Western Australian

Impaired Fasting Glucose/
Impaired Glucose Tolerance

Consensus Guidelines

2005

This document provides evidence-based guidelines for use by general practitioners. There may be specific circumstances, as judged by the general practitioner, in which the recommendations may not be applicable.
Acknowledgements

The development of the IFG/IGT Guidelines involved extensive consultations with input by medical specialists, clinicians and allied health professionals.

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Preface

The Consensus Guidelines for impaired fasting glucose/ impaired glucose tolerance (IFG/IGT) have been developed for use by Western Australian medical practitioners and allied health professionals who are involved in the primary prevention of Type 2 diabetes and management of IFG/IGT. The guidelines are based on the national evidence based guidelines for the management of Type 2 diabetes developed by the NHMRC and provide further information on the detection and management of IFG/IGT. This document provides the background rationale for the guidelines. The guidelines are based on available evidence to March 2005 and will be updated as more research is published.

The development of the guidelines involved extensive consultation with Western Australian medical specialists, general practitioners and allied health professionals. The IFG/IGT Guidelines Working Group and IFG/IGT Lifestyle Management Working Group were established to assist with specific components of the project. The IFG/IGT Guidelines Working Group assisted in the development and review of the IFG/IGT Guidelines Consensus Review Module 1, specifically Sections 1, 2, 3, and 5. The IFG/IGT Lifestyle Management Working Group assisted in the development and review process of the IFG/IGT Guidelines Consensus Review Module 1, specifically Section 4. Additionally, the Diabetes Australia Western Australia - Diabetes Consumer Reference Group, was consulted in the development of the consumer definition of IFG and IGT.

This was an inclusive research and development project that engaged medical specialists and general practitioners through the use of the Delphi process to analyse quantitative and qualitative data. The Delphi process involved two rounds of review with the aim of reaching consensus on the IFG/IGT guidelines. Participants were asked to read MODULE 1 which contained the evidence based research on IFG/IGT and to provide their feedback and comments in MODULE 2.

MODULE 1 and 2 of The IFG/IGT Guidelines Consensus Review consisted of five sections:

Section 1: Terminology & Physiology
Section 2: Detection
Section 3: Retesting
Section 4: Management
Section 5: Draft IFG/IGT Guidelines Desktop Resource

Participants were asked to provide feedback and comments where instructed. The information participants provided remained confidential and they were free to withdraw at anytime.

The total number of endocrinologists identified in Western Australia was twenty-four. There were nineteen endocrinologists who identified a special interest in diabetes. Of the twenty-four identified endocrinologists, seventeen volunteered to participate in the 1st & 2nd Round of the IFG/IGT Guidelines Consensus Review, which is a recruitment rate of 71%.

With the assistance of the Divisions of General Practice across Western Australia, a total of 22 general practitioners volunteered to participate in the consensus guidelines. Of the twenty-two identified general practitioners, twenty eventually participated in the 1st & 2nd Round of the IFG/IGT Guidelines Consensus Review, which is a recruitment rate of 91%. Eight of these were rural general practitioners and twelve were metropolitan general practitioners.

The IFG/IGT Guidelines Consensus Review was reviewed initially by the endocrinologists, followed by the general practitioners. The 1st Round of the IFG/IGT Consensus Review was collected and collated before the 2nd Round of the IFG/IGT Consensus Review was disseminated.

The IFG/IGT Guidelines have been formatted as an A4-sized laminated Desktop Resource for general practitioners across Western Australian.
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Abbreviations

ADA - American Diabetes Association
ADEA - Australian Diabetes Educators Association
ADS - Australian Diabetes Society
BMI - Body Mass Index
CVD - Cardiovascular Disease
DAWA - Diabetes Australia Western Australia
DoH WA - Department of Health Western Australia
FPG - Fasting Plasma Glucose
IDF - International Diabetes Federation
IDI - International Diabetes Institute
IFG - Impaired Fasting Glucose
IGT - Impaired Glucose Tolerance
IPH - Isolated Post Challenge Hyperglycaemia
NHMRC - National Health and Medical Research Council
NIDDKD - National Institute of Diabetes and Digestive and Kidney Disease
OGTT - Oral Glucose Tolerance Test
RPG - Random Plasma Glucose
2h PG - 2hour Plasma Glucose
WHO - World Health Organisation
Introduction

Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) represent categories of metabolism intermediate between normality and Type 2 diabetes. In 2000, the prevalence of IFG and IGT was estimated to be 16.3% in Australians over the age of 25 years. Many of these people remain unaware of their condition. People with IFG and IGT are at increased risk of developing Type 2 diabetes and have a substantially increased risk of heart disease (International Diabetes Institute, 2001).

Guidelines for the management of Type 2 diabetes have been developed by the National Health & Medical Research Council (NHMRC). However, the absence of consensus guidelines for IFG and IGT has led to inconsistent terminology, messages and management. For instance, IFG and IGT are also known as pre-diabetes or borderline diabetes.

In response, the Department of Health Western Australia (DoH WA) funded Diabetes Australia WA (DAWA) to facilitate the development of IFG and IGT guidelines. The IFG/IGT Guidelines Project has developed consensus guidelines for the detection and management of IFG and IGT that will:

- improve certainty for health professionals involved in the primary prevention and management of IFG, IGT and diabetes
- improve consistency
- reduce the potential for misinformation, and
- complement efforts to prevent Type 2 diabetes.

DAWA identified a number of medical specialists and other expert clinicians who contributed to development of the IFG/IGT guidelines. The Working Group is grateful for the assistance and enthusiasm of all the participants and looks forward to an improvement in the awareness, management and outcomes of abnormal glucose tolerance in Western Australia.
Section 1: Terminology & Physiology

Executive Summary

**Terminology: The Debate**

Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) are stages in the natural history of disordered carbohydrate metabolism, rather than a subclass of diabetes. They are not considered to be clinical entities in their own right (except during pregnancy) but rather are risk factors for the future development of diabetes and Cardiovascular Disease (CVD) (NHMRC, 2001).

Currently, a level of uncertainty exists in the nomenclature. The following groups have used the terms described below:

1. American Diabetes Association (ADA)

The ADA has adopted the term ‘pre-diabetes’ to describe IFG and IGT for the following reason:

“The condition has not changed, but what we know about it has. We are giving IGT/IFG a new name for several reasons. Pre-diabetes is a clearer way of explaining what it means to have higher than normal blood glucose levels. It means you are likely to develop diabetes and may already be experiencing the adverse health effects of this serious condition. People with pre-diabetes are at higher risk of cardiovascular disease. ..... We now know that people with pre-diabetes can delay or prevent the onset of Type 2 diabetes through lifestyle changes.”

(ADA website: the Frequently Asked Questions Section, 2004).

2. World Health Organisation (WHO)

WHO refers to IFG and IGT as ‘impaired glucose regulation’, which refers to a metabolic state intermediate between normal glucose homeostasis and diabetes. WHO also states that IFG and IGT are not interchangeable and represent different abnormalities of glucose regulation, affecting respectively the fasting state and the post-prandial state (WHO, 1999).

3. International Diabetes Federation (IDF)

The IDF convened a workshop to review the latest information relating to the risks associated with IGT and IFG. From this workshop, no clear consensus emerged as to whether IFG and IGT should be classified as diseases, but it was clear that both represent risk factors and risk markers** for diabetes and CVD (Unwin et al, 2002).

