



Complete Summary

GUIDELINE TITLE

Management of type 2 diabetes.

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). Management of type 2 diabetes. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2003 Dec. 143 p. [565 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [February 26, 2008, Avandia \(rosiglitazone\)](#): A new Medication Guide for Avandia must be provided with each prescription that is dispensed due to the U.S. Food and Drug Administration's (FDA's) determination that this medication could pose a serious and significant public health concern.
- [December 12, 2007, Carbamazepine](#): The U.S. Food and Drug Administration (FDA) has provided recommendations for screening that should be performed on specific patient populations before starting treatment with carbamazepine.
- [November 14, 2007, Avandia \(rosiglitazone\)](#): New information has been added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks.
- [August 16, 2007, Coumadin \(Warfarin\)](#): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.
- [August 14, 2007, Thiazolidinedione class of antidiabetic drugs](#): Addition of a boxed warning to the updated label of the entire thiazolidinedione class of antidiabetic drugs to warn of the risks of heart failure.
- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.
- [October 6, 2006, Coumadin \(warfarin sodium\)](#): Revisions to the labeling for Coumadin to include a new patient Medication Guide as well as a

reorganization and highlighting of the current safety information to better inform providers and patients.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

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SCOPE

DISEASE/CONDITION(S)

Type 2 diabetes and associated complications including cardiovascular disease, renal disease, eye disease, and foot disease

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Ophthalmology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Nurses
Patients
Physician Assistants

Physicians
Podiatrists

GUIDELINE OBJECTIVE(S)

- To provide an evidence-based summary of best practice in the management of some key aspects of type 2 diabetes in order to improve the outcome for people with diabetes
- To assist decision-making by health care providers and people with type 2 diabetes

TARGET POPULATION

Adults in New Zealand with type 2 diabetes.

Note: Parts of this guideline also apply to the care of those with type 1 diabetes.

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Diagnosis

1. Fasting venous blood plasma glucose
2. Oral glucose tolerance test (OGTT)
3. Cardiovascular risk assessment
4. Body mass index (BMI) measurement
5. Total cholesterol (TC) and TC:high-density lipoprotein (HDL) testing
6. Urinary albumin concentrations
7. Serum creatinine testing
8. Slit lamp biomicroscopy
9. Neuropathy screening with 10 g monofilament and vibration perception thresholds

Treatment/Management

1. Culturally appropriate approach
2. Dietary education
 - Cardioprotective dietary pattern
3. Weight management
 - Diet and physical activity
 - Medication
 - Surgery
4. Increased physical activity, with attention to minimizing patient risk
5. Smoking cessation
 - Nicotine replacement therapy
 - Bupropion or nortriptyline hydrochloride
6. Screening and treatment for depression
 - Mental health therapy
 - Selective serotonin reuptake inhibitors
7. Glycaemic control
 - Control of glycated hemoglobin (HbA1c) levels

- Drug treatments: metformin, insulin secretagogues, alpha-glucosidase inhibitors (acarbose), glitazone, insulin
- Self management education
- 8. Blood pressure management
 - Drug treatments: beta-blockers, angiotensin-converting enzyme (ACE)-inhibitors, A2-receptor-blockers, aspirin, statins, warfarin
- 9. Lipid management
 - Drug treatments: statins, aspirin, beta-blockers, ACE-inhibitors
 - Fibrate or combination therapy
- 10. Antiplatelet therapy with aspirin
 - Computed tomography (CT) scan to exclude intracranial haemorrhage
- 11. Complementary and alternative therapies
- 12. Diabetic foot disease/Charcot's foot
 - Foot care education
 - Footwear modification
 - Total contact casting
 - Arterial revascularisation procedures
 - Treatment of foot ulcers
 - Broad spectrum antibiotics regimen
 - Wound care including debridement
 - Diabetic neuropathy drug treatment: tricyclic antidepressants, gabapentin, topical capsaicin, analgesia (such as paracetamol), carbamazepine
- 13. Referral to specialist as indicated

MAJOR OUTCOMES CONSIDERED

Glycaemic Control

- Does improving glycaemic control (tight control) reduce microvascular and/or macrovascular complications of diabetes?
- What should be the target level(s) of glycated hemoglobin (HbA1c)?
- Which method of measuring HbA1c should laboratories use?
- What are the potential risks of tight glycaemic control?
- How does tight glycaemic control affect quality of life?
- How should glycaemic control be monitored?
- Which lifestyle interventions have been shown to improve glycaemic control?
- Which medications should be used to improve glycaemic control?
- When and how should insulin be used?
- In teenagers and youth with type 2 diabetes, should targets for glycaemic control and modes of treatment be the same as for adults?

Renal Disease

- What are the definitions of diabetic renal disease, microalbuminuria, and overt diabetic nephropathy?
- What are the risk factors for the development of diabetic renal disease, and how should risk be stratified?
- In people with diabetes, who should be tested for diabetic renal disease, when after diagnosis of diabetes should testing start, and should an attempt be made to achieve good glycaemic control before testing for diabetic renal disease?

- Which test(s) should be used for early detection of diabetic renal disease and for monitoring of diabetic renal disease?
- How often should testing for diabetic renal disease occur?
- Which interventions have been shown to be effective for preventing the onset and for delaying the progression of diabetic renal disease?
- When is specialist referral indicated in people with diabetic renal disease?

Eye Disease

- How is diabetic retinopathy defined?
- What are the risk factors for the development and progression of diabetic retinopathy?
- In people with diabetes, who should be screened for diabetic retinopathy, and when after diagnosis of diabetes should screening start?
- Which method(s) should be used to screen for diabetic retinopathy?
- How often should screening for diabetic retinopathy occur?
- Which interventions have been shown to be effective in preventing the onset of diabetic retinopathy, delaying the progression of diabetic retinopathy, and decreasing the risk of visual loss?

Diabetic Foot Disease

- How is diabetic foot disease defined?
- What are the risk factors for ulceration and for amputation in people with diabetes?
- In people with diabetes, who should be screened for diabetic foot disease, when after diagnosis of diabetes should screening start, and how often should foot screening occur?
- Which test(s) or method(s) should be used to screen for diabetic foot disease?
- Which interventions have been shown to be effective in preventing and treating ulceration, and in preventing amputation?
- Are there specific cultural issues which might affect the way in which foot examination and foot care should be carried out in particular groups of people with diabetes, for example Maori and Pacific peoples?

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The diabetes Guideline Development Team took a pragmatic approach to the development of this guideline. Evidence-based diabetes guidelines were published internationally in late 2001 and early 2002. As the diabetes literature is extensive and three sets of international guidelines had been rigorously and systematically developed, it was agreed that the New Zealand Management of Type 2 Diabetes Guideline would be an adaptation of some sections of these international

guidelines. Where issues were specific to New Zealand, such as issues for Maori and Pacific people with diabetes, a literature search was undertaken, using the Scottish Intercollegiate Guidelines Network (SIGN) search strategies, looking for new evidence that had emerged since the publication of the international guidelines. This search was done in May 2003. No papers were identified which changed any recommendations.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) diabetes guideline and the Royal College of General Practitioners (RCGP) Blood Glucose Management Guideline have different systems for grading both levels of evidence and recommendations. The Guideline Development Team discussed this issue extensively. A consensus decision was made to use the levels of evidence as assigned to each statement by the original guideline developers (either SIGN or RCGP).

SIGN Levels of Evidence

1++

High quality meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with a very low risk of bias

1+

Well conducted meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with a low risk of bias

1-

Meta-analyses, systematic reviews of randomized controlled trials, or randomized controlled trials with a high risk of bias

2++

High quality systematic reviews of case-control or cohort studies

High quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+

Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-

Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3

Non-analytic studies (e.g., case reports, case series)

4

Expert opinion

RCGP Levels of Evidence

Ia

Evidence from meta-analysis of randomized controlled trials

Ib

Evidence from at least one randomized controlled trial

IIa

Evidence from at least one controlled study without randomization

IIb

Evidence from at least one other type of quasi-experimental study

III

Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies, and case-control studies

IV

Evidence from expert committee reports or opinions and/or clinical experience of respected authorities

Appraisal of Other Guidelines

The AGREE appraisal instrument was used by the guideline development team to appraise the quality of the methods used to develop other diabetes guidelines. The team decided to adapt three international diabetes guidelines published in 2001 and 2002, which were assessed as being well-developed, and suitable for adaptation to New Zealand circumstances.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The New Zealand Guidelines Group (NZGG) convened a Guideline Development Team. The team first met in April 2002. Three face-to-face meetings and eight teleconferences were held. The team was divided into four subgroups to undertake the initial work on the four main areas:

- glycaemic control
- renal disease
- eye disease
- foot disease.

