- For people with diabetes from community groups who may have special needs eg people from Aboriginal, Torres Strait Islander or culturally and linguistically diverse backgrounds and the elderly, diabetes care should be specifically tailored to overcoming access barriers and providing opportunities for optimising diabetes care and outcomes

- Diabetes teams should routinely evaluate the effectiveness of the care they provide

1.3 Rationale for the Guidelines

The magnitude of the impact of diabetes on individuals and society in Australia is manifest in its status as a National Health Priority Area since 1996 and the current attention directed to it by the Council of Australian Governments' National Reform Agenda which seeks to address and avert a greater impact on productivity than already exists as a result of diabetes.

For tangible and lasting benefits, evidence based information is required which synthesises new and existing evidence to guide primary prevention efforts and assist clinicians to identify and treat modifiable primary risk factors, accurately diagnose type 2 diabetes, assess metabolic control, provide effective routine care, and make appropriate and timely referrals.

Since the initial suite of NHMRC diabetes guidelines was released there has been a vast improvement in both the volume and quality of the evidence about preventing type 2 diabetes which is detailed in the Primary Prevention Guideline. Nonetheless, there remain grave concerns that the rapidly increasing prevalence of obesity combined with decreasing levels of physical activity will continue to impact negatively on the incidence and prevalence of diabetes unless addressed as a matter of urgency. Consequently, the Primary Prevention Guideline also cites some of the emerging evidence about environmental influences on food consumption and physical activity.

Type 2 diabetes represents a complex interaction of patho-physiological factors and its prevention and successful management requires clinicians and public health practitioners to maintain a thorough understanding of these interactions especially since there is now irrefutable evidence that both the onset of diabetes and the onset of its complications can be prevented or significantly delayed. Given the typically long pre-clinical phase of type 2 diabetes and that half of all people with diabetes are undiagnosed, the Case Detection and Diagnosis Guideline is an important component of this suite of guidelines.

Integral to the successful management of diabetes is self care knowledge and skills, and the capacity of the person with diabetes to adapt their lifestyle to optimise their physical and psychological well being. The Patient Education Guideline presents evidence addressing these issues.

The care of type 2 diabetes is predominantly carried out by general practitioners, often under 'shared care' arrangements with local Diabetes Centres and/or private endocrinologists. In remote Australia, and even in more densely settled rural regions, the population base is insufficient to support specialist diabetes teams and the general practitioner may not have local access to specialist referral and support. Regardless of geographical factors, standards of diabetes clinical care in Australia are known to be variable. The Chronic Kidney Disease Guideline sets out diagnostic criteria and therapies for achieving the treatment targets to guide the identification, prevention and management of kidney disease in people with diabetes.

Microvascular complications (retinopathy, nephropathy and neuropathy) and the increased risk of macrovascular complications (ischemic heart disease, stroke and peripheral vascular disease) are associated with reduced life expectancy and significant morbidity in type 2 diabetes. Using therapeutic interventions to lower blood glucose and achieve optimal HbA1c levels is critical in preventing diabetes complications and improving the quality of life. The Blood Glucose Control Guideline examines the evidence and the relationships among these issues.

1.4 Funding source

The Type 2 Diabetes Guidelines project is funded by the DoHA under a head contract with DA as convenor of the Guideline Development Consortium. The development of the guidelines is managed in partnership with DA by The Diabetes Unit at the University Sydney under the direction of A/Professor Ruth Colagiuri.

1.5 The Guideline Development Consortium

The Guideline Development Consortium led by DA comprises organisations representing consumers, specialist diabetes practitioners and primary care physicians and includes:

- The Australian Diabetes Society (ADS)
- The Australian Diabetes Educators Association (ADEA)
- The Royal Australian College of General Practitioners (RACGP)
- The Diabetes Unit – Menzies Centre for Health Policy (formerly, the Australian Health Policy Institute), the University of Sydney.

Additionally there are a number of collaborators:

- The NSW Centre for Evidence Based Health Care (University of Western Sydney)
- The Cochrane Renal Review Group (Westmead Children's Hospital)
- The Cochrane Consumer Network
- The Caring for Australians with Renal Impairment Guidelines Group (CARI),
- Kidney Health Australia.

1.6 The scope of the Guidelines

The brief for the Guideline Development Project was to prepare a set of evidence based guidelines for type 2 diabetes to NHMRC standard.

The Type 2 Diabetes Guidelines target public health practitioners, clinicians (medical, nursing and allied health), diabetes educators and consumers and were designed to be appropriate for use in a wide variety of practice settings. The guidelines focus on care processes and interventions that are primarily undertaken in the non-acute setting ie they do not deal with highly technical procedural interventions such as renal dialysis.

1.7 Use of the Guidelines

Guidelines are systematically generated statements which are designed to assist health care clinicians and consumers to make informed decisions about appropriate treatment in specific circumstances (Field MJ & Lohr, 1990).

Guidelines are not applicable to all people in all circumstances at all times. The recommendations contained in these guidelines are a general guide to appropriate practice and are based on the best information available at the time of their development. The clinical guidelines should be interpreted and applied on an individual basis in the light of the health care practitioner's clinical experience, common sense, and the personal judgments of consumers about what is appropriate for, and acceptable to them.

