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The author is also grateful for the assistance given by James Conway, Assistant National Director, (Palliative Care & Chronic Illness) HSE and Dr. John Devlin, Deputy Chief Medical Officer, DoHC.

Finally thanks to Ms. Diane Dagg for her work on the formatting and editing of the document.

June 2008
Foreword

The explosion in the prevalence of diabetes mellitus, predominantly Type 2, has led to the recognition that the adequate care of such individuals requires a formal and more structured involvement of the primary care sector, together with the diabetes units and diabetes centres.

In the past the care of diabetes has often been unstructured and sometimes delivered in an opportunistic manner, not reflecting the requirements of those with a chronic disease. This is partly because care was delivered primarily in hospitals which themselves were developed over the decades to deal with infectious disease and trauma. As the population has aged, the majority of interactions are with people with chronic diseases who require a more pro-active model of care and this requires flexibility to deal with the diverse demands of people at different stages of their disease.

This has lead to the concept of “INTEGRATED CARE” which espouses the joint involvement of all levels of care, primary, secondary and tertiary, to optimise outcomes in people with diabetes mellitus. In practical terms this means that both primary and secondary care centres assume joint responsibility for the patients. The majority of patient visits will take place to their GPs with “annual review” taking place in the diabetes centre at a frequency to be agreed at a local level but certainly every 1-2 years.

This concept of integrated primary and secondary care has been agreed by, and has the support of, the following bodies:

- Expert Advisory Group in Diabetes of the HSE (2007),
- Office of the Chief Medical Officer, Department of Health & Children,
- Irish College of General Practitioners,
- Diabetes Section of the Irish Endocrine Society,
- Diabetes Federation of Ireland,
- Diabetes Nurse Specialists of Ireland,
- Diabetes Interest Group of the Irish Nutrition and Dietetics Institute,

and, we believe, the majority of people with diabetes mellitus in Ireland.

Dr. Richard Firth
Consultant Endocrinologist
Presently one in twenty of the Irish population have Type 2 Diabetes. Our obesity epidemic is resulting in dramatic annual increases in this prevalence.

The Expert Advisory Group in Diabetes in its 2007 report recognised the need for a new model of care for people with Type 2 Diabetes. This integration across primary, secondary and tertiary care requires agreed clinical guidelines.

Dr. Velma Harkins of the Irish College of General Practitioners as leader, with Dr. Richard Firth of the Irish Endocrine Society and Dr. John Devlin of the Department of Health and Children, are to be congratulated on providing these guidelines. They provide clarity in regard to diagnosis, targets for clinical care and the interventions that are appropriate at each stage of the disease.

We, at the Diabetes EAG see that these guidelines are not just a fundamental pillar of our integrated model of care but that they themselves will significantly improve the care of patients with type 2 diabetes.

Dr. Colm Costigan  
Chairman, Expert Advisory Group on Diabetes
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Type 2 diabetes is one of the commonest chronic diseases, affecting nearly five percent of Irish adults\textsuperscript{1}. The true prevalence of Type 2 is underestimated and many cases are undiagnosed because hyperglycaemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes.

Type 2 diabetes accounts for over eighty five to ninety percent of all cases of diabetes in European countries\textsuperscript{2}. The prevalence varies with age, sex, ethnic background and genetic susceptibility. Environmental risk factors such as nutritional status, lack of physical activity, central and overall obesity are associated with increased risk. The prevalence of Type 2 diabetes in Ireland is increasing due to ageing population and increased rates of obesity.
Aims and Objectives of this Document

Diabetes care aims to enable people with diabetes to achieve a quality of life and life expectancy similar to that of the general population by reducing the complications of diabetes. Primary diabetes care aims to deliver integrated, quality care uniformly to all affected people and their families.

How to use this Document

The guidance presented here is derived from previously developed full process guidelines, with updated evidence to support local implementation.

The level of evidence is used as a basis for the grade of recommendations. Therefore it should be remembered that the grade of recommendation reflects the strength of the evidence (quality of the study methods) and not the clinical importance.

The grading of recommendations involves assessment of evidence and processes of interpretation and consensus. A graded recommendation is made in the guideline, following considered judgement of the design and quality of each study and the consistency, clinical relevance and external validity of the whole body of evidence.

This is general guidance for those involved in the care of patients with Type 2 diabetes. It should be applied in the context of the local health system and using clinical expertise and judgement when applied to individual patients. See Appendix 1 for levels of evidence.
Classification and Diagnosis

Classification

Type 2 is the commonest type of diabetes and is characterised by disorders of insulin action and secretion, either of which may be the predominant feature. Both are usually present at the time that this type of diabetes is clinically manifest. The specific reasons for the development of these abnormalities are not yet known.

Type 2 diabetes has a long pre-clinical phase and may be asymptomatic until well after long term microvascular and macrovascular complications have occurred. Type 2 diabetes can be detected before the onset of symptoms and clinical signs by identifying people who are at risk, and performing diagnostic testing.

Diagnosis

The onset of Type 2 diabetes is subtle and early detection in general practice requires clinical suspicion combined with systematic and opportunistic case-finding, as diagnosis is frequently delayed until complications appear.

Table 1: Criteria for Testing for Diabetes

<table>
<thead>
<tr>
<th>Criteria for Testing for Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing for diabetes should be considered in all individuals who are 45 years and above:</td>
</tr>
<tr>
<td>- particularly in those with a BMI $\geq 25\text{kg/m}^2$;</td>
</tr>
<tr>
<td>- and if normal should be repeated at 3-year intervals</td>
</tr>
<tr>
<td>Testing should be considered at a younger age or carried out more frequently in individuals who are overweight (BMI $\geq 25\text{kg/m}^2$) and have additional risk factors:</td>
</tr>
<tr>
<td>- Are habitually physically inactive</td>
</tr>
<tr>
<td>- Have a first-degree relative with diabetes</td>
</tr>
<tr>
<td>- Are hypertensive ( $\geq 140/90\text{mmHg}$)</td>
</tr>
<tr>
<td>- Have a HDL cholesterol level $&lt;0.90\text{mmol/l}$ and/or a Triglyceride level $&gt;2.82\text{mmol/l}$</td>
</tr>
<tr>
<td>- Have symptoms of thirst, polydipsia, polyuria, dry mouth, tiredness, weight loss, unexplained abdominal pain</td>
</tr>
<tr>
<td>- Have repeated candidiasis, skin or urine infections</td>
</tr>
<tr>
<td>- Have established arterial disease (IHD, CVA, PVD)</td>
</tr>
<tr>
<td>- Are members of a high-risk ethnic population (e.g. African, African/American etc.)</td>
</tr>
<tr>
<td>- Have delivered a baby weighing $&gt;4.1\text{kgs/9lbs}$ or have a history of gestational diabetes mellitus (GDM)</td>
</tr>
<tr>
<td>- Have other clinical conditions associated with insulin resistance (e.g. polycystic ovary syndrome, acanthosis nigricans, long-term steroid use).</td>
</tr>
</tbody>
</table>

*Note: BMI level may not be correct for all ethnic groups e.g. WHO Expert Consultation 2002 gives a guide BMI for Asian Population of 18.5 to 23kg/m$^2$ as normal range.*
How to perform a 75g OGTT

The test should be done in the morning after an overnight fast of between 8 and 14 hours and after at least 3 days of unrestricted diet (> 150g carbohydrate per day) and unlimited physical activity. The person should remain seated and should not smoke throughout the test. Blood should be drawn at T0 and 2 hours.

75g Oral Glucose Tolerance Test

Use:
- 75g glucose packs prepared by community pharmacist, dissolved in water
- 410 ml Lucozade™ Energy Original (2007 update for new formulation Lucozade Original)
- 116 ml of Polycal™ (available on GMS) diluted if necessary for taste

Lesser Degrees of Glucose Intolerance

Impaired fasting glucose (IFG)
equals fasting blood glucose between 5.6 and 6.9mmols/L checked twice on separate days.

Impaired glucose tolerance (IGT)
equals a two hour plasma glucose between 7.8 and 11.0mmols/L during GTT.

In the absence of unequivocal hyperglycaemia, the fasting criteria should be confirmed by repeat testing on a different day. For screening of Type 2 diabetes probably the best combination of specificity and sensitivity is afforded by the first test being a fasting blood glucose. If this is above 5.6mmol/l, the second test should be a 75g OGTT with bloods drawn at T0 and 2 hours. This will allow for identification of impaired fasting glucose, impaired glucose tolerance, and Type 2 Diabetes.

Symptoms of diabetes plus random plasma glucose concentration > 11.1 mmol/l.

Random is defined as any time of day without regard to time since last meal.

The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

2-hr post-load glucose >11.1 mmol/l during a 75g Oral Glucose Tolerance Test.

The test should be performed as described by W.H.O., using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

Fasting Plasma Glucose ≥7.0 mmol/l.

Fasting is defined as no caloric intake for at least 8 hours.

5% of the Irish population have Type 2 Diabetes
The prevalence of Type 2 diabetes in Ireland is increasing due to an ageing population and increased rates of obesity.

Classification and Diagnosis

Prevention/Delay of Type 2 Diabetes

There is now substantial evidence that Type 2 diabetes can be prevented or delayed. Individuals at high risk of developing diabetes can be identified easily. Knowledge of the early stages of hyperglycaemia and research into the prevention of Type 2 diabetes clearly show that individuals at high risk can be identified and diabetes delayed, if not prevented.

The American Diabetes Association (ADA) note that the cost-effectiveness of intervention strategies is unclear, but the huge burden resulting from the complications of diabetes and the potential ancillary benefits of some of the interventions suggest that an effort to prevent diabetes may be worthwhile6.