The project manager drafted the four chapters for the subgroups. These draft chapters were first reviewed and revised by the relevant subgroup and then by the whole team. All other chapters, including resources and appendices were also drafted by the project manager, then reviewed and revised by the whole team. Chapters were re-drafted by the project manager. Agreement was by consensus.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

For the grades of recommendations used in this guideline it was decided to use the Scottish Intercollegiate Guidelines Network grades of recommendations, except in the sections on cardiovascular disease and lifestyle management where the New Zealand Guidelines Group grades described in the Assessment and Management of Cardiovascular Risk Guideline are used.

Levels of Recommendations

A

The recommendation is supported by good evidence.

B

The recommendation is supported by fair evidence.

C

The recommendation is supported by non-analytic studies or consistent expert opinion.

I

The evidence is insufficient, evidence is lacking, of poor quality or opinions conflicting, the balance of benefits and harms cannot be determined.

Good Practice Point (GPP)

Recommended practice based on the clinical experience of the Guideline Development Team

COST ANALYSIS

Economic Considerations

Both a full economic analysis of interventions for diabetes and a balance sheet were beyond the scope of this guideline. While the economic impact of many aspects of diabetes care is unknown, several recommended practices in this guideline have been found to be cost-effective in economic studies. The Price Waterhouse Cooper report also makes several recommendations which could reduce the serious economic consequences of the rising prevalence of diabetes.

Intensive blood glucose control was shown to be clearly cost-effective for those with type 1 and type 2 diabetes, and to be more cost-effective among younger people with type 2 diabetes compared with older people. Among people with type 2 diabetes, cost savings resulting from intensive blood glucose control largely resulted from lower hospitalisation costs.

Achieving an average blood pressure of 144/82 mm Hg reduced costs and improved health outcomes relative to moderate hypertension control (154/86 mm Hg). Control of blood pressure below 150/85 mm Hg was found to reduce the cost of complications and had a cost-effectiveness ratio that compared favourably with many accepted health care programmes.

Several economic studies examining retinopathy prevention have demonstrated that diabetic retinopathy screening programmes, which include treatment facilities, are clearly cost-effective.

Although the literature on economic studies of preventive foot care practices was limited, research suggests that aggressive, proactive care may result in fewer lower extremity amputations and be cost-effective and possibly cost-saving. A recent simulation model concluded that an intensified lower extremity amputation prevention programme including patient education, foot care, and appropriate

footwear for people with diabetes at risk or high risk for foot ulcers and amputations would be a cost-effective or even a cost-saving strategy. The same modelling study found that the provision of such a programme was not cost-effective in low risk people with diabetes without specific risk factors.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft of this guideline was widely distributed to many organizations including consumer groups, primary health organizations, district health boards (DHBs), service and provider organizations, expert reviewers, clinicians, and other health care practitioners for comment as part of the consultation and peer review process. At the time of peer review, the draft guideline was also available on the New Zealand Guidelines Group (NZGG) Web site.

Comment was received from many individuals, groups and organizations including consumers, health care practitioners and academics. Also, the guideline was assessed using the AGREE tool. Comments were considered by the Guideline Development Team and the NZGG, and amendments made.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the Levels of Evidence and Grades of Recommendation (**A - C, I, and Good Practice Points [GPP]**) are given at the end of the Major Recommendations field.

Type 2 Diabetes in New Zealand

Diagnosis of Diabetes, Impaired Glucose Tolerance (IGT), and Impaired Fasting Glucose (IFG)

C Two fasting venous plasma glucose results greater than or equal to 7 mmol/L on two different days are diagnostic of diabetes and an oral glucose tolerance test (OGTT) is not required.

C A random venous plasma glucose result of greater than 11 mmol/L on two different days is diagnostic of diabetes.

C A fasting venous plasma glucose of 6.1 to 6.9 mmol/L indicates impaired fasting glucose and an OGTT is recommended to assess for diabetes or IGT.*

C Some people with a fasting venous plasma glucose of 5.5 to 6.0 mmol/L show diabetes or impaired glucose tolerance with an OGTT.

C An OGTT is recommended in people with a fasting venous plasma glucose of 5.5 to 6.0 mmol/L who are not of European ethnicity or who have a family history of diabetes, a past history of gestational diabetes, or other features of the metabolic syndrome.

C A fasting venous plasma glucose result of less than 5.5 mmol/L is normal.

GPP Glycosylated hemoglobin (HbA1c) should not be used for the diagnosis of diabetes.

*A recent reexamination of the classification and diagnostic criteria of diabetes recommended that the cut-off point for IFG should be reduced from 6.1mmol/L to 5.6 mmol/L.

Lifestyle Management

Dietary Interventions

A Recommend a reduction in energy intake with weight loss as the primary objective for people with diabetes or the metabolic syndrome who are overweight or obese.

A Everyone with type 2 diabetes or the metabolic syndrome should receive intensive dietary advice. Intensive dietary advice should be given in individual/group sessions with a dietitian. Physical activity should also be encouraged.

A Encourage people with type 2 diabetes or the metabolic syndrome to gradually adopt a cardioprotective dietary pattern. Advise a reduction in the intake of foods rich in saturated fatty acids or added sugars and white flour bakery products.

Encourage a progressive replacement of these foods with vegetables, fruit, whole grain, high-fibre products, and dried peas and beans (legumes). Recommend an increase in the consumption of fish and include a source of polyunsaturated fat (see Appendix B in the original guideline document).

A Interventions that are known to reduce risk factors in people without diabetes are also recommended for people with diabetes. Assess salt and alcohol consumption and provide guidance for limited use. Consider adding plant sterols/stanols to the diet.

A For the optimal improvement of all risk factors, especially body weight and glycaemic control, employ intensive dietary interventions that include continuous education, behaviour modification, goal setting, and intensive monitoring.

C Identify and recommend qualitative dietary changes based on the habitual dietary pattern, and then progress to quantitative advice to promote the development of a structured eating plan.

A Specific dietary advice for people with diabetes and the metabolic syndrome includes advice about the saturated fatty acid content of foods and the quality of

carbohydrate choices to encourage a high-fibre intake of more than 40 g daily (see Appendix B in the original guideline document).

A To control postprandial hyperglycaemia the following advice is recommended:

- include high-fibre foods with a low to moderate glycaemic index at each meal
- distribute carbohydrate foods evenly throughout the day
- avoid a large volume of carbohydrate-rich foods at any one meal

A Refer or re-refer to a dietitian for specialised tailoring of advice and energy-balance assessments if treatment targets are not achieved.

A Reduce sodium intake to no more than two grams per day (6 g sodium chloride) by minimising added salt and limiting high salt containing foods.

B People with diabetes may consume up to 2 to 3 standard drinks of alcohol at one time with a minimal effect on blood glucose. They should be advised that, if exercise and consumption of alcohol are combined, there may be a greater lowering of blood glucose.*

GPP Everyone with type 2 diabetes or the metabolic syndrome should be offered a dietary review and tailored advice according to their readiness for change, energy requirements, profile of risk, prescribed medications, lifestyle, and cultural choices.

GPP Culturally appropriate dietary advice is of particular importance for Maori and Pacific people with diabetes. Referral to Maori and Pacific dietitians may be preferable, where possible.

GPP Use culturally appropriate dietary resources for people with diabetes. Resources developed for the free annual check programme are available in Maori and Pacific Island languages**.

*Grade of recommendation adjusted due to setting and sample sizes of trials.

**Pacific Islands Heartbeat (PIHB) has produced a resource entitled *Eat for Health*, available in Samoan, Tongan, Cook Island, Niuean and English versions (contact PIHB through the National Heart Foundation at www.heartfoundation.org.nz).

Dietary Education

A Use behavioural and motivational strategies in education and counselling to achieve and sustain dietary change.

A Everyone with diabetes should receive intensive dietary advice on interventions that have been shown to benefit people with their risk profile.

A Intensive dietary advice should be given in individual/group sessions with a dietitian.

Weight Management

B Encourage people with a 5-year cardiovascular risk above 15% or with diabetes and a body mass index (BMI) greater than 25 (especially anyone who has a BMI >30) to commence graduated lifestyle change aimed at weight reduction.

A For significant weight loss, recommend a reduction in energy intake and an increase in physical activity.