1.8 Review date

New information on type 2 diabetes is continually and rapidly becoming available. The Project Management Team and Steering Committee recommend that these guidelines are reviewed and revised at least every three years after publication. We anticipate this will be June 2012.

1.9 Economic analysis

Assessment of economic impact i.e., analysing the cost implications of recommendations has become a mandatory component of guideline development.

1.10 Socio-economic impact

The Expert Advisory Groups for each guideline were encouraged to adopt a framework that is recommended by the NHMRC to identify, appraise and collate evidence of the impact of socioeconomic position and other markers of interest eg income, education, occupation, employment, ethnicity, housing, area of residence, lifestyle, gender.

2.0 Organisational structure and staffing

The organisational structure of the Guideline Development Project (Figure 1) comprises:

- A Steering Committee
- Project Management Team
- Expert Advisory Groups
- Guidelines Assessment Register Consultant
- Research Officers
- Research team

The Steering Committee consists of a representation from each of the Consortium members, the Guideline Project Medical Advisor, and the DoHA. Refer to Appendix i for Terms of Reference. The Project Steering Committee provides guidance and directions to the project and to the DoHA via DA. The main role was to oversee the project progress and timeline.

Expert Advisory Groups (EAGs) were established for each of the five guideline areas. They have a core composition of a consumer, a general practitioner, content experts nominated by the Australian Diabetes Society and the Australian Diabetes Educators Association, and other representation as appropriate. Consumers on the expert advisory groups were provided by Diabetes Australia as being representative of people with type 2 diabetes who are experienced in acting as consumer representatives and who had a detailed understanding of issues affecting people with diabetes. Terms of Reference of the EAGs is provided in Appendix ii. Lists of the individual members of each of the EAGs are provided in each guideline.

The Project Management Team. The Diabetes Unit, at Menzies Centre for Health Policy (formerly, the Australian Health Policy Institute), University of Sydney was subcontracted by DA to manage the project on behalf of the Consortium. The Diabetes Unit provides guidance on methods, technical support, data management, co-ordinates the input of the EAGs and supervises the project staff on a daily basis. The Project Management Team consists of the Director of the Diabetes Unit, the CEO of Diabetes Australia and the project's Medical Advisor.

Guidelines Assessment Register (GAR) consultans. The NHMRC nominated a GAR consultant for each guideline (except the Blood Glucose Control guideline) to provide guideline developers with support in relation to utilising evidence-based findings and applying the NHMRC criteria. Specifically, the GAR consultants provided advice on evaluating and documenting the scientific evidence and developing evidence-based recommendations based on the scientific literature and NHMRC procedures.

Research Officers were recruited or seconded from a variety of research and health care disciplines and given additional training to conduct the literature searches, and review, grade and synthesise the evidence under the supervision of the Senior Research and Project Manager, Dr Seham Girgis, the Chairs of the EAGs and the Project Management Team.

Research Team refers to the Project Director, Senior Project Manager, Research Officers, and the project's Medical Advisor.

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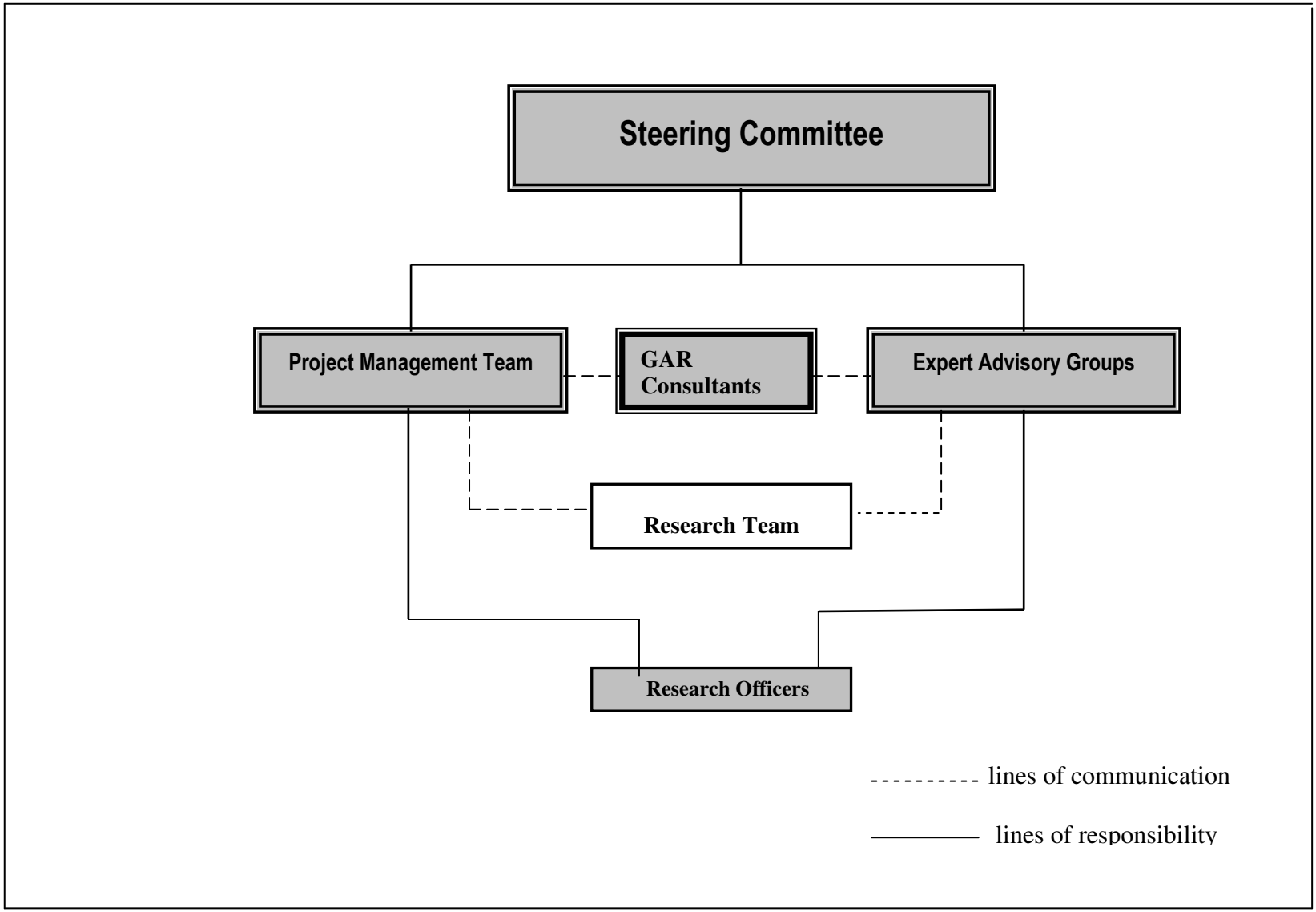
Figure 1: Organisational Structure