**the term ‘risk markers’ was used in the Position Statement to indicate that an association exists between either IGT and IFG and a specified outcome.
The use of inconsistent terminology such as "pre-diabetes" or "borderline diabetes" for IFG and IGT is strongly discouraged as it may mislead. A diagnosis of "borderline diabetes" or "pre-diabetes" may suggest either that treatment should be the same as diabetic treatment or that no abnormality exists at all. It is important for patients to understand the relationship between IFG and IGT as risk factors for diabetes and CVD and the appropriate control measures.

It is clear that identification of both IFG and IGT indicates the greatest risk of progressing to diabetes, but either abnormality predicts an increased risk of both future diabetes and cardiovascular disease. However, strong evidence shows that people diagnosed with IFG and IGT can delay or prevent the onset of Type 2 diabetes through lifestyle changes (Shaw & Chisholm, 2003).

The recent formative evaluation of the Don’t Ignore Diabetes (DID) campaign in Western Australia found that people at risk of diabetes did not perceive diabetes to be a serious health condition or perceive themselves to be at risk (Carter et al, 2003). Therefore, it is unlikely that terms such as "pre-diabetes" will prompt action. Raising awareness of IFG and IGT will ultimately allow consumers and health professionals to become familiar and confident with the terms and their importance.

**Physiology**

The physiological bases of IFG and IGT are different, as illustrated in Table 1. Normal control of fasting glucose depends on the ability to maintain adequate basal insulin secretion and an appropriate level of insulin sensitivity in the liver to control hepatic glucose output. Abnormalities of these metabolic functions characterise IFG. IGT is associated with peripheral insulin resistance, most importantly at the level of skeletal muscle (the main depot for glucose disposal post prandially) (Unwin et al, 2002).

<table>
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<th>Table 1: Progression of Type 2 Diabetes</th>
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<td>Factors</td>
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<td>FPG (mmol/L)</td>
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<tr>
<td>2 h PG (mmol/L)</td>
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<tr>
<td>Insulin resistance</td>
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<tr>
<td>Insulin levels</td>
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<td>Treatment</td>
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</table>

(Adapted from Reasner & DeFronzo, 2001, p 1689)

NGT = normal glucose tolerance; FPG = fasting plasma glucose; T2D = Type 2 Diabetes

The number of arrows indicates the magnitude of the change in insulin secretion
(i.e. ↑ = increased or ↓ = decreased)
### Issue

**Definition of IFG and IGT**

### Recommended Guidelines

- **Medical/clinical definition:** IFG and IGT represent stages in the natural history of disordered carbohydrate metabolism rather than a subclass of diabetes. Neither are considered clinical entities in their own right (except during pregnancy) but rather are risk factors for the future development of diabetes and cardiovascular disease.

- **Consumer explanation:**
  
  **Consumer explanation of IFG test result:**

  Your Oral Glucose Tolerance Test indicates that you have a condition known as Impaired Fasting Glucose. Impaired Fasting Glucose is identified when your fasting blood glucose result is equal to or more than 6.1 but less than 7.0 and your result 2 hours after a glucose drink is less than 7.8. Impaired Fasting Glucose is an intermediate stage which can lead to the development of Type 2 diabetes and is a risk factor for heart disease.

  However, by making lifestyle changes such as healthy eating, regular physical activity and quitting smoking, your risk can be reduced. Professionals such as General Practitioners, Diabetes Educators, Dietitians and Physiotherapists can assist you with these changes.

  Impaired Fasting Glucose is sometimes referred to as 'pre-diabetes', however Impaired Fasting Glucose is the preferred term.

  **Consumer explanation of IGT test result:**

  Your Oral Glucose Tolerance Test indicates that you have a condition known as Impaired Glucose Tolerance. Impaired Glucose Tolerance is identified when your fasting blood glucose result is less than 7.0 and your result 2 hours after a glucose drink is more than or equal to 7.8 but less than or equal to 11.0. Impaired Glucose Tolerance is an intermediate stage which can lead to the development of Type 2 diabetes and is a risk factor for heart disease.

  However by making lifestyle changes such as healthy eating, regular physical activity and quitting smoking, your risk can be reduced. Professionals such as General Practitioners, Diabetes Educators, Dietitians and Physiotherapists can assist you with these changes.

  Impaired Glucose Tolerance is sometimes referred to as 'pre-diabetes', however Impaired Glucose Tolerance is the preferred term.
Evidence Statements and Supporting References

The definition of IGT as established by the World Health Organisation (WHO) is generally accepted.


IFG - Individuals who have fasting glucose values above the normal range, but below those diagnostic of diabetes.

IGT - Classified as a stage of impaired glucose regulation, since it can be observed in any hyperglycaemic disorder and is itself not diabetes.


IFG/IGT are stages in the natural history of disordered carbohydrate metabolism rather than a subclass. They are not considered clinical entities in their own right (except in pregnancy) but rather as risk factors for the future development of diabetes and CVD.

National Health and Medical Research Council (NHMRC). 2001, National Evidence Based Guidelines for management of Type 2 Diabetes Mellitus, Primary Prevention. Case Detection and Diagnosis, NHMRC, Sydney.


Consumer definitions of IFG and IGT terminology are essential to eliminate confusion in the community due to inconsistent terminologies such as “pre-diabetes” or “borderline” diabetes.

Section 2: Detection

Executive Summary

Blood glucose measurement may be performed using venous plasma, capillary plasma, venous whole blood or capillary whole blood. For standardisation in Australia, measurement of venous plasma glucose by an accredited laboratory is recommended by the Australian Diabetes Society (ADS). Use of a blood glucose meter to measure capillary blood glucose levels as a method of diagnosing IFG, IGT or diabetes, is not recommended. There are major technical limitations as well as infection control issues associated with the use of random fingerprick blood determinations by reflectance meter (ADEA, 2003; NHMRC, 2001; Welborn, 1996).

A fasting plasma glucose (FPG) rather than a random plasma glucose (RPG) should be the initial screening test in people with risk factors for undiagnosed Type 2 diabetes. The reason is that FPG has the highest sensitivity and specificity for abnormalities of glucose tolerance. While the measurement of RPG may be more convenient, it has limited ability to correctly classify individuals.

An initial screening FPG in the range 5.5 - 6.9 mmol/L, should be followed up with an oral glucose tolerance test (OGTT). If collection of FPG is considered impractical, RPG may be used and a result in the range 5.5 - 11.0 mmol/L, should be followed up with an OGTT (NHMRC, 2001; Shaw & Chisholm, 2003; Welborn, 1996).

In 2001, a workshop was convened by the International Diabetes Federation (IDF) to review the latest information relating to IFG and IGT and, in particular, whether a single OGTT is sufficient to identify IFG or IGT. The ‘International Diabetes Federation IFG/IGT Consensus Statement’ recommended that the diagnosis of IFG/IGT should be based on the mean values of two OGTTs no more than three months apart (Unwin et al, 2002). There is significant individual day-to-day variability in the plasma glucose response to an OGTT and therefore, the mean value of two measurements represents the most accurate result. To validly identify and manage IFG and IGT, the diagnosis must be certain (Shaw J. pers comm. 2004). The Finnish Diabetes Prevention Study accepted this view and used the mean readings for paired OGTTs to select subjects for the study (NHMRC, 2001). Nevertheless, Western Australian endocrinologists considered this approach to be impractical and resource intensive.

In Australia, IFG and IGT are most often detected incidentally when screening for diabetes in a person who is deemed to be at risk of diabetes, as outlined in the current National Based Guidelines on Case Detection and Diagnoses for Type 2 Diabetes, endorsed by the NHMRC.