C Discourage the use of weight loss programmes that promote the exclusion of food groups from the cardioprotective dietary pattern or that increase saturated fatty acids intake.

GPP Consider referral to weight management health care practitioners for motivational counselling or specific energy balance assessment and advice when general lifestyle advice does not achieve a sustained weight loss.

GPP Review the indication for use of drugs that cause weight gain. Offer weight management support to people requiring drugs that cause weight gain.

GPP Only initiate pharmacological interventions as an adjunct to a comprehensive weight management programme that includes diet and physical activity and uses motivational and behavioural methods.

GPP Surgery may be considered for people with a BMI greater than 40. Decisions should take into account both the absolute cardiovascular risk and other health risks and comorbidities.

Physical Activity

B Physical activity is an integral part of the lifestyle advice for people with diabetes.

B Everyone should aim to do a minimum of 30 minutes of moderate-intensity physical activity (3 – 6 metabolic equivalents [METs]) on most days of the week.

B For people with time constraints, physical activity may be accumulated in bouts of 8 to 10 minutes.

B People who are already doing 30 minutes of moderate-intensity physical activity per day should be encouraged to do physical activity of higher intensity or for longer to increase the beneficial effect by further improving their cardiorespiratory fitness.

C A gradual introduction and initial low intensity of physical activity should be recommended for sedentary people with diabetes.

C Advice about physical activity should be individually tailored and diabetes-specific and should include implications for glucose management.

C To maximise adherence, physical activity programmes should be accompanied by ongoing support and should include advice tailored to the individual's stage of change.

GPP Physical activity programmes should be acceptable and appropriate for each individual. Many people may prefer home-based programmes. Some people with diabetes may prefer community-based group programmes, such as marae or church-based programmes.

GPP Green Prescription and Push Play resources may be useful (both available at www.pushplay.org.nz).

Minimizing the Risks of Physical Activity

C People with existing complications of diabetes should seek medical review before embarking on exercise programmes.

C Physical activity for people with diabetes with coronary heart disease should begin at a low intensity and gradually increase over several weeks.

B Individuals with a history of cardiovascular disease should consult their doctor before they undertake vigorous physical activity. Vigorous activity is generally not encouraged in people with diabetes with impaired left ventricular function, severe coronary artery disease, recent myocardial infarction, significant ventricular arrhythmias, or stenotic valve disease.

C Individualised advice on avoiding hypoglycaemia when exercising should be given to people taking insulin, including adjustment of carbohydrate intake, reduction of insulin dose, and choice of injection site.

GPP Advice on the spread of carbohydrate intake and/or a reduction of medication before planned exercise may be important for people with diabetes on oral therapies (especially those on sulphonylureas).

Smoking Cessation

A All smokers should be encouraged to stop smoking. Smoking cessation has major and immediate health benefits for smokers of all ages.

GPP The recording of current and past smoking habits is recommended as part of comprehensive diabetes management.

A Nicotine replacement therapy (NRT) is recommended as first-line pharmacotherapy in New Zealand. Bupropion or nortriptyline hydrochloride for smoking cessation are recommended as second-line agents.

C Use NRT cautiously (after discussion with a specialist) in the immediate period post myocardial infarction (4 weeks) and in those with serious arrhythmias or severe or worsening angina.

C Nortriptyline hydrochloride is contraindicated during the acute recovery period after myocardial infarction.

Depression and Life Stress in People with Diabetes

B Health care practitioners should be aware of the effects of depression in people with diabetes.

B All people with diabetes should be screened for depression and offered appropriate therapy.

B Selective serotonin reuptake inhibitors are recommended in preference to tricyclic antidepressants for treatment of depression in people with diabetes.

GPP Health care practitioners should be aware of the potential effects of life events on stress levels and self-care behaviour in people with diabetes.

Glycaemic Control

A Good glycaemic control should be a key goal of treatment, to delay the onset and progression of diabetic microvascular disease and macrovascular disease.

Target HbA1c Levels

D The goal of treatment is to achieve an HbA1c as close to physiologically normal as possible, preferably less than 7.0%. For each patient the risk of hypoglycaemia must be considered when determining the target HbA1c, especially people treated with insulin, particularly those with type 1 diabetes.

GPP The lower the HbA1c level the better. Any sustained reduction of HbA1c is worthwhile.

GPP For people on metformin and/or peroxisome proliferator-activated receptor (PPAR)- γ agonists (glitazones) who have no risk of hypoglycaemia, the target HbA1c should be as low as possible. The target HbA1c that is achievable for people on insulin secretagogues (sulphonylureas) or insulin is likely to be higher because of the risk of hypoglycaemia.

GPP The target HbA1c for an individual should take into account:

- side effects of therapy, particularly severe hypoglycaemia
- other risk factors for diabetes complications, such as age, BMI, blood pressure, and lipid status
- presence of complications of diabetes, or comorbidities
- individual choice
- psychosocial circumstances

Risks of Tight Glycaemic Control

A People with diabetes and health care practitioners should make every effort to avoid severe hypoglycaemia.

GPP Health care practitioners should be aware that more intensive glycaemic control treatment increases the risk of hypoglycaemia.

GPP The risks of tight glycaemic control should be weighed against the expected benefits in terms of delayed onset and rate of progression of complications for the individual.

GPP Tight glycaemic control may not be achievable or advisable in some people with type 2 diabetes, including:

- those who have frequent hypoglycaemic episodes
- those with hypoglycaemic unawareness
- those who are frail or have significant comorbidities
- those at risk of severe hypoglycaemia who live alone or have poor social support

Monitoring of Glycaemic Control

D Self-monitoring of blood glucose should be considered in conjunction with appropriate therapy as a part of integrated self-care. The purpose of blood glucose self-monitoring should be clear and agreed with the person with diabetes.

D Blood glucose self-monitoring should be taught by appropriately trained staff.

D HbA1c should be measured 3 to 6 monthly. The frequency of testing depends on:

- acceptability of HbA1c levels
- stability of self-monitored blood glucose results
- changes in diabetes therapies

D HbA1c should be measured using a National Glycosylated Hemoglobin Standardization Program certified method and results should be Diabetes Control and Complications Trial (DCCT)-aligned.

GPP Despite improvements in the standardisation of HbA1c assays, repeated testing in an individual should ideally be carried out at the same laboratory, to permit the best comparison between serial results.

Lifestyle Interventions Shown to Improve Glycaemic Control

Self-Management Education

GPP People with diabetes should be offered self-management education at diagnosis and then on an ongoing basis, based on formal regular assessment.

GPP People with diabetes should be encouraged to accept responsibility for self-management of their diabetes, including the appropriate lifestyle interventions and changes necessary to achieve good glycaemic control.

Pharmacological Interventions to Achieve Glycaemic Control

Combination Therapy

B When glycaemic control deteriorates to unsatisfactory levels on maximum doses of current therapy, another therapy should usually be added.*

*Grade of recommendation in Royal College of General Practitioners guideline: **B** (adjustment not necessary).

Metformin Therapy

A Metformin should be considered as the first-line oral therapy in overweight people (BMI >25) with type 2 diabetes.

GPP Metformin should not be used in situations where lactic acidosis is likely. Suggested contraindications and guidelines for withdrawing metformin are (Jones, Macklin, & Alexander, 2003):

- stop metformin therapy if serum creatinine is greater than or equal to 0.15 mmol/L*
- withdraw metformin during periods of suspected tissue hypoxia (e.g., due to myocardial infarction, sepsis)
- withdraw metformin for three days after contrast medium containing iodine has been given, and start treatment with metformin only after renal function has been checked
- withdraw metformin two days before general anaesthesia and reinstate when renal function is stable

GPP Metformin can be used for people with type 2 diabetes who are not overweight.

GPP Gastrointestinal intolerance to metformin is relatively common when initiating therapy (10–15%). Stepwise upward titration of the metformin dose over several weeks and taking metformin with food will often minimise side effects.

*Any concentration of creatinine that is chosen as a cut-off point for renal failure will be arbitrary in view of individual peoples' muscle mass and protein turnover, and caution should therefore be used in prescribing metformin for older people with diabetes.

Use of Insulin Secretagogues

A Insulin secretagogues can be considered as first-line therapy:

- if metformin is not tolerated
- if metformin is contraindicated
- in people who are not overweight

A Insulin secretagogues should be used in combination therapy in overweight people on metformin when glycaemic control is not satisfactory on metformin alone.

A Both health care practitioners and people with diabetes using insulin secretagogues should be aware of the risk of hypoglycaemia and be alert for its occurrence.