3.0 Methods

3.1 Development of Protocols

At the beginning of the project, a Methods Manual was developed for the EAGs and project staff. The Manual was based on the NHMRC *Standards and procedures for externally developed guidelines* (NHMRC, 2007) and the series of handbooks on the development, implementation and evaluation of clinical practice guidelines published by the NHMRC from 2000–03. The NHMRC Standards and procedures document (NHMRC, 2007) introduced an extended set of levels of evidence and an approach to assessing a body of evidence and grading of recommendations. These standards and handbooks have superseded *A guide to the development, implementation and evaluation of clinical practice guidelines* (NHMRC, 1999), which formed the basis of the initial suite of NHMRC guidelines for type 2 diabetes.

The NHMRC has introduced a requirement for guidelines to consider issues related to cost-effectiveness and socioeconomic impact. Two publications in the NHMRC toolkit for developing clinical practice guidelines have been used to address these issues - how to compare the costs and benefits: evaluation of the economic evidence (NHMRC, 2001) and using socioeconomic evidence in clinical practice guidelines (NHMRC, 2003).

The Methods Manual developed for the project contains definitions, procedures and protocols, descriptions of study type classifications, checklists and examples of steps and methods for critical appraisal of the literature. It also includes the revised level of evidence and the minimum requirements for formulating NHMRC evidence based guidelines.

3.2 Guideline Development Process

From the literature and expert opinion the following steps were identified as central to the process of identifying sources of rigorously objective, peer reviewed information and reviewing, grading, and synthesising the literature to generate guideline recommendations:

1. Define specific issues and generate clinically relevant questions to guide the literature searches for each guideline topic.
2. Search the literature systematically using a range of databases and search strategies.
3. Sort the search yield on the basis of relevance to the topic area and scientific rigour.
4. Document the search strategy and the search yield.
5. Critically review, grade and summarise the evidence.
6. Assess the body of evidence according to the published NHMRC standard and formulate guideline statements and recommendation/s in accordance with the evidence.
7. Formulate the evidence statements and recommendations.
8. Conduct quality assurance throughout all these steps.

Step 1: Defining issues and questions to direct the literature searches

Each EAG was asked to define key issues for the guideline and to generate a set of questions focusing on clinically relevant issues to guide the literature searches. These critical clinical issues also formed the focus of the guideline recommendations and accompanying evidence statements. A generic framework was developed and centred on issues such as:

- What are the key treatment/management issues for this area?
- What anthropometric, clinical or behavioural parameters need to be assessed?
- Should everyone be assessed or are there particular risk factors which warrant selective testing or preventative treatment?
- What assessment techniques should be used?
- How often should the assessment be done?
- How should the results be interpreted?
- What action should follow from the results (if abnormal) e.g., management, further investigation, referral?
- What are the overall costs of using the intervention? (particularly in relation to changes in costs if changes to management are recommended)
- What is the impact of socioeconomic position and other markers of interest e.g., income, education, occupation, employment, ethnicity, housing, area of residence, lifestyle, gender.

EAGs were also advised to frame each question using the **'PICO'** elements as follows: **P**opulation **or P**roblem; **I**ntervention (for a treatment intervention question), **or I**ndicator or exposure (for a prognosis or aetiology or question), **or I**ndex test (for a diagnostic accuracy question); **C**omparator; and **O**utcome.

The resulting questions developed by each EAG are presented at the beginning of each guideline and again in the Search Strategy and Yield Table.