The NHMRC guidelines for Type 2 diabetes recommend that in people with an initial test result in the range of 5.5-6.9 mmol/L (FPG) and 5.5-11.0 mmol/L (RPG), an OGTT must then be performed based on FPG and 2 hour Plasma Glucose (2h PG) measurements to confirm the diagnosis. The guidelines state that annual retesting for people diagnosed with IFG and/or IGT is required. However, they do not state the number of OGTTs an individual should undertake before confirmation of the diagnosis. However, feedback and comments from Western Australian endocrinologists and general practitioners during the IFG/IGT Guidelines Consensus Review indicated that from a practical point of view, a single OGTT result should trigger lifestyle interventions.
Studies have shown that people with elevated 2h PG but normal FPG (also known as isolated post challenge hyperglycaemia (IPH)) are at a higher risk of developing CVD. Because the FPG is normal, these people can only be identified using an OGTT although they are classified as having diabetes rather than IGT or IFG. The prevalence of IPH is variable but has been reported to account for as much as 70% of all undiagnosed diabetes in elderly women and is common amongst the non-obese (NHMRC, 2001).

Recently, there has been research published recommending lowering the diagnostic level of IFG from 6.1 mmol/L to 5.6 mmol/L (Borch-Johnsen et al, 2004). The World Health Organisation (WHO) may consider adopting the new level for IFG, which will be in agreement with a recommendation by the American Diabetes Association. The Australian Diabetes Society (ADS) has not yet adopted a stance on the matter and therefore this document supports the current WHO and ADS recommendations.
What process should be followed to detect IFG and IGT?

Recommended Guidelines for Diagnosis of Type 2 diabetes and identification of IFG or IGT

- Diagnosis must always be performed by assay of venous plasma in a laboratory. Portable blood glucose meters lack the accuracy required for definitive diagnosis.

- A Fasting Plasma Glucose (FPG) should be performed as the initial screening test in people with risk factors for glucose intolerance. If a FPG level on initial screening is in the range 5.5 - 6.9 mmol/L, it should be followed up with an oral glucose tolerance test (OGTT).

- A Random Plasma Glucose (RPG) may be used if collection of a FPG sample is considered impractical. If a RPG level on initial screening is in the range 5.5 - 11.0 mmol/L, it should be followed up with an OGTT.

- OGTT must be performed based on FPG and 2 hour Plasma Glucose (2h PG) measurements as outlined in the NHMRC guidelines, which are as follows:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>FPG (mmol/L)</th>
<th>2 h PG (mmol/l)</th>
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<tr>
<td>Normal Glucose Tolerance</td>
<td>&lt; 6.1</td>
<td>&amp;</td>
</tr>
<tr>
<td>IFG</td>
<td>6.1 – 6.9</td>
<td>&amp;</td>
</tr>
<tr>
<td>IGT</td>
<td>&lt; 7.0</td>
<td>&amp;</td>
</tr>
<tr>
<td>Diabetes</td>
<td>≥ 7.0</td>
<td>or</td>
</tr>
</tbody>
</table>
Evidence Statements and Supporting References

There is considerable variation in blood glucose measurement techniques. For standardisation in Australia, measurement of venous plasma glucose by an accredited laboratory is recommended.

Welborn, T. 1996, 1996 Screening for Non-Insulin Dependent Diabetes, Australian Diabetes Society Position Statements, Department of Endocrinology and Diabetes, Sir Charles Gairdner Hospital, Western Australia, Perth.

National Health and Medical Research Council (NHMRC). 2001, National Evidence Based Guidelines for management of Type 2 Diabetes Mellitus, Primary Prevention. Case Detection and Diagnosis, NHMRC, Sydney.

Venous fasting plasma glucose level is recommended as the initial screening test, but venous random plasma glucose may be used if collection of a fasting sample is considered impractical.

Fasting plasma glucose has the highest sensitivity and specificity for screening for undiagnosed Type 2 Diabetes.

A screening blood glucose level of less than 5.5 mmol/L is associated with a low risk of Type 2 Diabetes.

Blood glucose meters are not sufficiently accurate for screening.

National Health and Medical Research Council (NHMRC). 2001, National Evidence Based Guidelines for management of Type 2 Diabetes Mellitus, Primary Prevention. Case Detection and Diagnosis, NHMRC, Sydney.


The World Health Organisation (WHO) 1999 criteria provide the best framework to detect individuals with abnormalities of either FPG and/or 2h PG, and are supported by the Australian Diabetes Society and the Diabetes Australia Guidelines Development Consortium.

National Health and Medical Research Council (NHMRC). 2001, National Evidence Based Guidelines for management of Type 2 Diabetes Mellitus, Primary Prevention. Case Detection and Diagnosis, NHMRC, Sydney.


The report of an expert consensus workshop ‘International Diabetes Federation IGT/IFG Consensus Statement’ recommended that the diagnosis of IFG and IGT should be based on the mean values of two OGTTs no more than 3 months apart . Western Australian endocrinologists considered this approach to be impractical and resource intensive.

Section 3: Retesting

Executive Summary

A number of population based studies from many parts of the world have calculated the risk of progression to Type 2 Diabetes from IGT. Data is available from Europe, USA, India, Africa and Pacific Islands. These studies used OGTT interpreted according to the 1985 WHO criteria to define and monitor groups of people with IGT. The annual rate of progression to Type 2 diabetes in all people with IGT ranged from 1.8% to 12.6%. The average annual rate of progression was 4.7% in Caucasians, 7.7% in Aboriginal and Torres Strait Islander populations and 6.2% in Pacific Islanders (NHMRC, 2001). These studies provide valuable information for Australian researchers, as many of the groups with a high prevalence of diabetes are represented locally (NHMRC, 2001).

A smaller number of studies have reported on the annual conversion rate from IFG to Type 2 Diabetes. This is most likely because IFG has only recently been identified and defines a smaller subgroup of the non-diabetic population compared with IGT. The Australian Diabetes Obesity and Lifestyle Study (AusDiab) in 2000 estimated that the prevalence of IFG and IGT was 16.3% (5.7% and 10.6% respectively) in Australians over the age of 25 years. Many of these people remain undiagnosed (International Diabetes Institute, 2001).

Since IFG and IGT are associated with a high risk of progression to Type 2 Diabetes, individuals placed into either of these categories should be retested every year (NHMRC, 2001).

For those with other risk factors for which data on the rate of progression is available, 5% will progress to Type 2 diabetes over a 3-4 year period. Given this data and the risk of development of retinopathy over a 4-5 year period, the NHMRC recommends a retesting interval of 3 years for these individuals (NHMRC, 2001).

Similarly, the American Diabetes Association and the British Diabetes Association recommend a screening interval of 3 years for high risk people with an initially negative screening test.
**Issue**

How often should individuals with IFG or IGT be retested?

**Recommended Guidelines**

- Periodic testing for progression to Type 2 diabetes is recommended by measuring Fasting Plasma Glucose (FPG) according to the following schedule:
  - Each year for people with IFG and IGT
  - Every 3 years for people at high risk with a normal FPG
- Those individuals who have an abnormal FPG on retest should be referred for an OGTT as outlined in the diagnostic procedures.