Alpha-Glucosidase Inhibitors

A Acarbose may be considered as an alternative glucose lowering therapy in people unable to use other oral drugs.

GPP Acarbose must be started in small doses and titrated gradually.

GPP In the unusual situation of hypoglycaemia in people on acarbose therapy (used alone or in combination), the use of oral glucose rather than sucrose or fructose is recommended, to achieve a rapid increase in blood sugar level.

Glitazone Therapy

A Glitazone therapy can be considered for use in people with type 2 diabetes either as monotherapy or as combination therapy with either metformin or a sulphonylurea. There are limited data available on the safety of combined use with insulin.

GPP Glitazones should not be used in people with cardiac failure.

GPP After introduction of a glitazone, the effect on blood glucose lowering may be delayed for at least 6 weeks.

Insulin Therapy in Type 2 Diabetes

A Insulin therapy should be offered to people with type 2 diabetes inadequately controlled on optimised oral therapies.

A Insulin therapy can be used alone or in combination with oral therapies.

A Health care practitioners and people with diabetes who are using insulin should be aware of the risk of hypoglycaemia and be alert for its occurrence.

GPP Insulin is often started with a once-daily dose of intermediate-acting insulin, at night or in the morning, depending on the individual's blood glucose profile. A once-daily nocturnal dose in combination with continued oral medication is often a convenient way to initiate insulin. A twice-daily or more intensive regime can also be considered.

GPP It may be appropriate to consult a diabetes nurse specialist or a diabetologist (or specialist physician) for advice when starting a patient on insulin. Telephone advice may be sufficient.

GPP It is important to prepare people with type 2 diabetes, well in advance, that insulin will almost certainly be required at some stage, due to the progressive nature of the disease.

GPP For Maori and Pacific people with diabetes, it is particularly important to prepare for the introduction of insulin well in advance and to enquire about and address misconceptions about insulin therapy. A common misconception, especially among older Maori and Pacific people, is that starting insulin therapy means that one will die soon.

Management of Children and Adolescents

GPP Children and adolescents with type 2 diabetes should be under the care of a specialist diabetes service.

Diabetic Cardiovascular Disease

Cardiovascular Risk Assessment in People with Diabetes

C Cardiovascular risk assessments are recommended annually from the time of diagnosis for people with diabetes.

C Risk assessments should be provided at the primary care level by health practitioners with appropriate training, infrastructure support, systems for follow-up, and systems that improve quality.

C All those with cardiovascular disease should have comprehensive risk factor measurements to determine the best management approach.

Treatment Decisions

A All treatment decisions should be based on an individual's 5-year absolute cardiovascular risk.

C Everyone with risk factors should be involved in the decision-making process regarding their treatment.

C The higher an individual's absolute risk of a cardiovascular event the more aggressive management should be.

A Everyone with a history of a cardiovascular event and any risk factor above optimal levels should be considered for treatment to reduce their cardiovascular risk. Treatment should aim to lower the risk factors to optimal levels.

C Everyone with isolated very high risk factor levels, either a total cholesterol (TC) greater than 8 mmol/L or a TC:high-density lipoprotein (HDL) ratio greater than 8 or blood pressure greater than 170/100 mm Hg should have drug treatment and specific lifestyle advice to lower risk factor levels.

A Everyone with the specific genetic lipid disorders (familial hypercholesterolaemia, familial defective apolipoprotein B (ApoB), or familial combined dyslipidaemia) or diabetes with overt nephropathy should be considered for treatment to reduce their cardiovascular risk. Treatment should aim to lower the risk factors to optimal levels.

A Everyone with cardiovascular disease, a 5-year cardiovascular risk of greater than 20%, genetic lipid disorders, diabetes, or the metabolic syndrome should receive intensive lifestyle advice. Lifestyle changes that have been shown to benefit people with these risk profiles include:

- dietary change (**A**)
- smoking cessation (**A**)
- physical activity (**B**)

A Intensive dietary advice should be given in individual/group sessions with a dietitian.

C People with a 5-year cardiovascular risk greater than 20% should receive intensive lifestyle advice and drug treatment of all modifiable risk factors simultaneously.

C People with a 5-year cardiovascular risk of between 15 and 20% are likely to need treatment of all modifiable risk factors. Specific lifestyle advice may be given for 3 to 6 months prior to drug treatment.

C Among people with a 5-year cardiovascular risk greater than 15%, the aim of treatment is to lower 5-year cardiovascular risk to less than 15%.

B People with a 5-year cardiovascular risk between 10% and 20% should receive specific lifestyle advice on a healthy cardioprotective dietary pattern, physical activity, and smoking cessation from their primary health care team. This advice should be followed for 3 to 6 months prior to considering drug treatment.

C People with a 5-year cardiovascular risk of less than 15% should receive nonpharmacological approaches to treating multiple risk factors.

B People with a 5-year cardiovascular risk of less than 10% should receive general lifestyle advice on a healthy cardioprotective dietary pattern, physical activity, and smoking cessation.

GPP The order in which to start interventions should take into account individual risk factor profiles, potential side effects, other concurrent illness, adherence, personal preference, and cost. It is appropriate to treat multiple risk factors simultaneously.

Management of Blood Pressure

C The higher the calculated cardiovascular risk, the more aggressive the management of modifiable risk factors, including blood pressure, should be.

A People presenting after an acute myocardial infarction should be considered for a beta-blocker and angiotensin-converting enzyme (ACE)-inhibitor regardless of blood pressure level, concurrently with intensive lifestyle advice. This should be given in association with other appropriate medication, such as aspirin and a statin.

A People presenting after an acute ischaemic stroke or transient ischaemic attack should start blood pressure lowering medication unless the person has symptomatic hypotension. This medication should be given in addition to other appropriate medication, such as aspirin, a statin, or warfarin, if indicated. Treatment should start concurrently with intensive lifestyle advice. It is usually advisable to wait 7 to 14 days before starting blood pressure lowering medication.

C Everyone with blood pressure consistently greater than 170/100 mm Hg should have drug treatment and specific lifestyle advice to lower risk factor levels.

B Within the blood pressure range 115/70 to 170/100 mm Hg, all decisions to treat should be based on the individual's cardiovascular risk.

A A cardioprotective dietary pattern is strongly recommended as an integral component of blood pressure management.

B Dietary advice should include the limitation of both alcohol and sodium consumption.

B Among people with a 5-year cardiovascular risk greater than 15% the aim of treatment is to lower 5-year cardiovascular risk to less than 15%.

A Intensive blood pressure management is required (with early consideration of an ACE-inhibitor) in all people with diabetes due to the increased risk of renal complications.

B More than one drug is frequently required to lower blood pressure to optimum levels.

A Aggressive blood pressure control is indicated in people with diabetes and overt nephropathy, or diabetes and microalbuminuria, or diabetes and other renal disease.

A People with diabetes and overt nephropathy or diabetes and confirmed microalbuminuria should be started on an ACE-inhibitor or A2 receptor-blocker (if there are no contraindications) irrespective of blood pressure levels.

A Most of the treatment benefit is achieved by reaching the following blood pressure level:

130/80 mm Hg* in people with diabetes or cardiovascular disease.

GPP A blood pressure lower than 130/80 mm Hg is preferable for people with diabetes and overt nephropathy or diabetes with other renal disease.

*Where risk factor thresholds are given these should be interpreted as approximate guides to clinical practice only.

Management of Lipid Abnormalities

C The higher the calculated cardiovascular risk, the more aggressive the management of modifiable risk factors, including lipids, should be.

A People presenting after an acute cardiac event (myocardial infarction or unstable angina) should start treatment with a statin simultaneously with intensive lifestyle advice. Treatment should aim to lower low-density lipoprotein-cholesterol (LDL-C) to less than 2.5 mmol/L.* This should be given in association with other appropriate medication such as aspirin, a beta-blocker, and an ACE-inhibitor.

C Lipids should ideally be measured at the time of the acute event. Since the metabolic disturbance continues for 10 to 12 weeks after a myocardial infarction, further measurements should be deferred for three months.

C People presenting after an acute cardiac event with hypertriglyceridaemia and a low HDL-C should be considered for a fibrate or combination therapy.

A In people with venous coronary artery bypass grafting (CABG), treatment should aim to lower the total cholesterol to less than 3.5 mmol/L and LDL-C to less than 2.0 mmol/L.*

B Most people presenting after an ischaemic stroke or transient ischaemic attack should start treatment with a statin.