Step 2: Searching the literature

NHMRC clinical practice guidelines are required to be based on systematic identification and synthesis of the best available scientific evidence (NHMRC, 2007). A number of systematic strategies were used in this project to identify and assess scientific information from the published literature. The search strategies were designed to reduce bias and ensure that most of the relevant data available on type 2 diabetes were included in the present review and were similar to those detailed in the Cochrane Collaboration Reviewers Handbook (Higgins JPT et al). Several strategies were used to identify potentially relevant studies and reviews from the literature such as:

Electronic Databases
Searches were carried out using the following databases:

- Medline
- Cochrane Library: Databases of Systematic Reviews, DARE, Controlled Trials Register, Central, HTA.
- Additional databases searched where indicated included:
  Embase
  Cinahl
  Psycho Info
  Eric
  Other (where appropriate) such as Internet, Expert sources, Hand searching of reference lists at the end of relevant articles.

Key words
The key words (MeSH terms and some free text terms) used when searching these electronic databases are presented in detail in the Search Strategy and Yield Table at the end of each guideline topic. The EAGs limited their searches through a number of methods including:
- specification of temporal constraints (e.g. 1999-2008 for the updated guideline)
- language constraints (English only)
- where there were overwhelming amounts of literature or if there was a large volume of poor quality research, some groups imposed limits by experimental design to exclude the less rigorous forms of research.

Details of specific inclusion criteria for the EAG are also presented, together with the key words, at the end of each individual guideline.

Consultation with colleagues
The EAGs were encouraged to gather relevant information/articles from other experts and colleagues. The Project Management Team collated the questions developed by each EAG to direct the literature searches and highlight overlapping questions and requested EAGs and Research Officers to send any articles identified as applicable to other guideline topics to the EAG.

Step 3: Sorting the search yield

Two or more members of each EAG were responsible for sorting through the search results by scanning the lists of titles and abstracts generated by the electronic database searches, highlighting potentially relevant articles and requesting printed full articles. Full articles were retrieved and those which were relevant were assessed for quality. Articles were considered relevant if they provided direct or indirect information addressing one or more of the specified 'clinical issues' questions and were applicable to diabetes care or prevention in Australia.

Sorting according to study design

Articles with original data were sorted according to study design. Articles with the most rigorous experimental designs were reviewed in the first instance. Articles conducted to other study designs were included if they added new information not found in the papers of highest levels of evidence. Relevant papers were sorted as follows:

- Meta-analysis, systematic review of randomised controlled trials (interventions)
- Randomised controlled trials (RCT)
- Cohort studies
- Case control studies
- Case series, pre-post or post studies

Exclusion criteria

Articles were not included for review if it was apparent that their relevance to formulating a guideline recommendation was non-existent or negligible. Examples of reasons for non review included criteria such as:

- Studies of inappropriate patient population(s) for the question being addressed (epidemiology, specific diet)
- Hypothesis/mechanism/in vitro study/animal studies
- Genetic studies that are clinically inapplicable
- Non-systematic reviews which presented the author's opinion rather than evidence

Step 4: Documenting the search strategy and its yield

The search strategy (terms and limits) and yield were documented and are available for viewing in a table at the end of each guideline. In brief, the Search Strategy and Yield Table recorded details about the:

1. Questions being investigated
2. Electronic databases searched
3. MeSH terms and key words used to search the database
4. Methods for limiting the searches
5. Number of articles identified by each search
6. Number of articles relevant from that search
7. Number of relevant articles identified through other search processes
8. Number of articles obtained for review
9. Number of relevant articles which were systematic reviews, RCTs or well designed population based studies, quasi-experimental and other (these were documented in the tables according to the updated NHMRC Evidence Levels I –IV).
10. Number of articles reviewed
11. Highest level of evidence found for each question

Step 5. Critically reviewing, grading and summarising the evidence

All relevant articles were reviewed and critically assessed using checklists recommended by the NHMRC (2000) (NHMRC, 2000a; NHMRC, 2000b).The NHMRC checklist sets out an explicit standardised approach to reviewing and incorporating scientific evidence into clinical practice guidelines.

In addition, Research Officers were asked to construct tables to summarise extraction of data and to provide a brief summary of the key results for each article.

Overall assessment of individual studies
At the conclusion of reviewing each article, the reviewers rated the evidence in a summary form as shown in (Table 1) using the following criteria:

- *Levels of evidence*
  The 'interim' NHMRC levels of evidence (NHMRC, 2007) was used in this project to assess levels of evidence for a range of study designs (Appendix iv).
- *Quality rating*
- *Magnitude of effect*
- *Relevance rating*

Criteria for quality of evidence, magnitude of effect, and relevance of evidence were based on those provided by the NHMRC (2000a &b). These criteria are presented in Appendix iv.

Table 7: Example of an Overall Assessment Report

Assessment Category	**Rating**			
	Value	Low	Medium	High
Level of evidence				
Quality rating				
Magnitude of effect				
Relevance rating				

These assessments were then used in the evidence tables which summarises basic information about **Each Study** reviewed, including an overall assessment of the evidence (Table 2).

Table 8: Example of an evidence table with overall study assessment

Author, Year	**Evidence**				
	Level of Evidence		***Quality Rating***	***Magnitude of Effect Rating***	***Relevance Rating***
	Level	***Study Type***			
Author X (1999)	III-2	Cohort	High	Low	High

Step 6. Assessing the body of evidence and formulating guideline evidence statements and recommendations

In addition to considerations of the rigour of the research providing the evidence (Tables 1 and 2), principles for formulating guideline evidence statements and recommendations were derived consistent with the NHMRC recommended standard '*The NHMRC Standards for External Developers of Guidelines* (NHMRC, 2007).