**Evidence Statements and Supporting References**

**The rate of progression of IFG and IGT to diabetes warrants annual testing.**

**IFG and IGT are risk factors for the development of diabetes and require annual testing.**


**Interventions in people with IGT delay the onset of Type 2 diabetes.**


Section 4: Management

A) Lifestyle Interventions

Executive Summary

Behavioural change which incorporates healthy food choices and an increased amount of physical activity has been shown to improve glycaemic control, blood pressure and lipid profiles. This behaviour change is considered important for people diagnosed with IFG and IGT as they have the opportunity to delay or prevent the onset of Type 2 Diabetes.

People diagnosed with IFG and IGT are also at substantially increased risk of CVD and should be managed for their cardiovascular risk. In the absence of other proven interventions for IFG and IGT in relation to this cardiovascular risk, the lifestyle goals listed below are recommended.

Recommended Guidelines

<table>
<thead>
<tr>
<th>Weight Reduction and Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Waist measurement and BMI should be used to assess weight.</td>
</tr>
<tr>
<td>• For weight reduction and maintenance, achievable goals are:</td>
</tr>
<tr>
<td>○ Short term goal of 1-4kg per month</td>
</tr>
<tr>
<td>○ Long term goal of 5-10% of initial body weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>• At least 30 minutes of **moderate-intensity physical activity on most, preferably all, days of the week.</td>
</tr>
<tr>
<td>• 60-90 minutes of moderate to vigorous-intensity physical activity on most, preferably all, days of the week, to achieve weight reduction and prevent weight gain.</td>
</tr>
</tbody>
</table>

**Moderate-intensity physical activity will cause a slight, but noticeable, increase in breathing and heart rate and may cause light sweating.**

<table>
<thead>
<tr>
<th>Nutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dietary intake should:</td>
</tr>
<tr>
<td>○ Be of low energy density</td>
</tr>
<tr>
<td>○ Include less than 30% of energy from fat with less than 10% of energy from saturated fat</td>
</tr>
<tr>
<td>○ Include a wide variety of carbohydrate foods, particularly those which are high in dietary fibre and have a low glycaemic index</td>
</tr>
<tr>
<td>○ Be consistent with the Dietary Guidelines for Australian Adults and the Australian Guide to Healthy Eating</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Smoking</th>
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<tbody>
<tr>
<td>• Smoking cessation is recommended.</td>
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<table>
<thead>
<tr>
<th>Self Blood Glucose Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Self blood glucose monitoring is not recommended.</td>
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</table>

<table>
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<tr>
<th>Cardiovascular Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Blood pressure should be monitored as outlined in the Hypertension Management Guide for Doctors 2004 by the National Heart Foundation of Australia.</td>
</tr>
<tr>
<td>• Serum lipids should be screened as outlined in the Lipid Management Guidelines 2001 by the National Heart Foundation of Australia and The Cardiac Society of Australia and New Zealand.</td>
</tr>
</tbody>
</table>
General Referral Statements:

General referral statements for people with IFG and IGT as a result of screening for Type 2 diabetes are as follows:

- Ensure access to individualised, tailored assessment and ongoing advice and support to achieve nutrition, physical activity and weight management goals.
- Lifestyle advice should be tailored to the individual and interventions should incorporate goal setting, problem solving and other behavioural change strategies.
**Issue**

Does weight reduction assist with the management of IFG and IGT?

**Weight Reduction**

Obesity is a major independent risk factor for the development of Type 2 diabetes and CVD. In Australia, obesity is estimated to contribute to about two thirds of cases of Type 2 diabetes, one fifth of heart disease cases and one third of hypertension cases (NHMRC, 1997). Therefore, a strategy to prevent diabetes by weight reduction will also significantly contribute to the prevention of CVD (Garrard et al, 2004). Available evidence to support the prevention of diabetes by weight reduction comes from the Finnish Diabetes Prevention Study (FDPS) and the Diabetes Prevention Project (DPP) (U.S). These two studies have demonstrated that a combination of modest weight loss, dietary change and at least 30 minutes of moderate intensity physical activity per day can confer a 50-60% reduction in the risk of developing diabetes among those already at high risk (Lindström et al, 2003; Knowler et al, 2002).

To reliably assess the risk, both waist circumference and BMI measurements are used. BMI is defined as weight (kilograms)/height (metres)$^2$. BMI is not an accurate predictor of overweight since it does not differentiate between body fat and muscle mass. Therefore, it should be used in combination with waist circumference, which is a measure of central adiposity and a better predictor of health risk. Classifications of waist measurement and BMI are shown in Table 1.

**Table 1: Combining waist measurement and BMI to assess obesity and the risk of Type 2 diabetes and CVD.**

<table>
<thead>
<tr>
<th>Waist circumference (cm)</th>
<th>BMI (kg/m$^2$)</th>
<th>Men: 94-102</th>
<th>Women: 80-88</th>
<th>102+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Healthy weight</td>
<td>18.5-24.9</td>
<td>-</td>
<td>increased risk</td>
<td>high risk</td>
</tr>
<tr>
<td>Overweight</td>
<td>25-29.9</td>
<td>increased risk</td>
<td>high risk</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>≥ 30</td>
<td>high risk</td>
<td>very high risk</td>
<td></td>
</tr>
</tbody>
</table>

Note: For Maori and other Pacific Islanders, the upper range BMIs for overweight and obesity are 26 and 32; for Asians, BMI and waist circumference should be adjusted downwards (waist = 100 centimetres or less)

(Table adapted from NHMRC, 2003, p48)

As weight measurements can be a sensitive issue with overweight and obese people, it is recommended that patients first be asked if they wish to be measured. If they agree, a combination of BMI and waist circumference or weight and waist circumference should be used (NHMRC, 2003).

Achieving a sustainable weight reduction of 5-10% of initial body weight can result in significant improvements in health (NHMRC, 2003). The following are achievable weight reduction goals, as outlined by the NHMRC Clinical Practice Guidelines for Management of Overweight and Obesity in Australian adults (NHMRC, 2003):

- Short term goal of 1-4 kg per month
- Long term goal of 5-10% of initial body weight
These weight reduction goals were also those used in the FDPS and DPP. In the two studies, the weight loss goal was between 5-7% of initial body weight (Lindström et al, 2003; Knowler et al, 2002). These goals were adopted because they were achievable, sustainable and likely to be beneficial in preventing diabetes based on epidemiological data and the results of previous weight loss trials (Knowler et al, 2002; Lindström et al, 2003). To achieve weight loss of 0.5-2 kg per week, intensive behavioural strategies were used by the intervention team to maintain long-term changes in their fat and calorie intake. (Lindström et al, 2003; Knowler et al, 2002).

Once the weight loss goal has been achieved, weight maintenance is particularly important for people who are overweight, obese or have co-morbidities (NHMRC, 2003).

### Weight Reduction and Maintenance:

- Waist measurements and BMI should be used to assess weight.
- For weight reduction and maintenance, achievable goals are:
  - Short term goal of 1-4 kg per month
  - Long term goal of 5-10% of initial body weight

### Evidence Statements and Supporting References

If patients wish to be measured, a combination of BMI and waist circumference or weight and waist circumference should be used.


Achievable weight reduction goals are:

- Short term goal of 1-4 kg per month
- Long term goal of 5-10% of initial body weight


Physical Activity for the Management of IFG and IGT

Participation in at least 30 minutes of moderate intensity physical activity on most, preferably all, days reduces the risk of certain chronic diseases including Type 2 diabetes and CVD. It is estimated that up to 50% of new cases of Type 2 diabetes could be prevented by people increasing their physical activity (AIHW, 2001). Importantly, people with diabetes are two to four times at increased risk of CVD. This means that a strategy to prevent diabetes may also significantly contribute to the prevention of CVD (Garrard et al, 2004).