C Everyone with a total cholesterol greater than 8 mmol/L or TC:HDL ratio greater than 8* should have drug treatment and specific lifestyle advice to lower risk factor levels.

B Within the range of total cholesterol 4 to 8 mmol/L, all decisions to treat should be based on the individual's cardiovascular risk.

B People with low HDL-C and elevated triglycerides with a 5-year cardiovascular risk greater than 15% should be treated with intensive lifestyle interventions and are likely to need treatment with a fibrate or combination drug therapy.

A A cardioprotective dietary pattern is strongly recommended as an integral component of lipid management.

B Dietary advice should be tailored to the individual's risk factor and lipid profile.

B Among people with a 5-year cardiovascular risk greater than 15%, the aim of treatment is to lower 5-year cardiovascular risk to less than 15%.

C LDL-C should be used as the primary indicator of optimum lipid management and should be used to monitor lipid-modifying treatment.

*Where risk factor thresholds are given, these should be interpreted as approximate guides to clinical practice only.

Antiplatelet Therapy for People with Diabetes

A Everyone with a 5-year cardiovascular risk greater than 15% should be started on low-dose aspirin (75–150 mg/day) if there are no contraindications.

A Aspirin is contraindicated in people with aspirin allergies or intolerance, active peptic ulceration, uncontrolled blood pressure and in people with other major bleeding risks.

C In people with diabetes who have a stroke, a computed tomography (CT) scan should be performed prior to aspirin therapy to exclude intracranial haemorrhage.

Monitoring and Duration of Treatment for Cardiovascular Risk

GPP Lifelong treatment is advised for people with diabetes.

GPP People with diabetes receiving medication should have their lipids and blood pressure, glycaemic control, diet, and activity level monitored every 3 months until adequate control is achieved, then every 6 months.

Complementary and Alternative Therapies

GPP Clinicians should enquire about the use of alternative and complementary medicines when assessing cardiovascular risk or prescribing medication.

I There is insufficient evidence to recommend the following complementary and alternative therapies for the treatment or prevention of cardiovascular disease:

- herbal medicines, botanicals (Lin et al., 2001)
- garlic (Banerjee & Maulik, 2002; Beaglehole, 1996; Neil et al., 1996)/ginkgo biloba/rosemary/horse-chestnut seeds/xin bao
- acupuncture (Lin et al., 2001)
- chelation (Villarruz, Dans, & Tan, 2002)
- oriental medicine
- aromatherapy
- homeopathy
- hypnosis
- meditation
- yoga/tai chi
- intercessory prayer
- Strauss heart drops (Aviles et al., 2001)

C Feverfew, garlic, ginkgo biloba, ginger, and ginseng may alter bleeding time and should not be used concomitantly with warfarin (Miller et al., 1998).

C St John's wort reduces serum digoxin levels and can enhance the metabolism of Warfarin (Ernst, 1999).

C Herbs (e.g., karela and ginseng) may affect blood-glucose levels and should not be used in people with diabetes (Miller et al., 1998).

Diabetic Renal Disease

Risk of Diabetic Renal Disease

Blood Pressure Control

A Good blood pressure control should be maintained in all people with type 2 diabetes to reduce the risk of developing diabetic renal disease.

B The target blood pressure should be less than 130/80 mm Hg.

GPP While a blood pressure less than 130/80 mm Hg is preferable, any sustained reduction in blood pressure is beneficial.

Glycaemic Control

A Both the risk of developing diabetic renal disease and the rate of progression of diabetic renal disease are reduced by maintaining good glycaemic control.

GPP While the optimal HbA1c level is ideally as close to physiologically normal as possible, preferably less than 7%, any sustained reduction is beneficial.

GPP Health care practitioners should be aware that the risk of developing diabetic renal disease is higher if multiple risk factors are present.

GPP The prevalence of all stages of diabetic renal disease is increased in Maori, Pacific peoples, and people of Asian descent. More frequent monitoring of renal status may be prudent in people with diabetes from these ethnic groups.

Screening for Diabetic Renal Disease

D All people with diabetes should have their urinary albumin concentration and serum creatinine measured at diagnosis. For people with no microalbuminuria and normal serum creatinine, these tests should be repeated at least annually. Refer to the following good practice point for exceptions.

D Urinary albumin:creatinine ratio should be measured by a laboratory method where possible. If access to a laboratory is limited, a near-patient test specific for albumin at low concentration may be used, but a positive result must be confirmed by laboratory testing.

D Urinary albumin:creatinine ratio should be measured using a first morning urine sample where possible; otherwise a random urine sample may be used.

D An abnormal initial test requires confirmation by at least one further test.

GPP People with urinary albumin:creatinine ratio greater than or equal to 30 mg/mmol (indicating overt diabetic nephropathy or proteinuria) and/or with serum creatinine greater than or equal to 0.15 mmol/L or a calculated glomerular filtration rate (GFR) of less than 60 ml/min/1.73m² should be considered for referral to a specialist. Further testing for microalbuminuria is not indicated in this group.

Preventing Progression of Diabetic Renal Disease

Blood Pressure Control

A Aggressive blood pressure control is indicated in people with type 2 diabetes who have diabetic renal disease.

GPP A blood pressure lower than 130/80 mm Hg is preferable for people with type 2 diabetes and diabetic renal disease.

GPP The majority of people with type 2 diabetes who have diabetic renal disease will require more than one antihypertensive agent in order to achieve target blood pressure levels.

Drug Therapy

A People with type 2 diabetes and confirmed microalbuminuria or overt diabetic nephropathy, should be started on an ACE-inhibitor or an A2 receptor-blocker (if there are not contraindications) irrespective of blood pressure levels.

GPP In the presence of significant bilateral renal artery stenosis, ACE-inhibitor therapy is associated with acute renal failure and should not be used.

GPP ACE-inhibitors should be used with caution in people with raised serum creatinine. Serum creatinine should be checked one week after starting ACE-inhibitor therapy. An increase in serum creatinine of up to 25% above baseline is not, by itself, an indication to stop ACE-inhibitor therapy. However, a continued rise in serum creatinine may signify renal artery stenosis, and should be investigated promptly.

Management of Cardiovascular Disease

GPP People with diabetic renal disease should have their cardiovascular risk factors managed in the same way as people with established coronary disease (beta-blockers, ACE-inhibitor therapy, aspirin, lipid-lowering therapy, and smoking cessation).

Referral

GPP Referral to a specialist for an opinion or specialist management should be considered for people with type 2 diabetes if:

- serum creatinine greater than or equal to 0.15 mmol/L
- calculated GFR less than 60 ml/min/1.73 m²
- rapid increase in level of microalbuminuria or proteinuria
- difficulty in achieving blood pressure targets
- in situations where nondiabetic renal disease may be present or may coexist with diabetic renal disease:
 - absence of diabetic retinopathy in a person with diabetic renal disease
 - urinary abnormalities such as haematuria or casts (once infection has been excluded as the cause)

Diabetic Eye Disease

Preventing the Development and Progression of Diabetic Eye Disease

A Both glycaemic control and blood pressure control should be maintained to prevent the onset and progression of diabetic eye disease (retinopathy).

B People with multiple risk factors should be considered at particularly high risk of developing diabetic retinopathy.

GPP As type 2 diabetes may be present for many years before diagnosis, health care practitioners should be aware that retinopathy is often present at the time of diagnosis.

GPP Health care practitioners should be aware that Maori and Pacific people with type 2 diabetes are overrepresented among those with retinopathy.

Screening for Diabetic Retinopathy

B Systematic screening for diabetic retinopathy should be provided for all people with diabetes.

A People with type 2 diabetes should be screened for diabetic retinopathy from the time of diagnosis.

C Retinal photography or slit lamp biomicroscopy carried out by credentialed personnel should be used in a programme of systematic screening for diabetic retinopathy.

B People with ungradable retinal photographs should be examined by slit lamp biomicroscopy.

B Screening should occur at least every two years. For people with no retinopathy, 2-yearly screening is acceptable, but the number and severity of risk factors may indicate a shorter screening interval.

GPP All people with any degree of diabetic retinopathy should be under the supervision of an ophthalmologist, who can specify the appropriate monitoring interval for an individual, taking other risk factors into account.

GPP People with diabetes who present with symptomatic visual loss require assessment and examination by an ophthalmologist and are not candidates for screening.

GPP While visual acuity should be checked in all people with diabetes, health care practitioners should be aware that normal visual acuity does not preclude the presence of sight-threatening retinopathy.