For each identified clinical question, evidence statements are based on an assessment of all included studies for that question (**the Body of Evidence**). The NHMRC considers the following five components in judging the overall body of evidence (NHMRC, 2007) as specified in the '*NHMRC Body of Evidence Matrix'* (Table 3):

- The evidence base, in terms of the number of studies, level of evidence and quality of studies (risk of bias).
- The consistency of the study results.
- The potential clinical impact of the proposed recommendation.
- The generalisability of the body of evidence to the target population for the guideline.
- The applicability of the body of evidence to the Australian healthcare context.

Based on the body of evidence, recommendation/s was formulated to address each of the identified clinical questions for the area. Recommendation/s was written as an action statement.

Principles for formulating the guideline recommendation/s

In the course of the face-to-face meetings of the EAGs, and from published sources, principles were identified re-affirming the need for guideline recommendations to:

- Be developed systematically and objectively by synthesising the best available evidence.
- Have potential to improve health and related outcomes whilst minimising possible harms.
- Be clinically relevant and feasible.
- Take account of ethical considerations, and acceptability to patients.
- Centre on interventions which are accessible to those who need them.
- Propose activities within the scope of the role of those expected to use the guidelines e.g., interventions which could be expected to be conducted in routine general practice.

Grading of recommendation/s

The grading of each recommendation reflects the strength of the recommendation (Table 4) and is based on 'The *NHMRC Standards for External Developers of Guidelines* (NHMRC, 2007).

In face-to-face meetings, the EAG, initially graded each of the five components of the NHMRC Body of Evidence Matrix (Table 3) for each recommendation and then determined the overall grade for the body of evidence by summing the individual component grades (Appendix v).

Cost effectiveness analyses that were based on modelling, could not be evaluated using the NHMRC 'Body of Evidence Matrix'. Hence, cost-effectiveness recommendations were not graded.

Table 9: NHMRC Body of Evidence Matrix

Component	A	B	C	D
	Excellent	**Good**	**Satisfactory**	**Poor**
Evidence base	several level I or II studies with low risk of bias	one or two level II studies with low risk of bias or a SR/multiple level III studies with low risk of bias	level III studies with low risk of bias, or level I or II studies with moderate risk of bias	level IV studies, or level I to III studies with high risk of bias
Consistency	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	evidence is inconsistent
Clinical impact	very large	substantial	moderate	slight or restricted
Generalisability	population/s studied in body of evidence are the same as the target population for the guideline	population/s studied in the body of evidence are similar to the target population for the guideline	population/s studied in body of evidence different to target population for guideline but it is clinically sensible to apply this evidence to target population	population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population
Applicability	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

Table 10: Definition of NHMRC grades of recommendation

Grade of recommendation	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution

Step 7. Articulate the guidelines

For each guideline, clinical questions identified by EAGs are addressed in separate sections in a format presenting:

- *Recommendation(s*) - including grading.
- *Practice Point (s)* – including expert consensus in absence of gradable evidence.
- *Evidence Statements* - supporting the recommendations.
- *Background* - to issues for the guideline.
- *Evidence* - detailing and interpreting the key findings.
- *Evidence tables* - summarising the evidence ratings for the articles reviewed.
  At the end of the guideline, references and Search Strategy and Yield Tables documenting the identification of the evidence sources were provided.

To ensure consistency between the guidelines, a template was designed for writers to use when drafting the guidelines.

Step 8. Methods for Quality Assurance across the project

To ensure optimal accuracy and consistency within and between guideline areas, the Project Management Team conducted a range of quality assurance activities throughout the project:

Quality Assurance, Procedures and Protocols

- The provision of a Methods Manual which provides written instructions to the Chairs of the EAGs and research staff identifying the steps and processes to be followed.

- The provision to the EAGs of a selection of key published resource material relevant to the development of the guidelines (NHMRC tool kit 2000-2003; NHMRC, 2007).

- Specification and training of research staff on the search process.

Quality Assurance, Methods

- The appointment of a Senior Research Officer to the Project Management Team to advise on research methods, and provide a resource and support service to the research staff.

- The establishment of a Methods Advisory Group.

- The development of questions based on key clinical issues for each guideline topic to focus and guide the literature searches and the formulation of the guideline recommendations. As previously indicated, these are listed at the beginning of each guideline and the Search Strategy and Yield Table at the end of the guideline.

- The Project Management Team collated and reviewed the questions and undertook a Delphi - like process with the Chairs of EAGs to refine these questions. In addition, all EAGs and the Project Management Team reviewed the combined questions during one of the three face-to-face meetings.

- The design and provision to Chairs of EAGs and Research Officers of standardised forms documenting aspects of the search strategy used, the search yield, and the inclusion and exclusion of articles for review. A completed Search Strategy and Yield Table follows each guideline topic.

- The Senior Research Officer reviewed:
  - all search terms used to ensure that the searches were comprehensive and that the approach was similar across groups.

  - the documentation of the search process.

- The GAR Consultants worked closely with the Senior Research Officer and EAGs. The GAR Consultants provided advice on evaluating and documenting the scientific evidence, developing evidence-based recommendations based on the scientific literature, and NHMRC procedures.
- Double culling of the search yield for each guideline topic by project staff and members of the EAG.

- Double reviewing of a sample of completed reviews for each guideline topic by the Senior Research Officer or an experienced Research Officer, or by a member of the relevant EAG.

