



# Type 1 diabetes in adults: diagnosis and management

NICE guideline

Published: 26 August 2015 nice.org.uk/guidance/ng17

# Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The application of the recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

# Contents

ľ	ntroduction	. 5
	Reasons for the update	6
	Medicines	7
P	atient-centred care	. 8
K	ey priorities for implementation	. 9
	Education and information	9
	Blood glucose management	9
	Insulin therapy	10
	Awareness and management of hypoglycaemia	10
	Care of adults with type 1 diabetes in hospital	10
1	Recommendations	.11
	Blood glucose and plasma glucose	11
	1.1 Diagnosis and early care plan	11
	1.2 Support and individualised care	15
	1.3 Education and information	16
	1.4 Dietary management	18
	1.5 Physical activity	20
	1.6 Blood glucose management	21
	1.7 Insulin therapy	25
	1.8 Insulin delivery	27
	1.9 Referral for islet or pancreas transplantation	28
	1.10 Awareness and management of hypoglycaemia	28
	1.11 Ketone monitoring and management of diabetic ketoacidosis (DKA)	31
	1.12 Associated illness	33
	1.13 Control of cardiovascular risk	34
	1.14 Care of adults with type 1 diabetes in hospital	36
	1.15 Managing complications	37

2 Research recommendations	46
2.1 Improved methods and interventions for achieving HbA1c targets in adults with type 1 diabetes	. 46
2.2 Continuous glucose monitoring for adults with type 1 diabetes	. 46
2.3 Structured education programmes for adults with type 1 diabetes	. 47
2.4 Risk stratification tool for HbA1c targets for adults with type 1 diabetes	. 47
2.5 Technologies for preventing and treating impaired awareness of hypoglycaemia in adults with type 1 diabetes	48
3 Other information	49
3.1 Scope and how this guideline was developed	. 49
3.2 Related NICE guidance	. 49
4 The Guideline Development Group, National Collaborating Centre and NICE project team, and declarations of interests	
4.1 Guideline Development Group	. 52
4.2 National Clinical Guideline Centre	. 53
4.3 NICE project team	. 53
4.4 Declarations of interests	. 54
Update information	57
Recommendations from NICE guideline CG15 that have been amended	. 58
About this guideline	85
Strength of recommendations	85

This guideline replaces TA53 and TA60.

This guideline partially replaces CG15.

This guideline is the basis of QS109 and QS6.

#### Introduction

This guidance is an update of 'type 1 diabetes' (NICE guideline CG15) and replaces the guidance for adults. The recommendations are labelled according to when they were originally published (see <u>update information</u> for details).

Type 1 diabetes affects over 370,000 adults in the UK. It results from destruction of the cells that normally make insulin. Loss of insulin secretion results in high blood glucose and other metabolic and haematological abnormalities, which have both short-term and long-term adverse effects on health. Over years, type 1 diabetes causes tissue damage which, if not detected and managed early, can result in disability: blindness, kidney failure and foot ulceration leading to amputation, as well as premature heart disease, stroke and death. The risk of all of these complications is greatly reduced by treatment that keeps circulating glucose levels to as near normal as possible, reducing tissue damage. Disability from complications that are not avoided can often be prevented by early detection and active management.

Type 1 diabetes is treated by insulin replacement, supported by active management of other cardiovascular risk factors, such as hypertension and high circulating lipids. Modern insulin replacement therapy aims to recreate normal fluctuations in circulating insulin concentrations. This supports a flexible lifestyle with minimal restrictions and, properly done, can improve blood glucose levels, reducing the risk of both structural complications and episodes of hypoglycaemia. Flexible insulin therapy usually involves self-injecting multiple daily doses of insulin, with doses adjusted based on taken or planned exercise, intended food intake and other factors, including current blood glucose, which the insulin user needs to test on a regular basis. This self-management needs the insulin user to have the skills and confidence to manage the regimen. One of the most important roles of healthcare professionals providing diabetes care to adults with type 1 diabetes is to ensure that systems are in place to provide informed, expert support, education and training for insulin users, as well as a range of other more conventional biomedical services and interventions.

Although type 1 diabetes in adults is not rare, it is not common enough that all healthcare professionals who deal with it are able to acquire and maintain all the necessary skills for its

management. The aim of this guideline is to provide evidence-based, practical advice on supporting adults with type 1 diabetes to live full, largely unrestricted, lives and to avoid the short-term and long-term complications of both the disease and of its treatment.

## Reasons for the update

NICE last produced a guideline on type 1 diabetes in 2004. Since then, life expectancy for adults living with type 1 diabetes has increased, but it remains significantly shorter than for people without diabetes. There remain important deficiencies in care provision, most adults with type 1 diabetes have HbA1c above target levels, and rates of diabetic ketoacidosis (the acute complication of insulin deficiency) and renal failure have increased. This update focuses on areas where new knowledge and treatment opportunities have arisen in the last decade. These include improvements in technology to support better glucose levels, that should result in improved outcomes for adults with type 1 diabetes. These changes also present more challenges in terms of the diversity and complexity of the tools that can now be provided, and this guideline describes evidence-based best practice for their deployment.