Interventions

A Good glycaemic control (HbA1c preferably as close to physiologically normal as possible, ideally <7%) and good blood pressure control (<130/80 mm Hg) should be the goals, to prevent the onset and progression of diabetic eye disease.

B Any improvement in both glycaemic control and blood pressure control is beneficial for reducing the risk of onset and progression of diabetic eye disease, even if ideal target levels are not achievable for an individual patient.

A All people with diabetes with sight-threatening diabetic retinopathy or sight-threatening macular oedema should receive laser photocoagulation.

B Cataract extraction should not be delayed in people with diabetes who have coexisting diabetic retinopathy. Cataract extraction is advisable when sight-threatening retinopathy cannot be excluded due to the presence of the cataract.

GPP An ophthalmologist should assess people with diabetes who have cataracts, to determine the optimum time for cataract removal.

Diabetic Foot Disease

Screening for Diabetic Foot Disease

D All people with diabetes should be screened for foot disease by a health care practitioner. Screening should occur from the time of diagnosis, then at least annually, if there are no features indicating a high risk foot. More frequent examination (3–6 monthly) should occur if there are features of a high-risk foot.

Assessment of the Diabetic Foot

C Both 10-g monofilament and vibration perception thresholds (using a biothesiometer) are appropriate methods for neuropathy screening.

GPP Assessment for high risk feet in people with diabetes by a health care practitioner should always include:

- direct visual inspection
- assessment for peripheral neuropathy
- assessment for peripheral arterial disease

GPP A 10-g monofilament is a convenient and cost-effective way to assess for peripheral neuropathy. Monofilaments should be cleaned and replaced regularly according to manufacturer's recommendations.

General Management of Diabetic Foot Disease

B Foot care education is recommended as part of a multidisciplinary approach in all people with diabetes.

C People with diabetes and high-risk feet should be referred to a specialist diabetic foot clinic or multidisciplinary foot care team, where one is available. If

access to a foot clinic is not possible, people with high-risk feet should be under the care of a podiatrist.

B People with diabetic foot disease should be advised to wear high-quality, cushioned soled running or sports shoes rather than ordinary shoes.

B In people with high-risk feet, deformity, or previous amputation, custom-built footwear or orthotic insoles should be used to reduce callus severity and ulcer recurrence.

GPP Health care practitioners should be aware that the cost of appropriate off-the-shelf footwear and of consulting a podiatrist to get custom-made orthoses may be a barrier for many people with diabetes.

GPP The ability of the person to undertake regular foot self-care and self-assessment should also be assessed by the health care practitioner.

Total Contact Casting

B People with diabetes who have unilateral neuropathic plantar ulcers should be considered for treatment using total contact casting to optimise the healing rate of ulcers.

GPP Podiatrists or plaster technicians appropriately trained in total contact casting technique, and preferably part of a specialist diabetic foot clinic, are the appropriate people to carry out this treatment.

Arterial Revascularization

B All people with diabetic foot disease with tissue loss and arterial disease should be referred for consideration of arterial revascularisation procedures.

Treatment of Foot Ulcers

GPP Treatment of a clinically infected diabetic foot ulcer should be commenced with a broad spectrum antibiotic regimen in conjunction with appropriate debridement. Subsequent antibiotic regimens may be modified based on the swab culture and sensitivity results.

GPP Intravenous antibiotics are indicated in the presence of cellulitis or osteomyelitis, and prompt referral to hospital is required in these circumstances.

GPP Wound dressings for diabetic foot ulcers should be chosen with consideration of clinical experience, cost, patient preference, and the site of the wound.

GPP Wounds should be closely monitored, and dressings changed regularly.

Management of Painful Diabetic Neuropathy

A For more severe neuropathic pain, tricyclic antidepressants are indicated. The starting dose should be low and titrated upwards until adequate pain relief is achieved.

B Gabapentin is effective in painful diabetic neuropathy that is unresponsive to tricyclic antidepressant or anticonvulsant therapy and is associated with fewer side effects than tricyclic antidepressants and older anticonvulsants.

A Topical capsaicin should be considered for the relief of localised neuropathic pain.

GPP For mild neuropathic pain, simple analgesia (such as paracetamol) should be used as first-line therapy.

GPP Carbamazepine is another therapy to consider for more severe neuropathic pain.

Charcot's Foot

C Diagnosis of Charcot's foot should be made by clinical examination, supported by appropriate investigations.

D Total contact casting and non-weightbearing are effective treatments for acute Charcot's foot.

GPP People with suspected Charcot's foot should be referred for urgent specialist advice.

Diabetic Foot Disease in Maori and Pacific People

GPP Maori and Pacific people with diabetes are at high risk for diabetic foot disease and amputation.

GPP Health care practitioners should be aware of the following:

- It is culturally insensitive to expect Maori to wear outdoor shoes inside the house. A slipper with a rigid sole may provide some protection and be an acceptable alternative.
- It may be appropriate to explain the need for more frequent vacuuming or sweeping of floors (to reduce the chances of minor trauma occurring) and for daily foot examination (by the person with diabetes or a relative).
- Explain carefully the need for supportive, well-fitting shoes rather than jandals or sandals when outdoors.
- Feet should not be placed on a pillow for examination or treatment.
- Nails and wound debris should be disposed of appropriately. Find out the person's preference. They may prefer to dispose of nail clippings/debris themselves or may agree for the health care practitioner to dispose of them.

GPP For Pacific people with diabetes, health care practitioners should:

- explain carefully the need for supportive, well-fitting shoes rather than jandals or sandals when both indoors and outdoors
- negotiate an acceptable plan of regular and continuing foot care with each individual

Maori Perspectives

Treating a Maori Person with Type 2 Diabetes

GPP Always treat the person with diabetes and their whanau. If the person agrees, encourage whanau to come to appointments. Education, dietary advice, and lifestyle advice should always include whanau.

GPP Be sensitive to different styles of communication and to Maori protocol. Appropriate communication is very important.

GPP Consider that socioeconomic circumstances are likely to be difficult. Consultation fees, medication costs, and access to transport or a telephone may be issues.

GPP Find out what the person's attitudes and beliefs are concerning their diabetes and their ability and willingness to implement change. Find out what the barriers to change are for that individual and whanau, and negotiate the changes that are possible and achievable. Expectations of dietary change need to be realistic and culturally acceptable.

GPP Maori with diabetes may prefer to see Maori providers.

Pacific Perspectives

Treating a Pacific Person with Type 2 Diabetes

GPP Always treat the Pacific person with diabetes as part of their family. If the person agrees, encourage family members to come to appointments. Family members should always be involved in diabetes self-management, including dietary and lifestyle management.

GPP Recognise that each of the Pacific groups is unique. Each island group has specific characteristics which makes it different from its Pacific neighbours even though there are general similarities. The approach to the Pacific person should be specific depending on his or her origin.

GPP Consider that socioeconomic circumstances are likely to be difficult. There may be financial obligations (to the family and church) that may take priority over personal and health needs. Other issues may include difficulties with access to transport or to a telephone.

GPP Find out what the person's attitudes and beliefs are concerning their diabetes, and their ability and willingness to implement change. Find out what the barriers to change are for that individual. Negotiate the changes that are possible and achievable. Modification of diet should be realistic and culturally acceptable.

GPP Be aware that language is a barrier. When English is a second language, colloquial English may be excellent. Encourage a bilingual family member or practice nurse to assist with translation. Ideally, Pacific Island ethnic specific translators should be made available to services that provide for Pacific peoples.

GPP Pacific people with diabetes may prefer to see Pacific providers. Rapport, trust, and building a relationship with the Pacific person with diabetes is a core part of a diabetes service that is usually more readily achieved by a Pacific provider. Pacific providers in the area are a valuable resource and should be consulted for advice on approaches to management of diabetes in Pacific peoples.

Definitions:

Rating Scheme for the Strength of the Recommendations

A

The recommendation is supported by good evidence.

B

The recommendation is supported by fair evidence.

C

The recommendation is supported by non-analytic studies or consistent expert opinion.

I

The evidence is insufficient, evidence is lacking, of poor quality or opinions conflicting, the balance of benefits and harms cannot be determined.