The individual with lesser degrees of glucose intolerance (IFG and IGT) are subject to two major potential consequences:

1. A risk of premature cardiovascular disease almost equivalent to that conferred by Type 2 diabetes (especially for IGT). Thus risk factor intervention should be as aggressive as in those with Type 2 diabetes (e.g. smoking, hypertension, dyslipidaemia, etc).

2. There is a risk of progression from IGT to Type 2 diabetes of approximately 5% per year. This can be reduced by up to 60% by lifestyle modification and by 30% by the use of Metformin.

Thus individuals at high risk for developing diabetes and particularly those with IGT or IFG should be made aware of the many benefits of modest weight loss and regular physical activity and should be counselled and instructed in these areas. Follow up counselling and monitoring for the development of diabetes by glucose tolerance testing should be performed every 1-2 years.

If there appears to be a progression in the degree of glucose intolerance on follow up testing despite lifestyle modification or if the individual is unable or unwilling to implement such lifestyle medication then the use of Metformin at a dose of 500mgs b.d. should be considered. If Metformin is used then repeat glucose tolerance testing should be performed annually following withdrawal of the Metformin for 1 month beforehand.
How to perform a 100g OGTT

100g Oral Glucose Tolerance Test

Use:
- 100g glucose packs prepared by community pharmacist, dissolved in water
- 548 ml Lucozade™ Energy Original (2007 update for new formulation Lucozade)
- 155 ml of Polycal™ (available on GMS) diluted if necessary for taste

(This 100g OGTT screening test is probably the most commonly used in the Republic of Ireland. Some centres use a 50g glucose challenge test (GCT) without regard to fasting as the initial screening test and progress to a full 100g glucose tolerance test if the 1 hour value is greater than 8mmol/l).

The criteria for the diagnosis of gestational diabetes are currently being reviewed.

Screening for undiagnosed or new (gestational) diabetes in pregnancy

Gestational diabetes mellitus (GDM) is defined as the onset or first recognition of glucose intolerance during pregnancy. GDM is associated with increased risks for mother and baby during pregnancy and longer term risk of diabetes in both mother and baby. Women known to be at high risk of developing diabetes include those who:

- Have had previous gestational diabetes,
- Have had a baby weighing over 4.5 kilos,
- Have a strong family history (parent or sibling with diabetes),
- Have marked obesity - especially abdominal obesity,
- Are members of a population group with a high prevalence of diabetes.
- Have a macrosomic foetus, polyhydramnios or glycosuria in their current pregnancy.

Risk assessment for GDM should be undertaken at the first ante-natal visit.

At their first ante-natal visit, women found to be at high risk of GDM, should be:

- Provided with healthy lifestyle advice (nutrition and physical activity)
- Checked for hyperglycaemia (plasma glucose) and proceed to 100g OGTT if indicated.

At 24-28 weeks women at high risk who are found not to have GDM at the initial screening test should be rescreened.

Diagnosis of GDM with a 100g oral glucose load

<table>
<thead>
<tr>
<th>Glucose Type</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Glucose</td>
<td>5.3 mmol/l</td>
</tr>
<tr>
<td>1-hr Glucose</td>
<td>10.0 mmol/l</td>
</tr>
<tr>
<td>2-hr Glucose</td>
<td>8.6 mmol/l</td>
</tr>
<tr>
<td>3-hr Glucose</td>
<td>7.8 mmol/l</td>
</tr>
</tbody>
</table>

Two or more of the venous plasma concentrations must be met or exceeded for a positive diagnosis.
For most people diagnosed with Type 2 diabetes their condition is life-long and while new types of medication and medical devices are constantly being produced, the basic foundation for good diabetes care still focuses on healthy eating and physical activity, monitoring blood glucose levels and taking medication. The management of Type 2 diabetes involves behavioural change best achieved through integrated care and education. General practice is increasingly providing this service supported by current national policy.

Integrated Care

Three of the key components of a comprehensive diabetes service are patient registration, recall and regular review. Integrated care also includes allocation of protected time and adherence to a standard management protocol. An annual and comprehensive review is regarded as the crucial element of integrated diabetes care.

Routine integrated care involves the patient, GP, practice nurse, diabetologist, clinical nurse specialist in diabetes, dietician, ophthalmologist and podiatrist. All patients with Type 2 diabetes should have access to specialist services such as endocrinology, vascular, cardiology, nephrology and psychology as needed. Care provision begins with initial assessment and follows with regular review that includes a comprehensive annual review.

In order to provide this level of care, protected time is required and this has funding implications for all levels of service (primary, secondary and tertiary care).

Diabetes Register

A practice-based diabetes register facilitates the provision of quality diabetes care through improved processes of care. To expedite and facilitate integrated care, information using a standard format should be shared between the primary care and allied secondary or tertiary care centre to enable sharing of information for the benefit of the patient. Such a register would also allow collection of data at local, regional or national levels to allow audit and planning for resource allocation.

The register should contain:

- Address and other contact details
- Type of diabetes or related hyperglycaemic condition (including GDM, IFG and IGT)
- Other details such as the presence of complications only as required to facilitate audit and care planning.

A disease register carries responsibilities relating to patient consent and the Data Protection Act.
Initial assessment

Initial assessment includes the following elements

**Record taken of:**

- Blood Pressure
- Weight/Height (Calculate BMI), waist circumference
- Family History/Drug history and current medication
- Medical History

**Complications**

- Lifestyle, including smoking status, physical activity, diet
- Foot status, eye review

**Investigations:**

<table>
<thead>
<tr>
<th>Test</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>Serum Iron</td>
</tr>
<tr>
<td>Fasting Lipid profile</td>
<td>Serum Transferrin</td>
</tr>
<tr>
<td>Full blood count</td>
<td>Thyroid Function Tests</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>12-lead ECG</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td></td>
</tr>
</tbody>
</table>

**Provision of education and psychological support:**

- Explain
- Advise
- Follow-up

**Organisation of care:**

- Encourage patient to join integrated care programme with registration in both a primary care practice and nominated secondary centre agreed between patient and GP (usually involving signing consent),
- Add patient to practice register and give follow-up appointment.
- Patient should see ophthalmologist, podiatrist and dietician.
- Consider the need for review by diabetic nurse specialist.
- Set up a management plan for the control of glycaemia, lipid levels and blood pressure with defined targets appropriate for the individual patient as outlined later in this guideline.
- Identify lifestyle issues that need to be addressed.
- Issue patient with glucose monitor and instruct in its use.
Diabetes Care

Regular/Ongoing Care

There is a paucity of evidence base around the regularity with which the patient with Type 2 diabetes needs review. It is a generally accepted rule that regular review is needed every three months or more frequently during efforts to bring risk factors under control.

**Regular review includes a review of:**

- Recent life-events / new symptoms
- New difficulties in self-management of diabetes
- Self-monitored results; discussion of their meaning
- Dietary behaviours, physical activity and smoking
- Diabetes education, skills and foot care
- Blood glucose, lipid and blood pressure therapy and results
- Other medical conditions and therapy affecting diabetes
- Psychological, lifestyle and social aspects
- Arterial / foot risk factors identified at annual review
- Complications and other problems identified at annual review

While it is anticipated that the practice nurse will be able to deal with the routine investigations, it is important that the GP also sees the patient regularly.

Annual Review

Along with all of the areas monitored at regular review, the annual review also includes surveillance of the following:

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>ischaemic heart disease, peripheral vascular disease - neuropathy, erectile dysfunction. All patients with symptoms that might reflect vascular disease, particularly ischaemic heart disease, should be investigated.</td>
</tr>
<tr>
<td>Feet</td>
<td>footwear, deformity/joint rigidity, poor skin condition, ischaemia, ulceration, absent pulses, sensory impairment.</td>
</tr>
<tr>
<td>Eyes</td>
<td>visual acuity and retinal review by ophthalmologist / retinal screening programme.</td>
</tr>
<tr>
<td>Kidney</td>
<td>renal damage, albumin excretion and serum creatinine</td>
</tr>
<tr>
<td>Arterial risk</td>
<td>blood glucose, blood pressure, blood lipids, and smoking status</td>
</tr>
<tr>
<td>Attendance</td>
<td>podiatry / dietician / other as indicated.</td>
</tr>
</tbody>
</table>

Integrated care mandates joint care at primary and secondary levels. As outlined above, review of the patient in the Diabetes Centre should take place at 1-2 yearly intervals. This interval should be agreed locally between the integrated care partners at primary and secondary levels depending on their circumstances and resources.
Non routine or emergency visits to hospital

Agreed mechanisms should be set in place to allow the “fast tracking” of patients requiring urgent assessment and care within the nominated diabetes centre. Such assessment will be carried out by a specialist consultant or senior registrar.

For added protection

The ADA recommends that flu vaccination is offered annually to all patients with diabetes and that pneumococcal vaccine should also be offered.

Encourage adequate health protection, including vaccinations, prior to foreign travel.
Diabetes Patient Education

Diabetes is increasing at an alarming rate globally. It is a complex, chronic condition that affects all areas of a person’s life and requires high quality care. To this end, diabetes education is of critical importance and should be considered an integral part of diabetes prevention and care. A combination of lack of access to quality medical management and diabetes education can lead to poor clinical outcomes, reduced quality of life and high health-related costs due to service utilisation and the costs of treatment.

Education is a key component in the prevention and treatment of diabetes. It is considered best practice for diabetes education and care to be provided by an integrated multi-disciplinary team including, at a minimum, the person with diabetes, a nurse, a dietician and physician who are skilled in diabetes management. (E)\textsuperscript{10,11}

The following table is a comprehensive list of areas to be covered and facilitates the tailoring of an education programme to the patient’s individual needs.