Topics updated from the 2004 guideline include:

- diagnosing type 1 diabetes
- structured education programmes
- insulin preparations and regimens associated with improved glucose levels
- needle length for insulin injections
- new technologies for glucose monitoring and insulin delivery
- managing acute painful neuropathy associated with rapid blood glucose control, erectile dysfunction in men and gastroparesis
- primary prevention of cardiovascular disease.

The following topics were not included in 2004 and have been added:

- new insulin formulations
- identifying, quantifying and managing impaired awareness of hypoglycaemia
- monitoring for thyroid disease

- use of blood ketone measurement in preventing and monitoring diabetic ketoacidosis
- carbohydrate counting and glycaemic index diets
- referral criteria for transplantation therapies.

This guideline describes methods for achieving optimal outcomes for adults with type 1 diabetes and to inform service design and delivery. Its intended audience includes healthcare professionals involved in delivering services to adults with type 1 diabetes, service managers and commissioners, and adults with type 1 diabetes and their families.

#### **Medicines**

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's <u>Prescribing guidance: prescribing unlicensed medicines</u> for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.

#### Patient-centred care

This guideline offers best practice advice on the care of adults with type 1 diabetes.

Patients and healthcare professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. If it is clear that the child or young person fully understands the treatment and does not want their family or carers to be involved, they can give their own consent. Healthcare professionals should follow the Department of Health's advice on consent. If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in <u>patient experience in adult NHS</u> services.

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in section 1.

## **Education and information**

• Offer all adults with type 1 diabetes a structured education programme of proven benefit, for example the <u>DAFNE</u> (dose-adjustment for normal eating) programme. Offer this programme 6–12 months after diagnosis. [new 2015]

## Blood glucose management

- Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications. [new 2015]
- Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia. [new 2015]
- Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply:
  - the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved
  - the frequency of hypoglycaemic episodes increases
  - there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] At a glance guide to the current medical standards of fitness to drive)
  - during periods of illness
  - before, during and after sport
  - when planning pregnancy, during pregnancy and while breastfeeding (see the NICE guideline on <u>diabetes in pregnancy</u>)
  - if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, impaired awareness of hypoglycaemia, high-risk activities). [new 2015]

- Advise adults with type 1 diabetes to aim for:
  - a fasting plasma glucose level of 5-7 mmol/litre on waking and
  - a plasma glucose level of 4–7 mmol/litre before meals at other times of the day. [new 2015]

## Insulin therapy

 Offer multiple daily injection basal-bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin injection regimen of choice for all adults with type 1 diabetes. Provide the person with guidance on using multiple daily injection basal-bolus insulin regimens. [new 2015]

## Awareness and management of hypoglycaemia

 Assess awareness of hypoglycaemia in adults with type 1 diabetes at each annual review. [new 2015]

## Care of adults with type 1 diabetes in hospital

• Enable adults with type 1 diabetes who are hospital inpatients to self-administer subcutaneous insulin if they are willing and able and it is safe to do so. [new 2015]

#### 1 Recommendations

The following guidance is based on the best available evidence. The <u>full guideline</u> gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example, words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See <u>about this guideline</u> for details.

# Blood glucose and plasma glucose

This guideline refers frequently to circulating glucose concentrations as 'blood glucose'. A lot of the evidence linking specific circulating glucose concentrations with particular outcomes uses 'plasma' rather than 'blood' glucose. In addition, patient-held glucose meters and monitoring systems are all calibrated to plasma glucose equivalents. However, the term 'blood glucose monitoring' is in very common use, so in this guideline we use the term 'blood glucose', except when referring to specific concentration values.

## 1.1 Diagnosis and early care plan

## Diagnosis

- 1.1.1 Diagnose type 1 diabetes on clinical grounds in adults presenting with hyperglycaemia, bearing in mind that people with type 1 diabetes typically (but not always) have one or more of:
  - ketosis
  - · rapid weight loss
  - age of onset below 50 years
  - BMI below 25 kg/m<sup>2</sup>
  - personal and/or family history of autoimmune disease. [new 2015]
- 1.1.2 Do not discount a diagnosis of type 1 diabetes if an adult presents with a BMI of 25 kg/m<sup>2</sup> or above or is aged 50 years or above. [new 2015]

- 1.1.3 Do not measure C-peptide and/or diabetes-specific autoantibody titres routinely to confirm type 1 diabetes in adults. [new 2015]
- 1.1.4 Consider further investigation in adults that involves measurement of C-peptide and/or diabetes-specific autoantibody titres if:
  - type 1 diabetes is suspected but the clinical presentation includes some atypical features (for example, age 50 years or above, BMI of 25 kg/m<sup>2</sup> or above, slow evolution of hyperglycaemia or long prodrome) or
  - type 1 diabetes has been diagnosed and treatment started but there is a clinical suspicion that the person may have a monogenic form of diabetes, and C-peptide and/ or autoantibody testing may guide the use of genetic testing or
  - classification is uncertain, and confirming type 1 diabetes would have implications for availability of therapy (for example, continuous subcutaneous insulin infusion [CSII or 'insulin pump'] therapy). [new 2015]
- 1.1.5 When measuring C-peptide and/or diabetes-specific autoantibody titres, take into account that:
  - autoantibody tests have their lowest false negative rate at the time of diagnosis, and that the false negative rate rises thereafter
  - C-peptide has better discriminative value the longer the test is done after diagnosis
  - with autoantibody testing, carrying out tests for 2 different diabetes-specific autoantibodies, with at least 1 being positive, reduces the false negative rate. [new 2015]