Physical activity is defined as ‘any bodily movement produced by skeletal muscles that results in energy expenditure’ (Egger et al, 1999). It is described in terms of frequency (sessions per week), duration (minutes per week), intensity (amount of energy expended) and the context in which it is undertaken (occupational, leisure or recreation and day to day activity). It should be noted that physical activity of a specific intensity and duration is needed to confer a health benefit (Bouchard 2000; Egger et al, 1999).

The current physical activity recommendation for general health is 30 minutes of moderate-intensity** physical activity on most, preferably all, days of the week. This recommendation is based on evidence which shows that activity at, or above this level, is associated with a number of health benefits. It was a major finding of the US Surgeon General's Report on Physical Activity and Health (U.S Department of Health and Human Resources, 1996) that also provided the evidence for the development of the National Physical Activity Guidelines for Australians (Egger et al, 1999).

In the last few years, evidence of the effectiveness of physical activity and diabetes prevention has become available from numerous randomised controlled trials. In China, Finland and United States, studies have demonstrated that a combination of modest weight loss, dietary change and at least 30 minutes of moderate-intensity physical activity each day results in a 50-60% reduction in the risk of developing diabetes among those already at high risk (Lindström et al, 2003; Knowler et al, 2002; Pan et al, 1997). To achieve this health outcome, specific goals and intervention methods were established. It should be noted that the cohort treated in the China study was both relatively lean and physically active. The data may not, therefore, be directly extrapolated to people with IGT in western societies, for whom further research is needed (NHMRC, 2003).

In all three studies, the physical activity goal was at least 150 minutes of moderate physical activity per week; which is equivalent to at least 30 minutes on most days of the week. This goal was adopted because it was determined to be achievable and likely to be beneficial in preventing diabetes, based on previous studies (Knowler et al, 2002; Lindström et al, 2003). The lifestyle intervention stressed brisk walking (equivalent to moderate intensity) as the means to achieve the activity goal, although other physical activity was allowed to contribute to overall physical activity targets (Lindström et al, 2003; Knowler et al, 2002; Pan et al, 1997).

In the Finnish Diabetes Prevention Study (FDPS), the participants in the intervention group were individually coached to increase their overall level of physical activity. A nutritionist provided the coaching during dietary counselling sessions and the study physicians emphasised the benefits of exercise at the annual visits. Endurance exercise to increase aerobic capacity and cardiorespiratory fitness was recommended. Supervised, progressive and individually tailored circuit type sessions of moderate-intensity, resistance exercise were also offered free of charge. In addition, resistance training was offered to participants.

**Moderate-intensity physical activity will cause a slight, but noticeable, increase in breathing and heart rate and may cause light sweating (Egger et al, 1999).
In the Diabetes Prevention Study (DPP), the participants in the intensive lifestyle intervention were encouraged to perform at least 150 minutes of moderate physical activities similar in intensity to brisk walking. However, a maximum of 75 minutes of strength training could be applied towards the total 150 minutes weekly physical activity. Participants were encouraged to increase their activity slowly and to exercise at least three times per week for at least 10 minutes per session (DPPRG, 2004). In addition, two supervised exercise classes were offered at clinics each week.

These studies have demonstrated that 30 minutes of moderate-intensity physical activity per day is a major contributor to reducing the risk of Type 2 diabetes in high risk individuals.

Physical Activity for Weight Reduction and Maintenance

Physical activity plays an important role in weight reduction in overweight and obese adults. It is especially important for preventing or minimising weight regain after initial weight loss. To more effectively implement physical activity interventions to prevent weight regain, it is important to establish the optimal dose of physical activity.

There is now an increasing body of literature suggesting that levels of physical activity greater than the minimal recommendation are required for achieving sustainable weight loss in overweight and obese people (Jakicic, 2002; Saris, et al, 2003).

To reduce weight, the required amount of physical activity is 60 minutes of moderate-intensity activity accumulated over the course of the day, on most days of the week. In addition, for effective weight loss maintenance, the recommended amount of moderate physical activity is between 60 to 90 minutes or lesser amounts of vigorous intensity activity (NHMRC, 2003).

The evidence supporting 60 to 90 minutes is based on prospective studies. However, these studies do not suggest that the current physical activity recommendations of 30 minutes per day are ineffective in overweight or obese adults, but rather that these individuals can realise significant improvements in health and fitness by increasing their participation in moderate-intensity physical activity. When the basic level has been successfully achieved (i.e. 30 minutes per day), additional weight control benefits may be realised by increasing participation above the minimal recommended levels (i.e. 60 minutes per day) (Jakicic, 2002; Saris, et al, 2003).

In 2002, the International Association for the Study of Obesity (IASO) initiated the 1st Stock Conference series, where experts met to discuss the different aspects of physical activity in relation to the emerging problem of obesity worldwide (Sari et al, 2003). The IASO group developed a consensus statement. They concluded that there were many health benefits to be gained from 30 minutes of moderate intensity physical activity. However, for the prevention of weight gain in formerly obese individuals, at least 60-90 minutes of moderate intensity physical activity is required (Sari et al, 2003).
The sixth edition of the Dietary Guidelines for Americans (2005) now recommends 60-90 minutes of daily moderate-intensity physical activity to sustain weight loss. The Dietary Guidelines for Americans are based on the latest scientific and medical information and provide authoritative advice for people concerning proper dietary habits which promote health and reduce the risk of major chronic diseases (U.S Health Department and Human Services and U.S Department of Agriculture, 2005).

**Physical Activity Guidelines:**

- At least 30 minutes of moderate-intensity physical activity** on most, preferably all, days of the week.
- 60-90 minutes of moderate to vigorous-intensity physical activity on most, preferably all, days of the week to achieve weight reduction and prevent weight gain.

**Moderate-intensity physical activity will cause a slight, but noticeable, increase in breathing and heart rate and may cause light sweating.**
Evidence Statements and Supporting References

Physical activity can be defined as ‘any bodily movement produced by skeletal muscles that results in energy expenditure’.

Egger et al. 1999, Physical Activity Guidelines for Australians - Scientific Background Report. A Report by the University of Western Australia and The Centre for Health Promotion and Research Sydney for the Commonwealth Department of Health and Aged Care, The University of Western Australia and The Centre for Health Promotion and Research Sydney, Australia.

At least 30 minutes of moderate-intensity physical activity on most, preferably all, days of the week is recommended for all people.

Egger et al. 1999, Physical Activity Guidelines for Australians - Scientific Background Report. A Report by the University of Western Australia and The Centre for Health Promotion and Research Sydney for the Commonwealth Department of Health and Aged Care, The University of Western Australia and The Centre for Health Promotion and Research Sydney, Australia.


The prevention of weight gain in formerly obese individuals requires 60-90 minutes of moderate-intensity activity or lesser amounts of vigorous-intensity activity on most, preferably all, days of the week.


Nutrition for Management of IFG and IGT

In the past two decades the National Health and Medical Research Council (NHMRC) has developed and disseminated guidelines providing dietary advice for the Australian public. The ‘Dietary Guidelines for Australians’ and the ‘Australian Guide to Healthy Eating’ are the current food and nutrition guides for Australian adults. These two guidelines are based on evidence from various studies which strongly indicate that healthy eating behaviours are associated with protection against diabetes, CVD and other diet related chronic conditions (NHMRC, 2003).