**Diabetes Self-Management Training**

For people affected by diabetes, self-management education training is important as patients and their families provide 95% of own their care. Without appropriate education people cannot make the complex daily medical decisions required for good health, quality of life and survival. The goal of diabetes self-management training is to support the efforts of people with diabetes to:

- Understand the nature of their illness and its treatment, using established principles of adult education
- Identify emerging health problems in early, reversible stages;
- Adhere to self-care practices;
- Make needed changes in their health habits.

Healthcare providers must be active participants in facilitating quality diabetes self-care and in motivating their patients to undertake the demanding daily regimen associated with their illness.

**Quality Control**

Several models of quality control including evaluation and audit of diabetes education have been used in Ireland and elsewhere. Any diabetes education programme set up should undergo assessment for quality control at predefined periods.
### Topics to be Covered with Patient:
- What is Diabetes?
- Complications
- Dietary Management
- Aims of Diabetes Care
- Eye and Foot Care
- Why self-monitoring is needed

### Key Self-Care Issues to be Covered with Patient:
- Medications: Uses and Side-Effects
- Hypoglycaemia
- Hyperglycaemia
- Sick-Days
- Self-Monitoring
- Allowances, Entitlements
- Membership of the Diabetes Federation of Ireland

### Additional Issues as Appropriate for Specific Patient:
- **Lifestyle:**
  - smoking, alcohol, exercise, weight control
- **Cardiovascular Status:**
  - Hypertension, Hyperlipidaemia, Microalbumin
- **Managing Insulin**
- **Travel Advice**
- **Encouraging Self-care**
- **Discussion with Carers**
- **Family Planning or Pre-Conception Advice**
- **Employment, Insurance, Driving issues**
- **New Symptoms:**
  - Nocturia, frequency, dry mouth
  - Chest pain
  - Sensation
  - Visual disturbance
  - Foot problems
  - Impotence
  - Dyspepsia
Glycaemic Control

Tight control of blood glucose with diet and/or medication reduces long-term complication rates and is central to the overall management of diabetes.

**Composite criteria by the major organisations (IDF, EASD, ADA, Diabetes UK) recommend:**

- Target HbA1c for Type 2 diabetes should be set under 6.5%, which equates to fasting glucometer levels at home mainly in the 5s and 6s.
- A target Pre-prandial capillary glucose of less than 6.0mmol/l.
- Peak post-prandial capillary glucose should if possible be less than 8.0mmol/l.

Clinical Monitoring

The ADA recommends that HbA1c should be tested:

- At least twice per year in patients who are meeting treatment targets and who have stable glycaemic control. (E)
- Every three months in patients whose therapy has changed or who are not meeting glycaemic targets. (E)

They also state that point-of-care testing allows for timely decisions on therapy changes when needed. (E)

Patient Self-Monitoring

NICE recommend that self-monitoring should not be considered as a stand-alone intervention but used in conjunction with appropriate therapy as part of integrated self-care and that it should be taught if the need/purpose is clear and agreed with the patient*. Patients on insulin should strive to record their home blood glucose readings four times a day (before each meal and at bedtime). Patients with satisfactory HbA1c levels should test at least once daily between fasting levels and 1 hour post-prandial levels.

Glucometers

It is important that the quality control of the monitor should be checked four times a year at a minimum. Monitors should be changed / upgraded every two years. Patients should be advised to record home glucose readings in their patient record book, and to bring their book to each of their diabetic reviews.

Key Point

The ADA recommend (E):

- Achievement and maintenance of normal glycaemic goals
- Initial therapy with lifestyle interventions and metformin
- Rapid addition of medications and transition to new regimens when target glycaemic goals are not achieved or sustained
- Early addition of insulin therapy in patients who do not meet target goals²⁰.
Lifestyle Management

The main lifestyle management issues for people with Type 2 diabetes are healthy eating and physical activity and there is ample evidence (of varying levels) to support this. The Scottish Intercollegiate Guideline Network (SIGN) recommend that:

- Patients with diabetes should be offered lifestyle interventions based on a valid theoretical framework.
- Education programmes, computer assisted packages and telephone prompting should be considered as part of a multidisciplinary lifestyle-intervention programme.

Diet

Nutritional advice and information is an essential component of the overall management of Type 1 and Type 2 Diabetes. The aim is to keep blood glucose, cholesterol, triglycerides and weight within a normal range. Healthy eating is recommended as it is encouraged for the entire population. Some of the most successful programmes for long-term weight control have involved combinations of diet, exercise and behaviour modification.

Patients should be advised to maintain a healthy weight in order to maintain a BMI of between 20 and 24.99 kg/m².

The following are general recommendations in relation to referral to the dietetic service:

- Ideally all newly diagnosed patients need to be advised within 4 weeks of diagnosis. All patients should be reviewed every 3 months during the 1st year after diagnosis.
- Obese patients should see a dietician on a monthly basis during the first 6 months and then with reduced frequency over the next 6-12 months.
- It is advisable that all people with type 2 diabetes should have an annual dietetic review.

Target HbA1c for type 2 diabetes should be set under 6.5%.
Diabetes Care

Physical Activity

Along with diet and medication, exercise has long been considered as a key component of diabetes management. There is consistent evidence that programmes of increased physical activity and modest weight loss reduce the incidence of Type 2 diabetes in individuals with IGT\textsuperscript{15,16,17,18}. Physical activity also helps those diagnosed with Type 2 diabetes to maintain a healthy weight and reduce the risk of CVD.

Key Point

Before beginning a programme of physical activity more vigorous than brisk walking, people with diabetes should be assessed for conditions that might be associated with increased likelihood of CVD or that might contraindicate certain types of exercise or predispose to injury, such as severe autonomic neuropathy, severe peripheral neuropathy, and pre-proliferative or proliferative retinopathy. The patient's age and previous physical activity level should be considered\textsuperscript{18}.

The universal recommendation with regard to physical activity is that all individuals should aim to accumulate at least 30 minutes of moderate intensity physical activity on most days of the week\textsuperscript{20}. This has been adopted as the minimum requirement for health benefits. However, 30 minutes spread over the entire day is equally beneficial as one 30-minute walk. Activities of daily living such as housework and using stairs are valuable in increasing physical activity\textsuperscript{21}.

SIGN (level of evidence) recommend that exercise and physical activity involving aerobic and/or resistance training, should be performed on a regular basis. They also recommend that advice about exercise and physical activity should be individually tailored and diabetes specific and should include implications for glucose management\textsuperscript{12}.

The ADA recommends:\textsuperscript{19}

- At least 150 min/week of moderate-intensity aerobic physical activity and/or at least 90 min/week of vigorous aerobic exercise in order to improve glycaemic control, assist with weight maintenance and reduce the risk of CVD. They further recommend that the physical activity be distributed over at least 3 days a week with no more than 2 consecutive days without physical activity. (A)

- Performing ≥4hrs/week of moderate to vigorous aerobic and/or resistance exercise physical activity is associated with greater CVD risk reduction compared with lower volumes of activity. (A)

- For long term maintenance of major weight loss (≥13.6kg/30lbs), larger volumes of exercise (7hrs/week of moderate or vigorous aerobic physical activity) may be helpful. (B)
Treatment/Control with Oral Agents

Type 2 is a progressive disease with worsening glycaemia over time; therefore the addition of medications is the rule, not the exception, if treatment goals are to be met. The limited long-term success of lifestyle programmes to maintain glycaemic goals suggests that a majority of patients require medication. Baseline glycaemia, duration of diabetes, previous therapy and other factors affect the glucose-lowering effectiveness of individual therapies and combinations.

PLEASE NOTE: Oral hypoglycaemic drugs should not be considered in women of childbearing age who may be contemplating pregnancy. (See Section on Pregnancy) (E)

First Line Therapy

Many organisations recommend that the patient is started on a single oral agent. The ADA, IDF and NICE recommend metformin as an option for first-line or combination therapy.

In addition NICE also recommend metformin both for those who are overweight (BMI >25.0 kg/m²) and not overweight as the first-line glucose-lowering therapy where blood glucose is inadequately controlled using lifestyle interventions alone (A)

Metformin is contraindicated in those with renal impairment (serum creatinine >130 mmol/l), those at risk of sudden deterioration of renal function, end stage cardiac and hepatic failure.

Insulin Secretagogues

NICE recommend the following with regard to Insulin secretagogues, including the sulphonylureas and the rapid-acting insulin secretagogues (nateglinide and repaglinide):

Insulin secretagogues should be used in combination with metformin in overweight or obese people when glucose control becomes unsatisfactory. (A) Note: Glitazones, incretins and DPP4 inhibitors are also legitimate second line therapy.

Insulin secretagogues should be considered as an option for first line therapy when:
- Metformin is not tolerated or is contraindicated. (A)
- Patients are not overweight. (A)
- A generic sulphonylurea drug should normally be the insulin secretagogue of choice. (B)
- Long-acting once daily sulphonylureas may be useful where concordance with therapy is a suspected problem. (B)
- (B)Rapid-acting insulin secretagogues may have a role in attaining tight glucose control in patients with non-routine daily patterns. (B)
- Clinicians, and those using an insulin secretagogue, should be aware of the risk of hypoglycaemia and be alert to it. (A)
PPAR-\(\gamma\) Agonists

The currently available PPAR-\(\gamma\) agonists are the thiazolidinediones (commonly referred to as glitazones) pioglitazone and rosiglitazone. NICE recommend the following with regard to PPAR-\(\geq\) agonists.