- Review of the completed recommendations and written description of the literature review for each guideline area was undertaken to check for:
  - appropriate use of references
  - accurate application of evidence ratings
  - congruence between the recommendations and evidence statements
  - consistency between recommendations
  - clarity of the literature review findings

4.0 Consultation Process

The organisational structure for the Type 2 Diabetes Guidelines Development Project was designed to involve and ensure consultation between the Guideline Development Consortium (DA, ADS, ADEA, RACGP) and the Diabetes Unit. A number of other strategies were employed to ensure wide consultation with a range of stakeholders and interested groups and individuals.

Initial Consultation
Prior to commencement of the project, initial consultation included contacting relevant professional organisations to discuss the guideline development and to seek nomination of content experts.

Internal Consultation
The internal communication and interaction between the Project Management Team and the research officers included fortnightly meetings, email communications, and regular telephone contact. In addition, for each guideline, there was individual informal meetings between the research officers and their project managers.

The Project Steering Committee
The Project Steering Committee comprised representatives from various organisations (who should be consulting with their colleagues in that organisation) include:

- Diabetes Australia (Mr Matt O'Brien)
- Medical Advisor (Professor Stephen Colagiuri)
- Australian Diabetes Society (Dr Maarten Kamp)
- Australian Diabetes Educators Association (Ms Jane Giles)
- Royal Australian Collage of General Practice (Professor Mark Harris)
- Department of Health and Ageing (Ms Suzanne Prosser)
- The Diabetes Unit, Menzies Centre for Health Policy (Associate Professor Ruth Colagiuri)

During the course of the project, DA convened two face-to-face meetings and three teleconferences of the Project Steering Committee members to provide guidance and direction to the project.

Expert Advisory Groups
The EAGs consulted formally through the inclusion of specific interest groups on the individual EAG. Examples include dietitians, clinicians, educators, researches, and consumers.

Communication strategies with EAG members included:

- Face-to-face meetings
  - an initial meeting to scope the coverage of the guideline and view the processes required to develop it, identify and agree on the roles of the EAG.
  - a final meeting to review and grade the recommendations and body of evidence form.

- Email communication seeking advice on research questions and search terms and requesting review of material developed.

- Chairs and individual members of EAGs, consulted with additional content experts regarding approaches and clinical/content issues as required.

Consultation with Guidelines Assessment Register (GAR) Consultants.
The GAR consultant for each guideline provided guideline developers with support in relation to utilising evidence-based findings and applying the NHMRC criteria. GAR consultants attended face-to-face meetings with EAGs. They provided advice on evaluating and documenting the scientific evidence and developing evidence-based recommendations based on the scientific literature and NHMRC procedures.

Consultation with Consumers
Consumer representatives were selected and appointed by Diabetes Australia for each EAG to ensure the consideration of people with type 2 diabetes with respect to their acceptability of the proposed guideline recommendations.

Public Consultation
All guidelines went through a formal public consultation process. This process was as follows:

- The guidelines were released for public consultation by Diabetes Australia through the NHMRC designated public consultation process between August and October 2008.

- The call for submissions was advertised in the national public press and a front page website advertisement was placed on the Diabetes Australia website, which linked to a full website advertisement.

- The NHMRC also advertised the draft guidelines in their 'bulletin'.

- Key stakeholder organisations (Appendix vi) were notified directly by email of the availability of the guidelines for public review and requested to comment. The emailed notice provided a link to the advertisement on the Diabetes Australia website.

- As a result of public consultation, submissions were received and referred to the Project Management Team:
  - six submissions relating to the Primary Prevention Guideline
  - four submissions relating to Case Detection and Diagnosis Guideline
  - two submissions relating to Patient Education
  - two submissions relating to Chronic Kidney Disease
  - five submissions relating to Blood Glucose Control
  - one submission did not relate to any of the guidelines but made comments on the overall process of the guideline development which was subsequently referred to the Diabetes Australia Guideline Consortium Steering Committee.

- The issues raised in these submissions were considered and consulted about internally and externally by the guideline developers and were reviewed by the Project Management and Research Teams, the Medical Advisor, the relevant EAG, and the GAR Consultant.

- Key issues from the submissions for each guideline were summarised into table form and corresponding responses addressing each issue were presented in separate documents entitled *"Response to Public Consultation on ... "* and accompanied the guideline drafts presented to independent review by the NHMRC.

- Changes to the guidelines as a result of public consultation and as a result of independent review by the NHMRC were incorporated into the revised final guidelines.

Informal Consultation

Further consultation occurred throughout the project with a wide variety of groups and individuals in response to particular issues and needs. For example, the Chronic Kidney Disease Guideline has been reviewed by the CARI peer reviewers and presented at the Dialysis, Nephrology Transplant 2009 Workshop, Lorne Victoria. Comments from the peer reviewers and from the workshop have been incorporated into the subsequent revision of the draft guideline.

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APPENDICES

Appendix i: Terms of Reference of Steering Committee

Type 2 Diabetes Guidelines Project

1. Scope

The Steering Committee is a composite body which provides guidance and direction to the project and advice in relation to the project to the Department of Health and Ageing via Diabetes Australia.

2. Function

The role of the Steering Committee is to oversight and monitors the project progress and timelines.