The Dietary Guidelines for Australian Adults state (NHMRC, 2003):

1. Enjoy a wide variety of nutritious foods
   - Eat plenty of vegetables, legumes (dried peas, beans or lentils) and fruit
   - Eat plenty of cereals (including breads, rice, pasta and noodles), preferably wholegrain
   - Include lean meat, fish, poultry and/or alternatives
   - Include milks, yoghurts, cheeses and/or alternatives. Reduced-fat varieties should be chosen, where possible
   - Drink plenty of water

Take care to
   - Limit saturated fat and moderate total fat intake
   - Choose foods low in salt
   - Limit your alcohol intake if you choose to drink
   - Consume only moderate amounts of sugars and foods containing added sugars

2. Prevent weight gain: be physically active and eat according to your energy needs

3. Care for your food: prepare and store it safely

4. Encourage and support breastfeeding

Dietary recommendations specific to the prevention of Type 2 diabetes have been published in the NHMRC National Evidence Based Guidelines for the Management of Type 2 diabetes, and are outlined below (NHMRC, 2001).

- Individuals at risk of developing Type 2 diabetes should have dietary intake assessed and should receive individualised dietary advice and continued dietetic support.
- Individuals at risk should consume a diet with <30% energy as fat and <10% energy as saturated fat.
- Diets of low energy density and containing a wide range of carbohydrate foods rich in dietary fibre and of low glycaemic index (cereals, vegetables, legumes and fruits) are recommended to reduce the risk of Type 2 Diabetes.

These recommendations are consistent with the Dietary Guidelines for Australians and are supported by evidence from the Finnish Diabetes Prevention Study (FDPS), Diabetes Prevention Project (DPP) (U.S) and Da Qing IGT Study, which all explored the means of preventing Type 2 diabetes.
In the FDPS, the intervention group had an initial seven face-to-face consultation sessions with the study nutritionist and thereafter a consultation every three months. They were provided with detailed advice about how to achieve the goals of the intervention. These were: total intake of fat to less than 30% of energy consumed; intake of saturated fat to less than 10% of energy consumed; an increase in fibre intake to at least 15g per 1000kcal, and; frequent ingestion of wholegrain products, vegetables and fruit (Lindström et al, 2003).

In the DPP, the intensive lifestyle intervention comprised a detailed 16 session program. The dietary component focused on decreasing total fat intake, reduction in portion size, a target of 7% weight loss and general advice around healthy eating (Knowler et al, 2002).

In the Da Qing IGT Study, participants in the diet control arm with a BMI < 25 were encouraged to consume a diet equating to 55-65% carbohydrates, 10-15% protein and 25-30% fat, and to control alcohol intake, limit simple sugars and consume more vegetables. Participants received individual counselling about food intake and small group counselling sessions were conducted weekly for 1 month, monthly for three months, then once every 3 months for the remainder of the study (Pan et al, 1997). It should be noted that the cohort treated in this study was both relatively lean and physically active. The data may not therefore be directly extrapolated to people with IGT in western societies, for whom further research of this nature is needed (NHMRC, 2003).

The findings of these studies and the NHMRC National Evidence Based Guidelines for the Management of Type 2 diabetes strongly indicate that dietary intervention is a major contributor to a reduction in the risk of diabetes in high risk individuals.

Nutritional Guidelines:

- Dietary intake should:
  - Be of low energy density
  - Include less than 30% of energy from fat with less than 10% of energy from saturated fat
  - Include a wide variety of carbohydrate foods, particular those which are high in dietary fibre and are of lower glycaemic index
  - Be consistent with the Dietary Guidelines for Australian Adults and the Australian Guide to Healthy Eating
Evidence Statements and Supporting References

**Reduction in dietary fat to < 30% with restriction of saturated fat to <10% of energy intake reduces the risk of Type 2 diabetes.**


**Diets of low energy density containing a wide range of carbohydrate foods rich in dietary fibre and of low glycaemic index (cereals, vegetables, legumes and fruits) are recommended to reduce the risk of Type 2 Diabetes.**


**Issue**

What are the smoking recommendations for the management of IFG and IGT?

**Smoking and Development of Type 2 Diabetes**

Tobacco smoking is a widespread behaviour with severe health consequences. The risk of developing CVD increases with the duration and intensity of exposure to cigarette smoke (AIHW, 2001). Other lifestyle, physiological and genetic risk factors for CVD include high blood pressure, high blood cholesterol, poor nutrition, low levels of physical activity, overweight and obesity, diabetes and a family history of heart disease (AIHW, 2001). People diagnosed with IFG and IGT often have a combination of risk factors which together greatly increase their risk of Type 2 diabetes and CVD. Strategies to prevent the adoption of cigarette smoking or to facilitate smoking cessation can significantly reduce the incidence of diabetes and CVD.

Recent cohort studies suggest that smoking may also be an independent and modifiable risk factor for the development of Type 2 diabetes (Eyre et al, 2004; Will et al, 2001). In the Cancer Prevention Study, men and women participants who smoked greater than 2 or more packs per day at baseline had a 45% and 74% (respectively) higher diabetes mellitus incidence than men and women who had never smoked. In the same cohort, quitting smoking reduced the incidence of diabetes to that of non smokers after 5 years in women and after 10 years in men (Eyre et al, 2004).

In the Nurses’ Health Study, women who smoked 15 cigarettes or more per day had a 30% to 40% higher risk compared with those who had never smoked (Eyre et al, 2004). A similar association between smoking and Type 2 diabetes was observed among US male physicians, other health professionals, and middle-aged men in Britain and Japan (Eyre, et al, 2004). These results provide a positive incentive for at-risk individuals to avoid or quit smoking and avoid passive smoking to reduce their risk of developing Type 2 diabetes and CVD (Manson et al, 2000).

The initial assessment of an at-risk individual should specifically address smoking in order to determine the most appropriate intervention. If a smoker is not interested in quitting immediately, they should be offered brief advice on the risks of smoking and encouraged to consider the matter further. A person who is interested in quitting smoking but who is uncertain of how to go about it, should be offered information on smoking cessation including the availability of supportive resources such as Quitline (SNAP, 2004).

**Smoking Guidelines:**

- Smoking cessation is recommended.
Evidence Statements and Supporting References

Smoking may be an independent and modifiable risk factor for the development of Type 2 diabetes.


Patients who smoke should be advised to stop smoking.

Issue

Can Self Blood Glucose Monitoring be used in the management of IFG and IGT?

Role of Self Blood Glucose Monitoring in IFG and IGT

Self blood glucose monitoring (SBGM) is one of the key self-care behaviours in the management of diabetes. SBGM facilitates the development of technical and cognitive skills, and encourages the person with diabetes, in conjunction with their health care team, to reliably interpret blood glucose results and use them to adjust dietary intake, exercise and pharmacological therapy to achieve specific blood glucose targets (Mulcahy et al, 2003).

By definition, individuals with IFG and IGT, have a variation in blood glucose levels that occurs over a limited range even when subject to a glucose load. This limits the usefulness of SBGM as a self-directed learning tool in IFG and IGT. Oral hypoglycaemic agents are not routinely recommended or used in IFG and IGT and so the risk of pharmacologically induced hypoglycaemia does not exist. SBGM supplies are not subsidised on the National Diabetes Services Scheme for people with IFG and IGT and so SBGM would incur substantial cost for this group.