- People should be offered a thiazolidinedione as oral combination therapy if they are unable to take Metformin and insulin secretagogues as combination therapy (A), or the HbA1c remains unsatisfactory despite an adequate trial of metformin with insulin secretagogues. (A)

- The licensed thiazolidinediones are contraindicated in combination therapy with insulin. (A)

- The chief side effects of glitazones are weight gain and fluid retention. The latter may precipitate congestive cardiac failure in those at risk of this and should not thus be used in people with a history of cardiac failure, diminished left ventricular function and renal failure.

It should be noted that glitazones and in particular rosiglitazone are under suspicion of precipitating acute cardiac events and current recommendations contraindicate the use of rosiglitazone in patients with a history ischaemic heart disease.

Incretins and DPP-4 Agonists GLP-1 Receptor Agonists

The currently available GLP-1 Receptor Agonist is Exenatide which is approved for the use in Type II diabetes as combination therapy in patients unable to achieve adequate control on Metformin and/or sulphonureas. It is given in the form of an injection twice daily. The most common side effect is nausea but this usually lessens with longer duration of treatment. Mild hypoglycaemia can occur when Exenatide is used in combination with sulphonureas and this can be avoided by reducing the dose of the sulphonureas up to 50% prior to its commencement. Exenatide is not recommended in patients with severe renal impairment, creatinine clearance less than 30 or end stage renal disease. INR should be checked in patients receiving Warfarin. Patients on oral antibiotics or oral contraceptives should be recommended to take these medications one hour before injecting Exenatide as delayed gastric emptying may interfere with the absorption of these drugs.

DPP-4 Inhibitors

The currently available DPP-4 inhibitors are Sitagliptin and Vildagliptin. The DPP-4 inhibitors are approved as add on therapy to Metformin or a glitazone. They are well tolerated with few adverse effects. They do not appear to have GI effects. The DPP-4 inhibitors are administered orally once daily.

Alpha-glucosidase Inhibitors

- Acarbose may be considered as an alternative glucose-lowering therapy in people unable to use other oral drugs (A), but it has very little role.
Treatment/Control with Insulin

The ADA in their consensus statement on the management of hyperglycaemia in Type 2 diabetes note that Insulin:

- is recognised as the most effective therapy for lowering blood-glucose.
- can, when used in adequate doses, decrease any level of elevated HBAIC to, or close to, the required target.
- unlike other blood-glucose lowering medication, has no maximum dose beyond which a therapeutic effect will not occur, except in insulin resistant patients.
- therapy has beneficial effects on triglyceride and HDL cholesterol levels.
- is associated with weight gain of 2-4kgs, probably proportional to the correction of glycaemia and owing to the reduction of glycosuria, but potential for weight gain may be more than this.

IDF Guidelines 2005 make the following suggestions about insulin therapy:

- Insulin therapy should be initiated when glycaemic control is inadequate and suggest a HbA1c approaching 7.5%.
- Options for insulin regime include basal insulin, twice daily biphasic insulin, basal bolus regimes. Either of the latter two may be required when HbA1c is higher i.e. as endogenous insulin levels fall progressively. Clinicians and people using insulin should be aware of the risk of hypoglycaemia and be alert to it.
- Sulphonylureas and Metformin should be continued and used in combination therapy with insulin.

In those Type II diabetics failing all therapy, virtually all studies have shown that combination therapy using the addition of insulin to sulphonylureas has many advantages over insulin alone. Thus in general control is better, there is an insulin sparing effect with the result that less weight gain is seen using combination therapy rather than insulin alone. Sulphonylureas have the greatest insulin sparing effect of all the oral agents and thus potentially the greatest weight sparing effect when used with insulin.

The addition of insulin to oral agents may be either basal insulin therapy or prandial insulin therapy. Both have advantages. Basal insulin therapy will only be effective if there is a relative insulin deficiency. As progressive insulinopenia continues the addition of prandial insulin becomes necessary.

It is generally recommended that a dietician reviews the person in the month prior to proposed insulin initiation. The patient / carer must understand and be willing to perform home glucose monitoring. A senior dietician should instruct the patient where basal/bolus regime is proposed. IDF 2005 state patients with type 2 diabetes on insulin should be offered education on assessment of carbohydrate content of different types of food.

As the patient is the key player in the diabetes care team it is essential that they are trained and empowered to treat hypoglycaemia and all patients on insulin should be supplied with a Glucagon Hypokit and be familiar with its use.

Insulin initiation is usually carried out in a diabetes day care centre. Where it is being initiated in a general practice setting it is recommended that the GP practice undertakes training for GP and Practice Nurse and has access to a Clinical Nurse Specialist in Diabetes. The patient should have adequate visual acuity and manual dexterity to be able to perform blood glucose testing. Group education is the preferred method when initiating patients on insulin.
**Example of Insulin Initiation Programme in General Practice**

<table>
<thead>
<tr>
<th>Visit 1 - Week 1</th>
<th>Visit 2 - Week 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Education re device and administration of insulin, storage and care of insulin, importance of injection site rotation, hypoglycaemia, effects of exercise and diet, Importance of not stopping insulin unless under medical advice.</td>
<td>- Discuss principles of self adjustment and aims of glycaemic control, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same, effects of exercise and diet with insulin, sick day rules and insulin.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit 3 - Week 4</th>
<th>Pre - visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Education, establish if patient is performing self adjustment of insulin adequately, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same.</td>
<td>- Discuss principles of self adjustment and aims of glycaemic control, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same, effects of exercise and diet with insulin, sick day rules and insulin.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 4 - Week 8</th>
<th>Visit 5 - Week 16</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Education, review blood results and discuss, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same.</td>
<td>- Education, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pre - visit 6</th>
<th>Visit 6 - Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Repeat baseline bloods</td>
<td>- Education, check injection sites, weight, BP, glucose diary, ascertain if any episodes of hypoglycaemia, establish if any reasons for same.</td>
</tr>
</tbody>
</table>

Pre-visits involve the Practice Nurse, the GP and the Clinical Nurse Specialist in Diabetes. At Week 24 the Clinical Nurse Specialist in Diabetes will discuss the patient's blood results with GP and practice nurse and if basal insulin is suitable. If glycaemic control is adequate the patient will continue to be monitored by Practice Nurse and/or GP. If glycaemic control is sub-optimal the Clinical Nurse Specialist in Diabetes will also monitor and refer to specialist care as indicated.
Pre-Conceptual Care

With increasing numbers of women around the world developing Type 2 diabetes and doing so at a younger age, and with women in many cultures tending to delay starting a family, the issue of diabetes complicating pregnancy has become increasingly important. The issue of screening for GDM is already dealt with in a previous section. We focus on the care of women with new diabetes in pregnancy, as well as the care of those who already have Type 2 diabetes.

Planned pregnancies greatly facilitate preconception diabetes care. Unfortunately, nearly two-thirds of pregnancies in women with diabetes are unplanned, leading to a persistent excess of malformations in infants of diabetic mothers.

Standard Care

To minimize the occurrence of congenital malformations, standard care for all women with diabetes who have childbearing potential should include:

- Education about the risk of malformations associated with unplanned pregnancies and poor metabolic control and
- Use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive.

Women contemplating pregnancy need to be seen frequently by a multidisciplinary team experienced in the management of diabetes before and during pregnancy. This team may vary but must include a diabetologist, general practitioner, obstetrician, diabetes nurse specialist and senior dietician.

The goals of preconception care are to:

- Integrate the patient into the management of her diabetes,
- Achieve the lowest HbA1c test results possible without excessive hypoglycaemia,
- Assure effective contraception until stable and acceptable glycaemia is achieved, and
- Identify, evaluate, and treat long-term diabetic complications such as retinopathy, nephropathy, neuropathy, hypertension and cardiovascular disease.

Although management of diabetes in pregnancy has been improving, women and their infants remain at higher risk for a number of complications compared with non-diabetic pregnancy.

Post-Natally

At 45 to 60 days postnatally, women with gestational diabetes should be reviewed and screened with a 75gm glucose tolerance, if non-diabetic, they should be advised about healthy lifestyles, their risk about developing future diabetes, their need to plan future pregnancies and exclude diabetes before future pregnancies, and should be screened with a glucose tolerance test every 1-2 years.
Co-existing illness

The primary care team’s role involves co-ordinating diabetes care in the context of the patient’s life which includes managing co-existing illness, both acute and chronic.

Chronic illness and diabetes

Consider:

Combined risks

- mobility problems coupled with hypoglycaemia, failing sight or postural hypotension
- varicose veins/haemosiderin and peripheral vascular disease
- nutritional problems of specific population subgroups e.g. disadvantaged, ethnic minorities, elderly etc.

Drugs adversely affecting glucose control and other risks

- corticosteroids
- β-adrenergic blockers in the presence of peripheral vascular disease
- many drugs in deteriorating renal function

Social and psychological adjustments

- effects of changing living circumstances
- denial
- anxiety, for example regarding hypoglycaemia
- influence of depression or dependency on capacity for diabetes self-management
- loss of independence with failing sight or polypharmacy
- education concerning hypoglycaemia

Acute illness

Be Alert:

- Always consider worsening hyperglycaemia, particularly in elderly patients
- Advise more frequent glucose monitoring
- Ensure each patient has access to urine testing for ketones
- Maintain a low threshold for admission at all ages
- Prevent chest infections with pneumococcal and annual influenza vaccines
Emergencies

Hypoglycaemia

Hypoglycaemia can occur in any patient using insulin or sulphonylureas but not in those using acarbose, metformin, incretins and rarely when using PPARβ-agonists. Patients using acarbose need to use purified glucose instead of sucrose (table sugar) to correct a hypo, as they will not break down more complex sugars.