Good Practice Point (GPP)

Recommended practice based on the clinical experience of the Guideline Development Team

CLINICAL ALGORITHM(S)

The original guideline document provides the following clinical algorithms:

- Stepwise approach to glycaemic control
- Cardiovascular risk assessment for people with diabetes
- Identifying and managing diabetic renal disease
- Identifying and preventing visual impairment and blindness
- Preventing active foot problems and lower limb amputation

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

As the diabetes literature is extensive and three sets of international guidelines had been rigorously and systematically developed, it was agreed that the New Zealand Management of Type 2 Diabetes Guideline would be an adaptation of some sections of these international guidelines. Where issues were specific to New Zealand, such as issues for Maori and Pacific people with diabetes, a literature search was undertaken, using the Scottish Intercollegiate Guidelines Network (SIGN) search strategies, looking for new evidence that had emerged since the publication of the international guidelines. This search was done in May 2003. No papers were identified which changed any recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention

In people with impaired glucose tolerance (IGT), three randomized controlled trials have shown that prevention or delay in the onset of diabetes is possible through lifestyle interventions (dietary changes and increased exercise levels). The incidence of diabetes was reduced by up to 58% in the lifestyle intervention group compared to the control group. Although less effective, treatment with metformin has also been shown to prevent progression from IGT to diabetes.

Preventive Foot Care

Although the literature on economic studies of preventive foot care practices was limited, research suggests that aggressive, proactive care may result in fewer lower extremity amputations and be cost-effective and possibly cost-saving.

Diet

A cardioprotective dietary pattern lowers blood pressure, improves the lipid profile and glycaemic control, and reduces the risk of clotting.

Physical Activity

Regular physical activity is associated with reduced risk of cardiovascular disease morbidity and mortality.

Glycaemic Control

- Tight glycaemic control reduces the risk of and slows the progression of microvascular and macrovascular complications.
- Remission of depression is often associated with an improvement in glycaemic control.

Blood Pressure Control

- Optimum blood pressure control, below 130/80 mm Hg, reduces the risk of and slows the progression of microvascular and macrovascular complications.
- Achieving an average blood pressure of 144/82 mm Hg reduced costs and improved health outcomes relative to moderate hypertension control (154/86 mm Hg). Control of blood pressure below 150/85 mm Hg was found to reduce the cost of complications, and had a cost-effectiveness ratio that compared favourably with many accepted health care programmes

Smoking cessation

Smoking cessation has major and immediate health benefits for smokers of all ages. Former smokers have fewer days of illness, fewer health complaints, and view themselves as healthier. Within one day of quitting, the risk of having a myocardial infarction is reduced. The excess risk of heart disease is reduced by half after one year's abstinence. The risk of a coronary event reduces to the level of a never smoker within 5 years. In those with existing heart disease, cessation reduces the risk of recurrent infarction or mortality by half.

Medication

- Treatment with an ACE-inhibitor decreases the risk of cardiovascular disease complications in people with type 2 diabetes.
- Beta-blockers are widely used in people with type 2 diabetes and have been shown to have a cardioprotective benefit in people with diabetes and cardiovascular disease.

POTENTIAL HARMS

Risks of Physical Activity

Hypoglycaemia

Physical activity with normal insulin dose and no additional carbohydrates significantly increases the risk of hypoglycaemia during and after exercise. If physical activity can be anticipated, a reduction of the normal insulin dose (by up to 65% for vigorous physical activity of up to 45 minutes) will significantly reduce the risk of hypoglycaemia and delayed hypoglycaemia.

Injecting insulin into active muscle increases its absorption and the risk of hypoglycaemia and should therefore be avoided. High temperatures can also increase insulin absorption. This should be taken into consideration in hot climates. A further reduction in insulin dose may be required. People using oral antidiabetic drugs, such as sulphonylureas, may also be at risk of hypoglycaemia during physical activity.

Myocardial Infarction or Sudden Death

There is a small, transient increase in risk of myocardial infarction or sudden death with vigorous activity in people with coronary heart disease who do not undertake regular physical activity. The risk of myocardial infarction was found to be approximately six times higher during vigorous physical activity compared to the risk at rest. The level of risk with vigorous activity depends on the individual's baseline level of physical activity. Assessing risk prior to starting a physical activity programme and by beginning with exercise of a low intensity and steadily increasing duration and intensity over a couple of weeks, reduces this risk.

Risks of Glycaemic Control

The major risk of tight glycaemic control is hypoglycaemia. In the Diabetes Control and Complications Trial (DCCT) study of type 1 diabetes, the intensive treatment group had a three times greater risk of severe hypoglycaemia than the standard treatment group. Among people with type 2 diabetes in the UK Prospective Diabetes Study (UKPDS), major hypoglycaemic episodes occurred in 0.7% treated with diet alone, 1.0% on chlorpropamide, 1.4% on glibenclamide, and 1.8% on insulin. There is increasing evidence to suggest that, in people on multiple daily insulin injections, the use of insulin infusion pumps results in fewer severe hypoglycaemic episodes, while achieving similar overall levels of glycaemic control.

Another common adverse outcome of intensive glycaemic control treatment is weight gain, which is greater in people on insulin than on oral hypoglycaemic agents. In the UKPDS, mean weight gain was significantly greater (3.1 kg at 10 years) in the intensive treatment group compared with the conventional treatment group. Compared with the conventional treatment group, people assigned insulin had a greater weight gain (4.0 kg) than those assigned chlorpropamide (2.6 kg) or glibenclamide (1.7 kg). Weight gain is less with metformin treatment compared with insulin or sulphonylureas.

Rapid improvement of glycaemic control can occasionally result in short-term worsening of diabetic retinal disease and can occasionally exacerbate symptoms of neuropathic pain in the lower limb. However, long-term outcomes (after one year) remain beneficial.

Dietary Intervention

Attempts to lower risk without investigating dietary habits and weight history may result in the need to use larger doses of medications or combinations of medications due to inappropriate food choices and sedentary behaviours. This contributes to the increased risk of side effects and adverse drug interactions.

Medication

- Regular use of aspirin (at a dose of <300 mg/day) is associated with around a 2-fold increased risk of upper gastrointestinal bleeding (or perforation).
- Treatment side effects

- Biguanides (metformin): Gastrointestinal symptoms (diarrhoea), lactic acidosis (very rare)
- Sulphonylureas (Insulin Secretagogues): hypoglycaemia
- Glitazones (peroxisome proliferator-activated receptor [PPAR]- γ agonists): weight gain, fluid retention, mild dilutional anaemia
- Alpha-glucosidase inhibitors: gastrointestinal symptoms

CONTRAINDICATIONS

CONTRAINDICATIONS

- Metformin's main contraindications are when serum creatinine ≥ 0.15 or creatinine clearance < 60 ml/sec, or there is significant liver impairment or severe left ventricular dysfunction.
- Glipizide, gliclazide, glibenclamide, and tolbutamide are contraindicated when there is significant liver impairment.
- Rosiglitazone is contraindicated during cardiac failure and should not usually be considered in combination with insulin therapy.
- Nortriptyline hydrochloride is contraindicated during the acute recovery period after myocardial infarction.
- Suggested contraindications and guidelines for withdrawing metformin are:
 - stop metformin therapy if serum creatinine is greater than or equal to 0.15 mmol/L*
 - withdraw metformin during periods of suspected tissue hypoxia (e.g., due to myocardial infarction, sepsis)
 - withdraw metformin for three days after contrast medium containing iodine has been given, and start treatment with metformin only after renal function has been checked
 - withdraw metformin two days before general anaesthesia and reinstate when renal function is stable
- Aspirin is contraindicated in people with aspirin allergies or intolerance, active peptic ulceration, or uncontrolled blood pressure and in people with other major bleeding risks.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Evidence-based best practice guidelines are produced to help health care practitioners and consumers make decisions about health care in specific clinical circumstances. Research has shown that if properly developed, communicated, and implemented, guidelines can improve care. While they represent a statement of best practice based on the latest available evidence (at the time of publishing), they are not intended to replace the health care practitioner's judgment in each individual case.
- These guidelines are to be used in conjunction with the New Zealand guideline for *The Assessment and Management of Cardiovascular Risk* which recommends that, as part of a cardiovascular risk assessment, a fasting plasma glucose is performed. These risk assessments are recommended 10 years earlier in those people at risk of developing diabetes. A summary of the relevant sections of that guideline is included where appropriate, specifically

in the chapters on lifestyle management and diabetic cardiovascular disease. The complete guideline, *The Assessment and Management of Cardiovascular Risk* can be found at www.nzgg.org.nz

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Guideline Development Team recommended that multi-faceted strategies be adopted to disseminate this guideline widely and encourage its use throughout New Zealand. The guideline will be integrated into the Ministry of Health's existing free annual check programme for diabetes. A number of strategies for managing cardiovascular risk and assessing people at risk of developing diabetes are also identified in the guideline for the assessment and management of cardiovascular risk. This guideline is available at www.nzgg.org.nz.