Self Blood Glucose Monitoring Guidelines:

- Self blood glucose monitoring is not recommended.

Supporting Reference

How should CVD risk be managed in IFG and IGT?

Cardiovascular Risk Management for IFG and IGT

People with diabetes have a two to four times increased risk of developing CVD and people with IFG and IGT are at increased risk (Garrard et al, 2004).

A meta-analysis of 20 studies conducted from 1966 to 1996 concluded that the relationship between glucose levels and CVD risk extends below the diabetic diagnostic ranges. Therefore, the management of IFG and IGT should also take into account the management of CVD risk (Coutinho et al, 1999). The possible explanations for this relationship include: the role of hyperglycaemia in atherosclerosis; the clustering of glucose intolerance with the other factors of Syndrome X; and common predisposing factors of both IFG, IGT and CVD (i.e. genetics and low birth weight).

The Diabetes Epidemiology: Collaborative Analysis of Diagnostic Criteria in Europe (DECODE) was a collaborative prospective study of 29,714 subjects aged 30-89 years who were followed-up for 11 years (DECODE Study Group, 2003). DECODE concluded inter alia that the relationship between CVD mortality and 2 hour plasma glucose was graded and increasing (DECODE Study Group, 2003).

Currently, there are no published studies demonstrating the benefits of aggressive management of lifestyle risk factors in people with IFG and IGT. In the absence of specific cardiovascular lifestyle interventions for IFG and IGT, the current Hypertension Management Guidelines for Doctors by the National Heart Foundation of Australia and Lipid Management Guidelines by the National Heart Foundation of Australia & The Cardiac Society of Australia and New Zealand are recommended. Strict control of blood pressure and lipids is critical in all individuals who are at increased risk of CVD (National Heart Foundation of Australia 2003, Heart Foundation of Australia & The Cardiac Society of Australia and New Zealand, 2001).

Cardiovascular Risk Management Guidelines:

- Blood pressure should be monitored as outlined in the Hypertension Management Guide for Doctors 2004 by the National Heart Foundation of Australia.

- Serum lipids should be screened as outlined in the Lipid Management Guidelines 2001 by the National Heart Foundation of Australia & The Cardiac Society of Australia and New Zealand.
Evidence Statements and Supporting References

The progressive relationship between glucose levels and cardiovascular risk extends below the diabetic threshold.


The relationship between CVD mortality and 2h plasma glucose, is graded and increasing.

B) Pharmacological Therapies

Executive Summary

The medications discussed in this next section are not approved on the Pharmaceutical Benefits Scheme (PBS) for the management of IFG and IGT. The medications and doses given are based on various studies as outlined below. Most of these studies have not been replicated to date and in at least one study the validity of the methodology used remains questionable.

Although not as effective as lifestyle interventions, pharmacological therapy has been shown to prevent the progression of IGT to diabetes in some people. Intervention studies have not as yet been conducted in people diagnosed with IFG. The following are summaries of pharmacological therapies which have been shown to prevent the progression of IGT to diabetes.

**Metformin - U.S. Intervention**

The hypothesis of the Diabetes Prevention Program (DPP) was that the modification of risk factors for diabetes using a lifestyle intervention or metformin would prevent or delay the development of diabetes. In this study, 3,234 people with IGT and a Body Mass Index (BMI) ≥ 24 kg/m$^2$ (or ≥ 22 kg/m$^2$ in Asian Americans) were randomly assigned to one of three interventions: standard lifestyle recommendations plus metformin at a dose of 850 mg twice daily, standard lifestyle recommendations plus placebo twice daily or an intensive program of lifestyle modification. The study initially included a fourth intervention, pharmacotherapy with troglitazone, but this arm was discontinued in 1998 because of the drug’s potential liver toxicity (Knowler et al, 2002).

Treatment with metformin was initiated at a dose of 850 mg taken orally once a day, with placebo tablets also given once a day initially. At one month, the dose of metformin was increased to 850 mg twice daily, unless gastrointestinal symptoms warranted a longer titration period. The initiation of treatment with half a tablet was optional. Adherence to the treatment regimen was assessed quarterly on the basis of pill counts and structured interviews (Knowler et al, 2002).

Treatment with metformin was associated with a 31% relative reduction in the progression to diabetes with IGT. Metformin was more effective in younger patients with a higher BMI and higher fasting plasma glucose levels and was least effective in patients older than 60 years. The rates of adverse events, hospitalisation and mortality were similar in the three intervention groups, except that the rate of gastrointestinal symptoms was highest in the metformin group (Knowler et al, 2002).

**Orlistat - Swedish Intervention**

The Xenical in the Prevention of Diabetes in Obese Subjects (XENDOS) study was a four year double-blind, randomised, placebo-controlled prospective study carried out at 22 Swedish media centres. It was conducted to determine the long-term effect of orlistat, in combination with lifestyle changes, in reducing the progression to Type 2 diabetes and body weight over 4 years in obese, non-diabetic people who had either normal glucose tolerance (NGT) or IGT. In this study, 3,305 people with BMI ≥ 30 kg/m$^2$ and NGT or IGT were randomly assigned to lifestyle changes plus either orlistat 120mg, three times daily or lifestyle changes plus placebo, three times daily (Torgerson et al, 2004).

During four years of treatment, orlistat plus lifestyle changes significantly decreased progression to Type 2 diabetes by 37% compared with placebo plus lifestyle changes. Participants with IGT at baseline had a risk reduction of 45%. People with NGT had no risk reduction but the sample size was too small for reliable analysis. The overall incidence of adverse events was similar in the two treatment groups, with the exception of a higher incidence of gastrointestinal problems in the orlistat group (Torgerson et al, 2004).
Acarbose - International Intervention

The Study to Prevent Non-Insulin Dependent Diabetes Mellitus (STOP-NIDDM) trial was an international, multicentre, placebo-controlled, randomised study, conducted in Canada, Germany, Austria, Norway, Denmark, Sweden, Finland, Israel and Spain. In this study, 1,429 people were randomly allocated to treatment with either 100mg acarbose or placebo, administered three times daily. Acarbose is a complex oligosaccharide that reduces the postprandial rise in blood glucose by delaying digestion of certain carbohydrates. People with IGT who were treated with acarbose showed a reduction in diabetes incidence of around 25%, which became apparent over the first year of intervention. However, all trial participants completing the study were given placebo for a 3 month period. During this 3 month period, those that had been originally taking acarbose had a higher incidence of diabetes than those that had been on placebo throughout the trial. This suggests that the preventive effect of acarbose requires continued treatment (Chiasson et al, 2002).

A recent critical analysis by Kaiser and Sawicki (2004) of the STOP-NIDDM data alleged several serious flaws in the study. In particular: selection bias, inadequate blinding, bias in data analysis and reporting, and potential sponsoring bias. They concluded that the clinical benefit of acarbose and of the reduction of post-prandial glycaemia was unproven. Anecdotally, acarbose is not commonly used in Western Australia due to a poor side effect profile. In one European trial, one third of the patients could not continue the drug for the whole study period, mainly due to gastrointestinal side-effects (Scorpiglione et al, 1999).

Ramipril and Rosiglitazone

A further two large multicentre studies have recently been established. The DREAM (Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medications) study is investigating the ACE inhibitor ramipril and the glitazone rosiglitazone while the NAVIGATOR study is investigating the oral hypoglycaemic agent nateglinide and the angiotensin receptor blocker valsartan. The results of the NAVIGATOR and DREAM studies are awaited (Unwin et al, 2002).
Recommended Guidelines

- Certain medications used in the management of diabetes may be considered where lifestyle interventions do not achieve a pre-determined reduction in weight or glycaemia.