Hypoglycaemia is particularly hazardous for elderly patients (reduced awareness) or those living alone. Prevention includes using metformin or acarbose, shorter-acting sulphonylureas and/or titrated doses of long acting insulins.

Recurrent hypoglycaemia at a particular time or times of day implies a mismatch of glucose-lowering therapy to meal pattern and/or physical activity:

- Review whether a repeated change in meal or activity behaviour is occurring; if so advise on a specific adjustment for that change.
- Consider change in underlying insulin sensitivity (age / renal / endocrine).
- The possible role of alcohol in hypoglycaemia should be addressed.
- The GP is encouraged to obtain urgent specialist referral in the case of severe hypoglycaemia.

Hypoglycaemia unawareness

Repeated hypoglycaemia can induce hypoglycaemia unawareness. Consider (by self-testing) the possibility of undetected night-time or other hypoglycaemia, especially if HbA1c is lower than average and:

- Use adjustment of insulin doses or food intake to ameliorate such problems.
- Encourage more frequent self-testing and increased self-awareness.
- Ensure glucose and glucagon are available at all times.
- Avoid glucose falling to < 4.0 mmol/l.
- Ensure that friends and colleagues are made aware of the signs and treatment of hypoglycaemia.
- Provide education and training in recognising early cognitive dysfunction for people with the problem and their carers.
- Provide counselling on any resultant life-style problems; caution re driving.
Diabetes Care

Nocturnal hypoglycaemia

Nocturnal hypoglycaemia can be improved by careful attention to glucose-lowering therapy:

Consider:

- Taking a bed-time snack
- Using shorter-acting sulphonylureas or repaglinide
- Ensure that insulin dose and regime are appropriate

Specialist Referral

Many Primary Care physicians may wish to refer those with unrecognised hypoglycaemia, nocturnal hypoglycaemia and severe hypoglycaemia to their agreed specialist partner in the integrated care system. In such circumstances a priority appointment will be fast tracked to the patient.

Early hypoglycaemia treatment

When treating early hypoglycaemic attack use 1 glass of glucose drink or sugar containing mineral or 85-100mls of Lucozade or 4-6 glucose tablets. Follow this with a longer acting snack e.g. slice of bread if meal is not due within a half an hour. A severe hypo may require double carbohydrate intake i.e. 30gms.

Hypoglycaemic coma / fitting

If the hypoglycaemic episode has progressed to coma and/or fitting, give up to two doses of 50 mls of 20 % glucose IV if unconscious, or 2 doses of 1 mg glucagon IM. Beware of poor glucagon effect in the starved or inebriated patient. Follow with oral carbohydrate and review for possible relapse.

Train carers to use glucagon if hypoglycaemia is a recurrent problem and ensure supplies remain in date.

Note: Glucagon needs to be refrigerated and has a short shelf life
Severe hyperglycaemia (Diabetic ketoacidosis or non-ketotic hyperglycaemic coma):

- Is life-threatening
- May mimic hypoglycaemia
- Complicates concurrent illness (such as UTI in elderly patients)
- Can develop in less than a day
- Ketones are not always present, when onset is gradual (non-ketotic hyperglycaemia)

Assessment includes:

- Immediate glucometer reading
- Urinalysis for ketones
- Assessment of hydration status.
  Requires immediate admission and consider the need for pre-hospital IV hydration
  (non-glucose crystalline solution)

Nocturnal hypoglycaemia can be improved by careful attention to glucose-lowering therapy.
A recent report from the Department of Health in the UK states that ‘the greatest cost of diabetes is to the people who have it, their families, carers and friends. The impact on them of reduced life expectancy and quality of life is considerable’.

**Key Point**

**In patients with diabetes:**

- Life expectancy may be reduced by five to ten years, mainly because of premature cardiovascular disease.
- The risk of myocardial infarction and stroke is two to five times higher than in the general population.
- Pre-menopausal women lose their protection against macrovascular disease.
- It is the most common cause of non-traumatic lower limb amputation.
- It is the most common cause of blindness in adults of working age.
- It is the single most common cause of end-stage renal disease.
- About 30% of patients will develop overt kidney disease.
- Impotence may affect up to 50% of men with longstanding diabetes.

The long term vascular complications of diabetes include:

<table>
<thead>
<tr>
<th>Microvascular Complications</th>
<th>Macrovascular Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy</td>
<td>Cerebrovascular disease</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>Ischaemic heart disease</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>Peripheral arterial disease</td>
</tr>
</tbody>
</table>

**The risk of developing microvascular complications varies according to:**

- Duration of diabetes
- Glycaemic control
- Hypertension

**The risk of developing macrovascular complications varies according to:**

- Smoking
- Glycaemic control
- Hypertension
- Lipids
- Albuminuria
A range of measures will prevent or delay the development of vascular complications in patients with diabetes. They are summarised in the table below.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose Control</td>
<td>HbA1c target should be set below 6.5%, based on the risk of macrovascular and microvascular complications. Pre-prandial capillary plasma glucose target of &lt;6.0mmol or post-prandial capillary plasma glucose &lt; 8.0mmol/l</td>
</tr>
<tr>
<td>Blood Pressure</td>
<td>Systolic &gt;130mm/hg (A)5 (over 65 years 140 could be considered to avoid postural hypotension) Diastolic &lt; 80mm/hg (B)5 (A)^14 Hypertension should be treated aggressively with lifestyle modification and drug therapy (A)^14 Measure blood pressure annually and at every routine practice visit if found to be above target level</td>
</tr>
<tr>
<td>Lipid Management</td>
<td>LDL Cholesterol: &lt; 2.5mmol/l (A)^5 Total Cholesterol: &lt; 4.5mmol/l Triglycerides: &lt; 2.0mmol/l HDL Cholesterol: &gt;1.0mmol/l Second generation statins should be prescribed if triglycerides are &gt; 2.3mmol/l and LDL values are &gt; 2.5 mmol/l, followed by Omega 3 fish oils and then fibrates as a third line therapy. HDL cholesterols should be brought into the normal range by exercise and prescription of nicotinic acid.</td>
</tr>
<tr>
<td>Statins</td>
<td>Statins should be prescribed for all age groups in those failing to meet lipid targets or those with a history of micro or macrovascular complications, hypertension, metabolic syndrome or a strong family history of cardiovascular disease. Side effects of statins are quite uncommon. Abnormal liver function tests are much more likely to be due to a fatty liver than by statin therapy. A fatty liver causes insulin resistance and should be treated by achieving ideal body weight and the use of statins, omega 3 supplements and fibrates to reduce hypercholesterolaemia and possibly glitazones to reduce insulin resistance.</td>
</tr>
<tr>
<td>Aspirin</td>
<td>No studies have been carried out on the primary prevention of CVD in patients with diabetes but low dose aspirin is usually recommended even in the absence of overt CVD. Aspirin should be prescribed for all patients over 40 or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidaemia or albuminuria) (A)^5</td>
</tr>
<tr>
<td>Lifestyle</td>
<td>Patients should be encouraged to lose weight, if necessary, exercise and eat a healthy diet. (see section on lifestyle management)</td>
</tr>
<tr>
<td>Smoking</td>
<td>Patients should be encouraged to stop smoking and given access to prescription medications which encourage smoking cessation.</td>
</tr>
</tbody>
</table>
Early Detection of Complications

The key to the management of complications is early detection and prompt intervention. Therefore systematic screening for complications forms part of a diabetes integrated care programme. The management of the risk factors associated with the development of these complications has already been outlined.

Macrovascular Complications

The risk of cardiovascular disease is increased 2-4 fold in patients with diabetes. It is the main cause of death in Type 2 diabetes with excess mortality seen in all age groups, especially younger age groups. The underlying pathology is usually atherosclerosis which develops insidiously over many years and is usually advanced by the time symptoms occur.

<table>
<thead>
<tr>
<th>Complication</th>
<th>To Detect</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cardiovascular disease</strong></td>
<td>A full clinical history including history of CVD should be taken at initial diagnosis and once a year. (D)</td>
</tr>
<tr>
<td></td>
<td>The 10-year risk of CVD should be estimated annually for all patients without overt CVD using risk assessment charts. (C)</td>
</tr>
<tr>
<td><strong>Peripheral arterial disease</strong></td>
<td>Inquire about symptoms of peripheral vascular disease.</td>
</tr>
<tr>
<td></td>
<td>Ask about previous foot ulceration or amputation.</td>
</tr>
<tr>
<td></td>
<td>Ask about physical or visual difficulty in self management of foot care.</td>
</tr>
<tr>
<td></td>
<td>Inspect feet for evidence of deformity, neuropathy, ischaemia or infection.</td>
</tr>
<tr>
<td></td>
<td>Detect neuropathy with a 10g monofilament</td>
</tr>
<tr>
<td></td>
<td>Assess arterial circulation by measuring dorsalis pedis and posterior tibial foot pulses; measure Doppler ankle : brachial pressure ratio if available (see comprehensive section on Diabetic Foot)</td>
</tr>
</tbody>
</table>
Microvascular Complications

Delivering microvascular complications together with halting their progress, when they occur, is possible through tight glycaemic and blood pressure control along with the management of risk factors. Early detection is the key to preventing and delaying their progression.