3. Membership

The Steering Committee will comprise representatives from the following organisations:

- Diabetes Australia
- The Diabetes Unit, Australian Health Policy Institute
- Australian Diabetes Society
- Australian Diabetes Educators Association
- Royal Australian College of General Practitioners
- Medical Advisor
- Consumer – person with type 2 diabetes nominated by Diabetes Australia.

The Department of Health and Ageing (the Department) will be represented in an advisory role.

The final composition of the Steering Committee, the operating procedures and the Chair of the Committee will be agreed by the Department.

If a representative is unable to attend a meeting/teleconference they may nominate a proxy representative from their own organisation.

4. Quorum and Voting

The quorum for Steering Committee meetings is to be 50% of membership plus one additional member.

The Steering Committee shall always attempt to achieve consensus. In the event of decisions requiring a vote, each member of the Committee shall exercise a single vote. Decisions will be by a majority and the Chair shall have a casting vote.

5. Communication

The Steering Committee will communicate directly with Diabetes Australia who in turn will liaise with the Department. Communication between the Steering Group and other teams and groups is essential and will be facilitated by the Chair of the Committee.

Frequency of Meetings

The Steering Committee will meet on at least five occasions throughout the contract period. These meetings will comprise two face-to-face meetings and three teleconferences, throughout the contract period.

6. Executive and Operational Support

The Steering Group Secretariat will be provided by Diabetes Australia. The Secretariat will provide support in writing minutes and co-ordinating meetings

7. Funding

The costs of travel, accommodation, meeting location (or teleconference) expenses and other activities proposed by the Steering Committee will be agreed and borne by Diabetes Australia.

Appendix ii: Terms of Reference for Expert Advisory Groups

Type 2 Diabetes Guidelines Project

Purpose

The Expert Advisory Groups (EAGs) for the National Evidence Based Guidelines for Type 2 Diabetes are convened by The Diabetes Unit, Menzies Centre for Health Policy (formerly Australian Health Policy Institute), The University of Sydney under the head agreement between Diabetes Australia and the Department of Health and Ageing to support the development of the guidelines by providing:

1. Overall technical and content advice and critical comment

2. Input into the development or revision of research questions to guide the literature reviews

3. Guidance on search terms and for the literature review

4. Review of drafts of the guidelines and recommendations at critical points along the continuum of their development

5. Perspectives on the feasibility and applicability of the guidelines from the perspective of their own disciplines and their peers and colleagues

Duration

The EAGs are convened for the duration of the project. It is anticipated this will cover approximately 18 months up to end 2008.

Frequency of Meetings

It is anticipated that there will be three meetings of the EAGs mainly by teleconference with one face-to-face meeting at commencement.

The EAG members may also be asked to comment on emailed information from time to time.

Expenses

Reasonable expenses for travel to meeting will be reimbursed on presentation of original receipts

Conflict of Interests

EAG members are asked to declare any/all perceived conflict/s of interest

Appendix iii: NHMRC Evidence Hierarchy, designations of 'levels of evidence' according to type of research question

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening Intervention
I	A systematic review of level II Studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls:	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls:

	▪ Historical control study ▪ Two or more single arm study ▪ Interrupted time series without a parallel control group				▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

(Source: NHMRC 2007)

Appendix iv: Study Assessment Criteria

I. Study quality criteria

Systematic reviews

1. Were the questions and methods clearly stated?
2. Is the search procedure sufficiently rigorous to identify all relevant studies?
3. Does the review include all the potential benefits and harms of the intervention?
4. Does the review only include randomised controlled trials?
5. Was the methodological quality of primary studies assessed?
6. Are the data summarised to give a point estimate of effect and confidence intervals?
7. Were differences in individual study results adequately explained?
8. Is there an examination of which study population characteristics (disease subtypes, age/sex groups) determine the magnitude of effect of the intervention?
9. Were the reviewers' conclusions supported by data cited?
10. Were sources of heterogeneity explored?

Randomised controlled trials

1. Were the setting and study subjects clearly described?
2. Is the method of allocation to intervention and control groups/sites independent of the decision to enter the individual or group in the study ?
3. Was allocation to study groups adequately concealed from subjects, investigators and recruiters including blind assessment of outcome?
4. Are outcomes measured in a standard, valid and reliable way?
5. Are outcomes measured in the same way for both intervention and control groups?
6. Were all clinically relevant outcomes reported?
7. Are factors other than the intervention e.g. confounding factors, comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?
8. Were >80% of subjects who entered the study accounted for at its conclusion?%
9. Is the analysis by intention to intervene (treat)?
10. Were both statistical and clinical significance considered?
11. Are results homogeneous between sites? (Multi-centre/multi-site studies only).

Cohort studies

1. Are study participants well-defined in terms of time, place and person?
2. What percentage (%) of individuals or clusters refused to participate?
3. Are outcomes measured in a standard, valid and reliable way?
4. Are outcomes measured in the same way for both intervention and control groups?
5. Was outcome assessment blind to exposure status?
6. Are confounding factors, comparable between the groups and if not comparable, are they adjusted for in the analysis?
7. Were >80% of subjects entered accounted for in results and clinical status described?
8. Was follow-up long enough for the outcome to occur
9. Was follow-up complete and were there exclusions from the analysis?
10. Are results homogeneous between sites? (Multicentre/multisite studies only).