- The following medications may be used for individuals with Body Mass Index over 30 kg/m²
  - Metformin (850 mg bd)*
    *(The dosage regimen for metformin is that used in the Diabetes Prevention Program. Lower doses (e.g. 500mg bd) may be necessary in individuals exhibiting side-effects on the higher dose but there is no evidence that this regimen is beneficial.)*
  - Orlistat (120 mg tds)*

- The following medications have equivocal or insufficient evidence to support their use:
  - Rosiglitazone* or Pioglitazone*
  - Acarbose (100 mg tds)*

* These medications are not approved on the Pharmaceutical Benefits Scheme (PBS) for people with IFG and IGT.
Evidence Statements and Supporting References

**Metformin has proven to be effective in preventing or delaying the onset of Type 2 diabetes in certain individuals.**


**Orlistat plus lifestyle changes resulted in a reduction in the incidence of Type 2 diabetes over four years.**


**The STOP-NIDDM trial evaluated the effectiveness of acarbose, (an alpha-glucosidase inhibitor) and results indicate a reduction in diabetes incidence of around 25%, all apparent over the first year of intervention.**


**The STOP-NIDDM trial is seriously flawed. The clinical benefit of acarbose and of the reduction of post-prandial glycaemia remains unproven.**

Detection of categories of abnormal glucose tolerance, with special reference to IFG and IGT

**Initial Test:** Must always be performed by assay of venous plasma in a laboratory *

- FPG (mmol/L) < 5.5
- RPG (mmol/L) < 5.5

**Conduct an Oral Glucose Tolerance Test**

- FPG (mmol/L) < 6.1
- 6.1 - 6.9 < 7.0
- 2h PG (mmol/L) < 7.8

**IFG**

- Fasting
- Normal

**IGT**

- Any Post Prandial ≥ 11.1

**Diabetes**

- Any Fasting ≥ 7.0

Refer to Management Section of IFG/IGT Guidelines

- Retest 3 years (FPG)
- Retest 1 year (FPG)

IFG: Impaired Fasting Glucose  
IGT: Impaired Glucose Tolerance  
FPG: Fasting Plasma Glucose  
RPG: Random Plasma Glucose

*Can be combined with fasting lipid profile and other tests as part of a detailed vascular risk assessment.*
References


Egger et al. 1999, Physical Activity Guidelines for Australians - Scientific Background Report. A Report by the University of Western Australia and The Centre for Health Promotion and Research Sydney for the Commonwealth Department of Health and Aged Care, The University of Western Australia and The Centre for Health Promotion and Research Sydney, Australia.


National Health and Medical Research Council (NHMRC). 2001, National Evidence Based Guidelines for management of Type 2 Diabetes Mellitus, Primary Prevention. Case Detection and Diagnosis., NHMRC, Sydney.


Detection of categories of abnormal glucose tolerance, with special reference to IFG and IGT

**Initial Test:** Must always be performed by assay of venous plasma in a laboratory*

<table>
<thead>
<tr>
<th>FPG (mmol/L)</th>
<th>5.5 - 6.9</th>
<th>≥ 7.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 11.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPG (mmol/L)</td>
<td>5.5 - 11.0</td>
<td>≥ 11.1</td>
</tr>
<tr>
<td>&lt; 5.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conduct an Oral Glucose Tolerance Test

**FPG (mmol/L)**
- < 6.1
- And
- < 7.8

**2h PG (mmol/L)**
- < 7.8

**NORMAL**
- Normal
- Recheck FPG after 3 years

**IFG / IGT**
- IFG
- Refer to Lifestyle Interventions (see reverse)
- Recheck FPG after 1 year

**DIABETES**
- Diabetes
- Refer to Type 2 Diabetes Guidelines
- Retest with FPG to confirm diabetes diagnosis


*Can be combined with fasting lipid profile and other tests as part of a detailed vascular risk assessment.
Clinical Management of IFG/IGT

1 Definition:
IFG and IGT represent stages in the natural history of disordered carbohydrate metabolism rather than a subclass of diabetes. Neither are considered clinical entities in their own right (except during pregnancy) but rather are risk factors for the future development of diabetes and cardiovascular disease.

2 Diagnosis must always be performed by assay of venous plasma in a laboratory. Portable blood glucose meters lack the accuracy required for definitive diagnosis.

3 A Fasting Plasma Glucose (FPG) should be performed as the initial screening test in people with risk factors for glucose intolerance. If a FPG level on initial screening is in the range 5.5–6.9 mmol/L, it should be followed up with an oral glucose tolerance test (OGTT).

4 A Random Plasma Glucose (RPG) may be used if collection of a FPG sample is considered impractical. If a RPG level on initial screening is used and in the range 5.5–11.0 mmol/L, it should be followed up with an OGTT.

5 OGTT must be performed based on FPG and 2 hour Plasma Glucose (2h PG) measurements as outlined in the NHMRC guidelines, which are as follows:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>FPG (mmol/L)</th>
<th>2 h PG (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Tolerance</td>
<td>&lt; 6.1 &amp; &lt; 7.8</td>
<td></td>
</tr>
<tr>
<td>IFG</td>
<td>6.1–6.9 &amp; &lt; 7.8</td>
<td></td>
</tr>
<tr>
<td>IGT</td>
<td>&lt; 7.0 &amp; 7.8–11.0</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>&gt; 7.0 or ≥ 11.1</td>
<td></td>
</tr>
</tbody>
</table>

6 Periodic testing for progression to Type 2 diabetes is recommended by measuring Fasting Plasma Glucose (FPG) according to the following schedule:
- Each year for people with IFG and IGT
- Every 3 years for people at high risk with a normal FPG

7 Those individuals who have an abnormal FPG on retest should be referred for an OGTT as outlined in the diagnostic procedures.

Lifestyle Interventions for IFG/IGT

Nutrition
- Dietary intake should:
  - Be of low energy density
  - Include less than 30% of energy from fat with less than 10% of energy from saturated fat
  - Include a wide variety of carbohydrate foods, particularly those which are high in dietary fibre and are of lower glycaemic index
  - Be consistent with the Dietary Guidelines for Australian Adults and the Australian Guide to Healthy Eating.

Physical Activity
- At least 30 minutes of moderate-intensity** physical activity on most, preferably all, days of the week.
- 60–90 minutes of moderate to vigorous-intensity physical activity on most, preferably all, days of the week, to achieve weight reduction and prevent weight gain.

**Moderate-intensity: will cause a slight but noticeable increase in breathing and heart rate and may cause light sweating.

Self Blood Glucose Monitoring
- Self blood glucose monitoring is not recommended.

Cardiovascular Risk
- Blood pressure should be monitored.
- Serum lipids should be screened yearly.

Smoking
- Smoking cessation is recommended.

Referral
Refer for intensive intervention to allied health professionals. These can include your local diabetes educator, dietitian, physiotherapist, exercise physiologist. Contact your local Division of General Practice for advice.

For further assistance in management the following contacts may be useful:
- Western Australian Diabetes Strategy website: www.diabetes.health.wa.gov.au
- Diabetes Information Advice Line: 1300 136 588 or www.dawa.asn.au
- Heartline: 1300 362 787
- Quitline: 131 848 or www.quitnow.info.au

1 Western Australian IFG/IGT Consensus Guidelines 2005.