<table>
<thead>
<tr>
<th>Complication</th>
<th>To Detect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy</td>
<td>All patients should have an initial dilated and comprehensive eye examination by an ophthalmologist shortly after diagnosis. (B) Subsequent examinations should be repeated annually. (B) Screening with static or ‘mobile’ cameras can be performed in the community; the retinal images are read on site or at a distant centre.</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>Serum creatinine and urine albumin/creatinine ratio (ACR) should be measured at diagnosis and annually thereafter. The urine ACR should be measured on an early morning specimen. Two out of three urine ACR results need to be positive over a 6 month period to indicate nephropathy.</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>See section on Peripheral Arterial Disease under macrovascular complications.</td>
</tr>
</tbody>
</table>

Please refer also to further guidance on eye care, renal care and foot care. (Pages 32 -35)

Hypertension

Hypertension is a major risk factor for the development of CVD and increases the risk of stroke and heart failure.

In their review of hypertension in Type 2 diabetes Vijan and Hayward found that:

- Studies of hypertension control in diabetes show a clear and consistent effect,
- Improved control of blood pressure leads to substantially reduced risks for cardiovascular events and death,
- In patients with diabetes, aggressive hypertension control also reduces the risk for microvascular events, including end-stage functional impairment (such as decreased visual acuity and end-stage renal disease),
- The risk reduction seen with hypertension control in patients with diabetes is substantially greater than that seen in persons in the general population who have similar blood pressure levels,
- It is also clear that blood pressure targets for patients with diabetes should be more aggressive.
Prevention, Early Detection and Management of Complications

### Hypertension Target

| SBP < 130 mmHg | DBP < 80 mmHg |

In the management of Type 2 diabetes, blood pressure control is as important as blood glucose control. As previously stated the target blood pressure for patients with Type 2 diabetes is:

- Systolic blood pressure of <140mm/Hg may be acceptable in those over 60 years to avoid postural hypotension.
- Blood pressure should be measured at every routine diabetes clinic visit. Therefore all diabetic patients should have their blood pressure checked at least 4 times a year.

### Treatment of Hypertension

Before beginning treatment, patients with elevated blood pressure should have their blood pressure re-examined within one month to confirm the presence of hypertension. A sustained (two or more) reading of systolic blood pressure >160mmHg or a diastolic pressure >100mmHg suggest that pharmacological therapy should be initiated immediately.

The choice of initial antihypertensive drug is less important than reducing blood pressure. Tight targets are difficult to reach and require at least three antihypertensive drugs. Drugs that are taken once daily and that have good 24 hour cover should be used. 

- **Lifestyle measures** should be instituted whenever appropriate in all patients, including subjects with high normal blood pressure and patients who require drug treatment (A)

- **However life style measures should never delay unnecessarily the initiation of drug treatment, especially in patients with higher levels of risk, or detract from compliance with drug treatment. (A)**

- **Initial drug therapy should be with a drug class demonstrated to reduce CVD events in patients with diabetes (ACE inhibitors or ARBS, diuretics and calcium channel blockers and Beta Blockers (A)) avoiding use of atenolol**

- **In patients with Type 2 diabetes, hypertension and microalbuminuria, ACE inhibitors and Angiotension Receptor Blockers (ARBs) have been shown to delay the progression to macroalbuminuria. (A)**

- **The use of ACE inhibitors or ARBs in type 2 diabetes can be associated with acute renal failure since patients often have significant renovascular disease. These medications should be avoided if there is a high suspicion of renal artery stenosis. Renal function should be assessed prior to initiating therapy and in the weeks following by measuring serum creatinine and eGFR (see Page 36)**

All patients should be examined and assessed for a potential secondary cause of their hypertension.
Smoking

It has been shown that smokers have poorer glycaemic control than non-smokers or ex-smokers. Smoking affects the body’s metabolic control, increases insulin resistance and interferes with the action of insulin in the body. Research has shown that smokers with diabetes have a heightened risk of morbidity and premature death associated with the development of macrovascular complications. Smoking is also related to the premature development of microvascular complications.

All smokers, but especially those with diabetes, should be professionally encouraged to permanently stop smoking all forms of tobacco. Quitting smoking can dramatically improve diabetes control.

Some of the most effective methods of helping smokers to quit include brief intervention advice. One of the most important aspects about advising or giving support is to determine where the person is in relation to the cycle of change as outlined by Prochaska + DiClemente (1983), Cycle of Change.

A model using stages of change may help to understand how ready the person is to quit smoking. Smoking cessation counselling and other forms of treatment should be included in routine care.

Diabetes and Nicotine Replacement Therapy:

Nicotine replacement therapy enhances cessation rates when used as an adjunct to smoking cessation counselling. Pharmacotherapy seems to limit withdrawal symptoms and increase abstinence. To date there is no evidence of the impact of pharmacotherapy specific to diabetic smokers. However the research suggests that the extensive benefits of quitting versus the heightened risks of continuing to smoke, should guide the decision regarding use of nicotine replacement therapy and other pharmacological aides for cessation.

In the case of the cardiovascular patient, current clinical evidence, suggests that undue caution may have been applied to the use of NRT. It appears sensible to advise that NRT should not be used in acute MI, unstable angina or severe cardiac arrhythmias, although the risk can be assumed to be lower than with continued smoking.

Nicotine replacement therapy or varenicline should be provided for smokers of more than 15 cigarettes per day who are trying to quit. Therapy in a form acceptable to the patient should be offered for appropriate length of time.
Lipids

The guidance in relation to primary prevention of vascular risk factors is previously outlined. Patients with Type 2 diabetes have an increased prevalence of lipid abnormalities and lipid management is aimed at lowering LDL cholesterol, raising HDL cholesterol and lowering triglycerides.

Targets

- Total Cholesterol: < 4.5mmol/l and LDL Cholesterol: < 2.5mmols (A). Dietary intervention, statin therapy and ezetimibe are the first line treatments for hypercholesterolaemia.
- Hypertriglyceridaemia is an independent risk factor in diabetes. Aim for triglycerides <2.0mmol/l. Weight and alcohol reduction, second generation statins, omega 3 fish oil supplements and fibrates are all recognized treatments for hypertriglyceridaemia.

Diabetic Foot

The Diabetic foot is defined as a group of syndromes in which neuropathy, ischaemia, and infection lead to tissue breakdown, which results in morbidity and ultimately possible amputation. Neuropathy and peripheral disease are the main pathologies underlying diabetic foot disorders:

Key Point

- Peripheral vascular disease leads to poor circulation and ischaemia
- Peripheral neuropathy of the feet leads to loss of sensation.
- These pathologies can lead to ulceration, infection, gangrene, and amputation.
- Diabetic foot ulcers are prone to infection, often with polymicrobial invasion. Foot infections are a major cause of hospital admissions among people with Type 2 diabetes and an important cause of lower limb amputation.

The absence of reliable symptoms and the high prevalence of asymptomatic disease make foot screening essential. All patients with diabetes should be screened for foot disease and should be assessed annually by a Physician, General Practitioner, Diabetes Nurse Specialist, or Practice Nurse with training in diabetes to look for the presence of neuropathy, ischaemia or deformity, following relevant protocols. Immediate referral to diabetes centre where available with subsequent referral to a diabetologist, podiatry, vascular or orthopaedic services is essential where problems are detected.

- All patients with diabetes should be screened for foot disease (D)
- Education plays a primary role in the prevention of ulcer recurrence. This should encompass foot hygiene, the need for daily foot inspection, suitable foot wear, prompt treatment of new lesions, and the importance of regular podiatric visits (B)
- Integrated patient education should be made available to all patients with diabetes at the time of initial diagnosis and then as needed on an ongoing basis, based on formal, regular assessment of the need. Foot Care education improves the knowledge and behaviour towards foot care in the short term in people with diabetes. Education may reduce foot ulceration and complications (C)
Footwear

Callus formation can precede the development of a neuropathic ulcer. The provision of orthoses or therapeutic shoes or both can reduce abnormal foot pressure, callus formation and therefore ulcer development (B)12

Eye Disease

Retinopathy screening

Detection and surveillance of eye problems are a routine part of annual review. Early retinopathy is common at the time of diagnosis of Type 2 diabetes. Current management involves early specialist intervention including focal laser treatment at pre-proliferate stages. Diabetes also predisposes to a number of other eye conditions including cataract. Surveillance should only be conducted by a physician, ophthalmologist or ophthalmic optician with training, experience and confidence in diabetic retinal disease5, 12.

- Patients with multiple risk factors should be considered at high risk of developing diabetic retinal disease (B)12.
- Patients with Type 2 should be screened at diagnosis (Grade A Recommendation SIGN) and at least annually thereafter (B)12,36

Screening for complications and management of associated risk factors is an essential part of a diabetes integrated care programme.
Renal Disease

Microalbuminuria is the earliest indicator of renal disease (nephropathy) attributable to diabetes. Microalbuminuria relates to a range of albumin values in the urine that, while low, are above normal levels. A review of longitudinal studies has shown microalbuminuria to be predictive of total mortality and of cardiovascular mortality morbidity.

Measurement of the urine albumin:creatinine ratio (urine ACR) provides the most consistent and reliable measurement of urine albumin excretion. A urine ACR between 2.5 and 25 is indicative of microalbuminuria and a urine ACR greater than 25 suggests macroalbuminuria or proteinuria. As a general rule-of-thumb the urine ACR multiplied by 10 is approximately equivalent to the 24 hour urine albumin excretion in mgs. An ACR of 50 therefore is equivalent to around 500mgs of urine albumin excretion in a 24 hour period.

Renal impairment is reflected by an increase in the serum creatinine above normal. Because the serum creatinine is affected by factors such as age and muscle mass, a more standardised and accurate way of describing renal function is now provided by estimating the creatinine clearance by formulae. This is referred to as the ‘eGFR’ or estimated glomerular filtration rate. The eGFR result is approximately equal to the degree of renal function expressed as a percentage. For instance an eGFR of 40 suggests renal function of around 40% of normal. Calculation of the eGFR which is now provided automatically by laboratories in conjunction with the reporting of the serum creatinine allows the degree of renal function to be graded in terms of severity.