Dissemination of the Guideline

The guideline should be disseminated as widely as possible. In addition to making the complete guideline and guideline summaries available on the New Zealand Guidelines Group website at www.nzgg.org.nz, copies of the guideline should be sent to the following key groups:

- general practitioners
- primary health care nurses
- Independent Practitioner Associations and Primary Health Organisations
- Maori health providers
- Pacific health providers
- Diabetes New Zealand Inc and affiliated diabetes societies
- District Health Boards
- local diabetes teams
- disease state management nurses
- diabetologists and specialist physicians
- diabetes nurse educators and specialists
- dietitians
- podiatrists
- renal physicians
- ophthalmologists
- optometrists
- final year medical students

Education

Opportunities for education using this guideline include:

- publication of a summary of key guideline recommendations in a weekly magazine with a general practitioner readership
- working with relevant organisations to promote and facilitate educational programmes. The New Zealand Guidelines Group, with the support of the Ministry of Health, will work closely with District Health Boards, local diabetes

- teams, and Primary Health Organisations on implementation of the guideline in each region.
- working with organisations (such as the New Zealand Family Physician journal) to prepare continuing medical education (CME) case studies and CME points-rewarded questionnaires for general practitioners, based on the guideline.
 - developing a facilitator's pack, suitable for use in regional continuing education targeted at specific groups (such as general practitioners, primary health care nurses, pharmacists, podiatrists, dietitians, and diabetes consumer organisations).
 - working together with Maori and Pacific stakeholders, to ensure that all resources based on the guideline for Maori and Pacific people with diabetes are appropriate, acceptable, and can be implemented. Examples include developing links with Maori provider organisations, Pacific provider organizations, and Pacific Island churches.

Tools

Various tools to facilitate the use of this guideline could be developed, such as:

- incorporation of the guideline recommendations into electronic decision support systems such as PREDICT and general practitioner practice management systems (e.g., Med Tech 32, Houston and IntraHealth). The systems would provide prompts to users based on the guideline recommendations and allow practitioners to generate letters specifically for individuals with diabetes.
- personal management plans for people with type 2 diabetes, which might contain individualized targets, current drug treatment, and key messages regarding diet, physical activity, smoking cessation, and preventive care.
- development of an interactive tool that could be situated on both the New Zealand Guidelines Group and the Diabetes New Zealand Web sites. The tool would allow people with diabetes to enter results of blood tests, for example, and then get a comment or advice based on the guideline. Other options include quizzes, for example a quiz on preventive foot care, eye care or diabetic renal disease.

Effective Implementation

Changes in clinical practice resulting from the implementation of these guidelines should be monitored. While different aspects of the guideline implementation can be monitored and evaluated, data collected through the national "Get Checked" programme could be utilised to this end. The Ministry of Health is currently revising diabetes indicators collected in primary care and collated by Primary Health Organisations or Independent Practitioners Associations. The proposed revised indicators are listed in Appendix G in the original guideline document.

IMPLEMENTATION TOOLS

Clinical Algorithm
Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New Zealand Guidelines Group (NZGG). Management of type 2 diabetes. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2003 Dec. 143 p. [565 references]

ADAPTATION

As the diabetes literature is extensive and three sets of international guidelines had been rigorously and systematically developed, it was agreed that the New Zealand Management of Type 2 Diabetes Guideline would be an adaptation of some sections of these international guidelines.

These guidelines were:

- Scottish Intercollegiate Guidelines Network (SIGN). Management of Diabetes (2001)
- Royal College of General Practitioners (UK). Clinical guidelines and evidence review for type 2 diabetes. Four guidelines: foot problems, retinopathy, blood glucose management, renal disease (2000-2002)
- Diabetes Australia Guideline Development Consortium. National evidence-based guidelines for the management of type 2 diabetes mellitus – various draft guidelines available for public consultation. Guideline considered: foot disease (2001).

DATE RELEASED

2003 Dec

GUIDELINE DEVELOPER(S)

New Zealand Guidelines Group - Private Nonprofit Organization

SOURCE(S) OF FUNDING

Ministry of Health

GUIDELINE COMMITTEE

Guideline Development Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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*Indicates team members who developed the original Primary Care Guidelines for the Management of Core Aspects of Diabetes Care (1998).

**Dr North and Dr Webster were also on the Guideline Development Team for the Assessment and Management of Cardiovascular Risk guideline and focused on areas common to both guidelines.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declaration of Competing Interests

Ms **Marilyn Cullens** has received funding to attend conferences or for laboratory test kits for research purposes from:

- Eli Lilly
- Novartis
- Abbott Laboratories

Ms **Angela Bayley** has received funding to attend conferences from:

- Convatec

- NZ Diabetes Foundation
- NZ Society of Podiatrists

Dr **Rick Cutfield** has received funding to attend conferences or advisory board meetings from:

- Merck Sharp and Dohme
- GlaxoSmithKline
- Eli Lilly

Dr **Paul Drury** has received funding or consultation fees for clinical trials, to attend meetings, and for delivering lectures from:

- NovoNordisk
- Servier
- Eli Lilly
- NHMRC Australia (the FIELD Study)
- Pharmacia
- The Direct Study
- GlaxoSmithKline
- Bristol-Myers Squibb
- Ministry of Health, New Zealand
- PHARMAC Sub-Committee on Diabetes

Ms **Mary Sievers** has received funding to attend a conference from NovoNordisk.

The other members of the Guideline Development Team did not report any competing interests.

ENDORSER(S)

Australasian Faculty of Public Health Medicine - Professional Association
 Cardiac Society of Australia and New Zealand - Disease Specific Society
 Nurses Society of New Zealand - Professional Association
 Royal Australasian College of Physicians - Professional Association
 Royal College of Pathologists of Australasia
 Royal New Zealand College of General Practitioners - Medical Specialty Society
 Sports & Recreation New Zealand - Professional Association
 Stroke Foundation of New Zealand, Inc. - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [New Zealand Guidelines Group Web site](#).

Print copies: Available from the New Zealand Guidelines Group Inc., Level 10, 40 Mercer Street, PO Box 10 665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- New Zealand Guidelines Group (NZGG). General summary management of type 2 diabetes. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2003 Dec. 10 p. Available from in Portable Document Format (PDF) from the [New Zealand Guidelines Group Web site](#).
- New Zealand Guidelines Group (NZGG). Evidence-based guidelines for management of type 2 diabetes: draft terms of reference. Wellington (NZ): New Zealand Guidelines Group (NZGG); 2003 Dec. 3 p. Available from in Portable Document Format (PDF) from the [New Zealand Guidelines Group Web site](#).
- Baxter J. Barriers to health care for Maori with known diabetes. A literature review and summary of issues. Wellington (NZ): New Zealand National Working Group on Diabetes; 2002 Sep. 69 p. Available from in Portable Document Format (PDF) from the [New Zealand Guidelines Group Web site](#).
- New Zealand Guidelines Group (NZGG). New Zealand cardiovascular guidelines handbook: developed for primary care practitioners. Wellington (NZ): New Zealand Guidelines Group (NZGG). 2005. Available in Portable Document Format (PDF) from the [New Zealand Guidelines Group Web site](#).

Print copies: Available from the New Zealand Guidelines Group Inc., Level 10, 40 Mercer Street, PO Box 10 665, The Terrace, Wellington, New Zealand; Tel: 64 4 471 4180; Fax: 64 4 471 4185; e-mail: info@nzgg.org.nz

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 21, 2004. The information was verified by the guideline developer on July 19, 2004. This summary was updated by ECRI on August 15, 2005, following the U.S. Food and Drug Administration advisory on antidepressant medications. This summary was updated by ECRI on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone. This summary was updated by ECRI on March 6, 2007 following the FDA advisory on Coumadin (warfarin sodium). This summary was updated by ECRI Institute on September 5, 2007 following the U.S. Food and Drug Administration advisory on the Thiazolidinedione class of antidiabetic drugs. This summary was updated by ECRI Institute on September 7, 2007 following the revised U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin). This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on November 28, 2007 following the U.S. Food and Drug Administration advisory on the Avandia (rosiglitazone maleate) Tablets. This summary was updated by ECRI

Institute on January 10, 2008, following the U.S. Food and Drug Administration advisory on Carbamazepine. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone maleate).

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