Case-control studies

1. Was the definition of cases adequate?

2. Were the controls randomly selected from the source of population of the cases?
3. Were the non-response rates and reasons for non-response the same in both groups?
4. Is possible that over-matching has occurred in that cases and controls were matched on factors related to exposure?
5. Was ascertainment of exposure to the factor of interest blinded to case/control status?
6. Is exposure to the factor of interest measured in the same way for both case and control groups in a standard, valid and reliable way (avoidance of recall bias)?
7. Are outcomes measured in a standard, valid and reliable way for both case and control groups?
8. Are the two groups comparable on demographic characteristics and important potential confounders? and if not comparable, are they adjusted for in the analysis?
9. Were all selected subjects included in the analysis?
10. Was the appropriate statistical analysis used (matched or unmatched)?
11. Are results homogeneous between sites? (Multicentre/multisite studies only).

Diagnostic accuracy studies

1. Has selection bias been minimised
2. Were patients selected consecutively?
3. Was follow-up for final outcomes adequate?
4. Is the decision to perform the reference standard independent of the test results (ie avoidance of verification bias)?
5. If not, what per cent were not verified?
6. Has measurement bias been minimised?
7. Was there a valid reference standard?
8. Are the test and reference standards measured independently (ie blind to each other)
9. Are tests measured independently of other clinical and test information?
10. If tests are being compared, have they been assessed independently (blind to each other) in the same patients or done in randomly allocated patients?
11. Has confounding been avoided?
12. If the reference standard is a later event that the test aims to predict, is any intervention decision blind to the test result?

(Sources: adapted from NHMRC1999, NHMRC 2000a, NHMRC 2000b, Liddle et al 96; Khan et 2001)

Study quality – Rating

The following was used to rate the quality of each study against the study type criteria listed above.

High: all or all but one of the criteria were met

Medium: 2 or 3 of the criteria were not met

Low: 4 or more of the criteria were not met

II. Classifying magnitude of the effect

Ranking	Statistical significance		Clinical importance of benefit
High	Difference is statistically significant	AND	There is a clinically important benefit for the full range of estimates defined by the confidence interval.
Medium	Difference is statistically significant	AND	The point estimate of effect is clinically important BUT the confidence interval includes some clinically unimportant effects
Low	Difference is statistically significant OR Difference is not statistically significant (no effect) or shows a harmful effect	AND AND	The confidence interval does not include any clinically important effects The range of estimates defined by the confidence interval includes clinically important effects.

(Source: adapted from the NHMRC classification (NHMRC 2000b)

III. Classifying the relevance of the evidence

Ranking	Relevance of the evidence
High	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival *Or* Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention
Medium	Evidence of an effect on proven surrogate outcomes but for a different intervention *Or* Evidence of an effect on proven surrogate outcomes but for a different intervention and population
Low	Evidence confined to unproven surrogate outcomes.

(Source: adapted from the NHMRC classification (NHMRC 2000b)

Appendix v: NHMRC Evidence Statement Form

Key question(s):		**Evidence table ref:**
1. Evidence base *(number of studies, level of evidence and risk of bias in the included studies)*		
	A	**Several Level I or II studies with low risk of bias**
	B	**one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias**
	C	**Level III studies with low risk of bias or Level I or II studies with moderate risk of bias**
	D	**Level IV studies or Level I to III studies with high risk of bias**
2. Consistency *(if only one study was available, rank this component as 'not applicable')*		
	A	**All studies consistent**
	B	**Most studies consistent and inconsistency can be explained**
	C	**Some inconsistency, reflecting genuine uncertainty around question**
	D	**Evidence is inconsistent**
	NA	**Not applicable (one study only)**
3. Clinical impact *(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)*		
	A	**Very large**
	B	**Moderate**
	C	**Slight**
	D	**Restricted**
4. Generalisability		
	A	**Evidence directly generalisable to target population**
	B	**Evidence directly generalisable to target population with some caveats**
	C	**Evidence not directly generalisable to the target population but could be sensibly applied**
	D	**Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply**
5. Applicability		
	A	**Evidence directly applicable to Australian healthcare context**
	B	**Evidence applicable to Australian healthcare context with few caveats**
	C	**Evidence probably applicable to Australian healthcare context with some caveats**
	D	**Evidence not applicable to Australian healthcare context**

Other factors *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation)*

EVIDENCE STATEMENT MATRIX

Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.

Component	Rating	Description
Evidence base		
Consistency		
Clinical impact		
Generalisability		
Applicability		

Indicate any dissenting opinions

RECOMMENDATION	**GRADE OF RECOMMENDATION**	
What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.		

IMPLEMENTATION OF RECOMMENDATION *Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*	
Will this recommendation result in changes in usual care?	**YES**
	NO
Are there any resource implications associated with implementing this recommendation?	**YES**
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	**YES**
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	**YES**
	NO

Appendix vi: Key stakeholder organisations notified of public consultation

- Diabetes Australia State and Territory member organisations including:
    - Australian Diabetes Society
    - Australian Diabetes Educators Association

- University Schools of Nursing, Medicine, Podiatry, Nutriton/ Dietetics
- Australian Podiatry Association
- Australian Podiatry Council
- Eyes on Diabetes
- Cooperative Centre for Aboriginal Health
- Australian Centre for Diabetes Strategies
- Public and private Diabetes Centres throughout Australia (for which we were able to obtain email addresses)
- State and Federal health departments