<table>
<thead>
<tr>
<th>Degree of Chronic Kidney Disease</th>
<th>eGFR</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>&gt;90</td>
<td>Normal</td>
</tr>
<tr>
<td>Stage 2</td>
<td>60-90</td>
<td>Mild</td>
</tr>
<tr>
<td>Stage 3</td>
<td>30-60</td>
<td>Moderate</td>
</tr>
<tr>
<td>Stage 4</td>
<td>15-30</td>
<td>Severe</td>
</tr>
<tr>
<td>Stage 5</td>
<td>&lt; 15</td>
<td>End-stage</td>
</tr>
</tbody>
</table>

A significant proportion of patients with type 2 diabetes develop proteinuria and renal impairment. Diabetes is now the most common cause of end-stage kidney disease requiring dialysis. This outcome however is rare in comparison with cardiovascular mortality and morbidity associated with diabetes.

Microalbuminuria Testing

| Negative Result | Re-screen in one year and maintain good blood glucose and blood pressure control (A)\(^\text{15,16}\) |
| Positive Result | Arrange early evaluation with a diabetologist. If 2 out of 3 tests are positive for microalbuminuria begin treatment with drug therapy (ACE inhibitors are the drug of first choice) (A)\(^\text{15,18}\) |
Suggested shared protocol for management of Microalbuminuria and Protein Diabetes

**TYPE 2 DIABETES**

- **Microalbuminuria or hypertension**
  - **Microalbuminuria**
    - Urinary albumin/creatinine ratio >2.5 mg/mmol (or higher than laboratory reference range) on at least 2 out of 3 occasions
  - **Hypertension in Diabetes**
    - Blood pressure persistently higher than 130/80

- **Risk of Renovascular disease**
  - **Consider Renovascular Disease if**
    - Age >65 years
    - Cigarette smoker
    - History of ischaemic heart disease peripheral vascular disease, cerebrovascular disease or abdominal aortic aneurysm.
    - Abdominal vascular bruits
    - Absent peripheral pulses
    - SCreatinine >150 μmol/l
    - SPotassium >5.0 mmol/l
    - Hypercholesterolaemia
    - Asymmetric kidneys on renal ultrasound

  - **Cautious introduction of Angiotensin Receptor Blockade**
    - Start at 50% usual starting dose
    - First dose to be taken at bedtime
    - Instruct patient to stop therapy if it makes him/her unwell
    - Check urea and electrolytes 1-2/62 after starting therapy
    - Stop therapy if serum potassium >5.0 mmol/l or >30% rise in serum creatinine

- **Targets of Treatment**
  - BP<130/80 mmHg AND Urinary albumin/creatinine ratio normal
  - If urine protein >1-2G/24hrs, consider lowering target to 120/75

- **Indications for referral to hospital clinic**
  - BP uncontrolled on triple therapy
  - frank proteinuria (dipstick testing persistently positive or uACR>200)
  - SCreatinine>150 μmol/l

**Microalbuminuria**

- Start ARB (with thiazide if hypertensive)
- Titrate to maximum dose
- Add ACEi
- Titrate to maximum dose
- Add type 1 CCB (diltiazem)
- Consider addition of doxazosin or β blocker
- Consider Hospital Referral

**Hypertension in Diabetes**

- Blood pressure persistently higher than 130/80

**Consider Renovascular Disease if**

- Age >65 years
- Cigarette smoker
- History of ischaemic heart disease peripheral vascular disease, cerebrovascular disease or abdominal aortic aneurysm.
- Abdominal vascular bruits
- Absent peripheral pulses
- SCreatinine >150 μmol/l
- SPotassium >5.0 mmol/l
- Hypercholesterolaemia
- Asymmetric kidneys on renal ultrasound

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**Indications for referral to hospital clinic**

- BP uncontrolled on triple therapy
- frank proteinuria (dipstick testing persistently positive or uACR>200)
- SCreatinine>150 μmol/l
Erectile Dysfunction

Erectile Dysfunction (ED) or impotence means not being able to have or maintain an erection long enough to have sexual intercourse.

Erectile Dysfunction affects:

- All men at some stage in their lives
- One man in ten over the age of 40 is affected whether they have diabetes or not
- May affect half of all men with diabetes.

Erectile Dysfunction (ED) is very common amongst middle aged and elderly men with type 2 diabetes and may develop in younger men with type 1 diabetes. Patients may be reluctant to discuss the problem. Usually libido is not reduced initially and the problem is identified as not being able to sustain an erection satisfactory for intercourse.

Support and counselling should be available for men with erectile dysfunction. Investigations to exclude other causes (measurement of prolactin, follicle stimulating hormone, luteinising hormone, testosterone, and sex hormone binding globulin) may be necessary. Oral phosphodiesterase type 5 inhibitors are effective in about 60% of men with diabetes, less than in the non-diabetic population. Alternatives include sublingual apomorphine, intrarethral drugs, intracavernosal drugs, vacuum devices, and penile prostheses.

Erectile Dysfunction Questionnaire may be of some help to commence the assessment process.
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34. Edmonds ME, Foster Managing the diabetic foot 2000


38. Edmonds ME, Foster Managing the diabetic foot 2002 Oxford Blackwell Science


42. Edmonds ME, Foster Managing the diabetic foot 2002 Oxford Blackwell Science

43. Young MJ, Arisidis Veves, Boulton AMJ The Diabetic Foot: Aetiopathogenesis and Management 2002

44. Edmonds ME, Foster Managing the diabetic foot 2000


Appendix 1

Levels of Evidence

Not all evidence is of the same quality and strength. Generally it ranges from high quality meta-analyses and systematic reviews of randomised controlled trials to expert opinion. For this reason many organisations formulating guidelines have highly developed systems for categorising evidence, that take into account a number of features of the study/information presented. While this adds to the overall credibility of the guideline produced, it can present problems for those formulating derived guidelines using a number of sources as there is no international system for categorising levels of evidence.

Scottish Intercollegiate Guideline Network (SIGN)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or 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</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>
### Grades of recommendations

Scottish Intercollegiate Guideline Network (SIGN)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>

### Good practice points

Recommended best practice based on the clinical experience of the guideline development group.

### References:

Audit

Monitoring the quality of care.

Quality assurance is an integral feature of modern structured diabetes care. A protocol for monitoring the quality of care includes the following:

<table>
<thead>
<tr>
<th>Aggregate</th>
<th>the data gathered at regular and annual reviews onto a database</th>
</tr>
</thead>
<tbody>
<tr>
<td>Choose</td>
<td>indicators (see below) to reflect outcome as well as process of care</td>
</tr>
<tr>
<td>Analyse</td>
<td>data in line with published recommendations</td>
</tr>
<tr>
<td>Compare</td>
<td>performance with pre-determined standards or other providers of diabetes care</td>
</tr>
<tr>
<td>Review</td>
<td>performance at regular meetings with peer performance of education programmes</td>
</tr>
<tr>
<td>Act</td>
<td>to design and implement action plans for improvement</td>
</tr>
</tbody>
</table>

This describes an internal audit cycle, which may be conducted within a practice or shared locally in a shared care scheme, CME or other peer group, or nationally through the ICGP or another professional forum. Published audits in Ireland are uncommon, but increasingly will provide material for comparison with positive consequences for standards of diabetes care. The table below lists some of the process and outcome indicators frequently analysed. There is some merit in evaluating process measures initially, and moving on to outcome measures later.

<table>
<thead>
<tr>
<th>Measure:</th>
<th>Calculate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate outcomes</td>
<td></td>
</tr>
<tr>
<td>HbA1c</td>
<td>Percent with HbA1c &gt;7.5 and &gt;6.5 %</td>
</tr>
<tr>
<td>Albumin excretion</td>
<td>Percent with abnormal albumin excretion</td>
</tr>
<tr>
<td>Eye damage</td>
<td>Percent with retinal damage</td>
</tr>
<tr>
<td>True outcomes</td>
<td></td>
</tr>
<tr>
<td>Amputation above ankle</td>
<td>Incidence</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>Incidence</td>
</tr>
<tr>
<td>Stroke</td>
<td>Incidence</td>
</tr>
<tr>
<td>Foot ulceration</td>
<td>Incidence</td>
</tr>
<tr>
<td>Risk factor control</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>Percent with blood pressure &gt;130/80mmHg</td>
</tr>
<tr>
<td>Smoking</td>
<td>Percent people still smoking</td>
</tr>
<tr>
<td>Process of care</td>
<td></td>
</tr>
<tr>
<td>Eyes screened</td>
<td>Percent people examined in year</td>
</tr>
<tr>
<td>Education performed</td>
<td>Percent people seeing nurse educator in year</td>
</tr>
<tr>
<td>Feet examined</td>
<td>Percent people examined in year</td>
</tr>
<tr>
<td>Flu vaccination</td>
<td>Percent patients offered vaccination each year</td>
</tr>
</tbody>
</table>

These are examples; many other indicators are possible.
Dietary Advice for Patients

Healthy Eating includes:

Regular meals containing starchy foods such as bread, cereals, pasta, rice or potatoes. Whenever possible, choose wholegrain varieties that are high in fibre, like wholemeal bread or cereals.

Low glycaemic index carbohydrate foods are preferable, such as pulses, dairy products, and oats, pasta, basmati rice, noodles, sweet potato, plantain and pitta bread. Glycaemic index measures how high blood sugars increase after eating a food. Low glycaemic index foods avoid blood sugar rises and may keep excessive body fat at bay.

Snacking levels between meals will depend upon the patients’ lifestyle, activity levels, personal preferences and the diabetes medication prescribed.

Fruit and vegetables; at least five portions of fruit and vegetables should be taken daily. Intake of fruit should be spread evenly over the course of the day. NO more than a small glass of unsweetened juice at any one time as it can raise blood sugars easily.

Reduce sugar. Sugary foods can be eaten occasionally in small amounts after a meal. Sugar-free, low sugar or diet squashes and fizzy drinks can be used. Non-nutritive sweeteners (e.g. Canderel, Hermesetas) are safe.

Reduce fat, particularly saturated (animal) fats, as this type of fat is linked to heart disease. Choose monounsaturated fats, eg olive oil and rapeseed oil. Eating less fat and fatty foods will also help to lose weight. Use less butter, margarine, cheese and fatty meats. Choose low fat dairy foods. Avoid frying. Include oily fish twice a week, as its omega-3 fats lower the risk of heart disease and helps reduce triglyceride levels. Fish oil supplements are not generally recommended.

Use less salt, because a high intake of salt can raise blood pressure. Try flavouring food with herbs and spices instead.

Alcohol in moderation – 2 units of alcohol / day for women and 3 units / day for men. For example, a small glass of wine or half a pint of normal-strength beer is approximately one unit. Never drink on an empty stomach, as alcohol can bring about hypoglycaemia.

No Diabetic products. They are expensive and unnecessary. They contain a sweetener that can cause stomach upset.

Source: Midland Diabetes Structured Care Programme
Physical Activity

What is the Recommended Level of Physical Activity?
It is recommended that all individuals should aim to accumulate at least 30 minutes of moderate intensity physical activity on most days of the week.

Remember:
This has been adopted as the minimum requirement for health benefits. However, 30 minutes spread over the entire day is equally beneficial as one 30 minute walk. Also ‘activities of daily living’ such as housework and using stairs are valuable in increasing physical activity.

What activities should be recommended
The most important considerations are:
- What activity the individual would enjoy doing the most
- What activity the individual is most likely to sustain long-term.
- To maximise adherence, exercise programmes should be home-based and should be accompanied by ongoing support which includes education in cognitive behaviour skills and advice tailored to the individual’s stage of change.

Safety Issues to consider when giving advice on Physical Activity:
Being active at moderate intensity should mean that:
- The person is always able to talk while being active & should not be out of breath.
- Physical activity levels should only be increased gradually on a weekly basis.
- It is a good idea to recommend regular exercise of short duration initially.
- The length of each session can then be increased gradually every week
- Regular breathing while exercising should be encouraged. e.g. holding of breath while lifting or pushing can increase blood pressure - a risk with diabetic retinopathy

Pre- activity warm up
It is important to warm up by doing the activity at a slower pace for the first 5-10 minutes

Post- activity cool down
Equally, it’s important to cool down afterwards by doing the activity at a slower pace for 5-10 minutes

Foot Care
Feet should be checked after every activity session

Insulin
If the person is on insulin, injection sites should be away from the muscles used while exercising

Snacks
Fast-acting carbohydrate snacks should be at hand while being active

Source: Midland Diabetes Structured Care Programme
Appendix 5

The Diabetic Foot

Diabetic foot review & risk classification protocol

Figure 1: Protocol for the assessment of risk of the diabetic foot adapted from the Tayside foot assessment protocol

Patients should be categorised according to the presence of the following symptoms/signs

<table>
<thead>
<tr>
<th>Normal sensation</th>
<th>Loss of sensation</th>
<th>Previous ulcer due to neuropathy or ischaemia</th>
<th>Active foot ulceration, painful neuropathy which is difficult to control</th>
</tr>
</thead>
<tbody>
<tr>
<td>and good pulses</td>
<td>or Absent pulses</td>
<td>or Absent pulses and neuropathy</td>
<td></td>
</tr>
<tr>
<td>and no previous ulcer</td>
<td>or Significant visual impairment</td>
<td>or Callus with risk factor (neuropathy, absent pulse, foot deformity)</td>
<td></td>
</tr>
<tr>
<td>and no foot deformity</td>
<td>or Physical Disability</td>
<td>or Previous amputation</td>
<td></td>
</tr>
<tr>
<td>and normal vision</td>
<td>(e.g. stroke or gross obesity)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Midland Diabetes Structured Care Programme

In addition, patients with any of the following sign of ischaemia or infection should be considered for emergency referral to the hospital surgical receiving service or diabetic foot clinic, where appropriate.

**Critical Ischaemia**
- Rest or night pain
- Pale/ Mottled Feet
- Dependant rubor
- Ischaemic ulceration
- Gangrene

**Severe Infection**
- Abscess
- Cellulitis

Neuropathy screening can be performed by using clinical neuropathy disability scores, 10g monofilaments, or by use of vibration perception thresholds.

All these methods, singly or in combination, have shown benefits in selecting patients at increased risk of foot ulceration.
Assessment of the Diabetic Foot

Assessment should include:

- Skin/soft tissue examination - inspection of legs; dorsal, plantar, and posterior surfaces of the foot; and between the toes.
- Neurological examination - tingling or pain, loss of sensation, loss of perception of pressure and vibration, reflexes.
- Vascular evaluation - palpation of the pulses of the lower limbs, inspection of the feet and legs for evidence of ischemic changes.
- Musculoskeletal evaluation - evaluation of the foot and ankle range of movement, inspection for bone abnormalities, analysis of gait and stance.
- Consider infection whenever local (e.g. foot pain, swelling, ulceration) or systemic (e.g. poor glycaemic control, fever, malaise) problems develop. The usual signs of infection may be absent due to immunosuppression.
- Footwear examination - inspection of the type and fit of shoe, pattern of wear of shoes and lining, presence of foreign bodies, use of insoles or orthoses.
- Measurement of sensation using a 10g monofilament predicts people at increased risk of ulceration due to neuropathy:
- The 10g monofilament is convenient and easy to use in primary care. For further information on the use of the 10g monofilament see below.

Foot Ulcer Classification

Clinical features that distinguish neuropathic and ischaemic foot ulcers:

<table>
<thead>
<tr>
<th>Sign/Symptom</th>
<th>Neuropathic Ulcer</th>
<th>Ischaemic Ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Painless</td>
<td>Pain may be relieved by hanging legs down</td>
</tr>
<tr>
<td>Location</td>
<td>Commonly seen on plantar</td>
<td>Commonly located at edges of foot</td>
</tr>
<tr>
<td></td>
<td>surface of foot</td>
<td></td>
</tr>
<tr>
<td>Skin Temperature</td>
<td>Warm Foot</td>
<td>Cool Foot</td>
</tr>
<tr>
<td>Foot Pulses</td>
<td>Bounding</td>
<td>Absent or Weak</td>
</tr>
<tr>
<td>Callus Formation</td>
<td>Often present especially on Plantar surfaces</td>
<td>Absent</td>
</tr>
</tbody>
</table>

Patients whose feet have a high risk of ulceration or gangrene need support and education about foot care. These measures can reduce amputation rates by 30-50% and early referral of patients with ulcers, along with those who have a history of ulcers, to a podiatrist is essential.
Use of a 10 gram Monofilament

1. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.

2. Ask the patient to turn his/her head and close his/her eyes or look at the ceiling.

3. Ask the patient to say “yes” when he/she feels you touching his/her foot with the monofilament. DO NOT ASK THE PATIENT “did you feel that?”

4. Hold the monofilament perpendicular to the skin and use a smooth motion when testing. Try a 3 second sequence that includes:

   - placing the end of the monofilament on the sole of the foot
   - pushing the monofilament until it bends, then
   - lifting the monofilament from the skin

   Repeat the sequence at another testing site on the foot (see below). DO NOT use a rapid or tapping movement. If the monofilament accidentally slides along the skin, retest that area later in the testing sequence.

5. Use the monofilament in a random sequence, NOT moving from right to left.

6. If the patient does not say “yes” when you touch a given testing site, continue on to another site. When you have completed the sequence RETEST the area(s) where the patient did not feel the monofilament.

7. Apply the filament along the perimeter of, and not on, an ulcer site, necrotic tissue, callus or scar.

Loss of protective sensation = absent sensation at one or more sites.

The 5.07 monofilament will last indefinitely if you ALWAYS place it back in the case after use. This will keep you from accidentally bending or breaking the monofilament. To clean the monofilament, sodium hypochlorite (household bleach) 1:10 solution is recommended.

Sites on the sole of the foot for monofilament testing
(from the Group Health Cooperative Seattle Diabetes Foot Screening Guideline)

Diabetic Foot Assessment Tool

Sensation

**Touch**
Cotton wool

10mg Monofilaments

A “+” marked in the circles indicates where the Monofilament was felt.

Pain

Neurotips

Neurothesiometer reading: Great Toe (Volts)

Vibration

Circulation

**Pulses**
Dorsalis Pedis Artery
Posterior Tibial Artery

**Colour**
**Temperature**
**Filling Time (sec)**

Doppler Test

Arm Systolic Pressure
Ankle/Arm Indices

<table>
<thead>
<tr>
<th>Pressure Measurements</th>
<th>Right Dorsalis Pedis</th>
<th>Right Great Toe</th>
<th>Right Posterior Tibial</th>
<th>Left Posterior Tibial</th>
<th>Left Great Toe</th>
<th>Left Dorsalis Pedis</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABPI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

References:

A PRACTICAL GUIDE TO INTEGRATED TYPE 2 DIABETES CARE

by Dr. Velma Harkins