## Early care plan

- 1.1.6 At the time of diagnosis (or if necessary after the management of critically decompensated metabolism), the diabetes professional team should develop with and explain to the adult with type 1 diabetes a plan for their early care. To agree such a plan will generally require:
  - medical assessment to:
    - ensure security of diagnosis of type of diabetes

- ensure appropriate acute care is given when needed
- review and detect potentially confounding disease and medicines
- detect adverse vascular risk factors
- environmental assessment to understand:
  - the social, home, work and recreational circumstances of the person and carers
  - their preferences in nutrition and physical activity
  - other relevant factors, such as substance use
- cultural and educational assessment to identify prior knowledge and to enable optimal advice and planning about:
  - treatment modalities
  - diabetes education programmes
- assessment of emotional state to determine the appropriate pace of education.

The results of the assessment should be used to agree a future care plan. Some items of the initial diabetes assessment:

- acute medical history
- social, cultural and educational history/lifestyle review
- complications history/symptoms
- long-term/recent diabetes history
- other medical history/systems
- family history of diabetes/cardiovascular disease
- medication history/current medicines
- vascular risk factors
- smoking
- general examination

- weight/BMI
- foot/eye/vision examination
- urine albumin excretion/urine protein/serum creatinine
- psychological wellbeing
- attitudes to medicine and self-care
- immediate family and social relationships and availability of informal support. [2004]
- 1.1.7 Elements of an individualised and culturally appropriate plan will include:
  - sites and timescales of diabetes education, including nutritional advice (see sections 1.3 and 1.4)
  - initial treatment modalities, including guidance on insulin injection and insulin regimens (see sections 1.7 and 1.8)
  - means of self-monitoring and targets (see <u>section 1.6</u>)
  - symptoms, risk and treatment of hypoglycaemia
  - management of special situations, such as driving
  - means and frequency of communication with the diabetes professional team
  - management of cardiovascular risk factors (see <u>section 1.13</u>)
  - for women of childbearing potential, implications for pregnancy and family planning advice (see the NICE guideline on <u>diabetes in pregnancy</u>)
  - frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review. [2004, amended 2015]
- 1.1.8 After the initial plan is agreed, put arrangements in place to implement it without inappropriate delay, and to provide for feedback and modification of the plan over the ensuing weeks. [2004]

## 1.2 Support and individualised care

- 1.2.1 Take account of any disabilities, including visual impairment, when planning and delivering care for adults with type 1 diabetes. [new 2015]
- 1.2.2 Advice to adults with type 1 diabetes should be provided by a range of professionals with skills in diabetes care working together in a coordinated approach. A common environment (diabetes centre) is an important resource in allowing a diabetes multidisciplinary team to work and communicate efficiently while providing consistent advice. [2004]
- 1.2.3 Provide adults with type 1 diabetes with:
  - open-access services on a walk-in and telephone-request basis during working hours
  - a helpline staffed by people with specific diabetes expertise on a 24-hour basis
  - contact information for these services. [2004]
- 1.2.4 Regard each adult with type 1 diabetes as an individual, rather than as a member of any cultural, economic or health-affected group (see also recommendations 1.4.5 and 1.4.13 about the cultural preferences of individual adults with type 1 diabetes). [2004, amended 2015]
- 1.2.5 Set up an individual care plan jointly agreed with the adult with type 1 diabetes, review it annually and modify it taking into account changes in the person's wishes, circumstances and medical findings, and record the details. The plan should include aspects of:
  - diabetes education, including nutritional advice (see <u>sections 1.3 and 1.4</u>)
  - insulin therapy, including dose adjustment (see <u>sections 1.8 and 1.9</u>)
  - self-monitoring (see <u>section 1.6</u>)
  - avoiding hypoglycaemia and maintaining awareness of hypoglycaemia
  - for women of childbearing potential, family planning, contraception and pregnancy planning (see the NICE guideline on <u>diabetes in pregnancy</u>)
  - cardiovascular risk factor monitoring and management (see section 1.13)

- complications monitoring and management (see section 1.15)
- means and frequency of communicating with the diabetes professional team
- frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review. [2004, amended 2015]
- 1.2.6 Use population, practice-based and clinic diabetes registers (as specified by the National service framework for diabetes) to assist programmed recall for annual review and assessment of complications and cardiovascular risk. [2004]
- 1.2.7 The multidisciplinary team approach should be available to inpatients with type 1 diabetes, regardless of the reason for admission (see <a href="section 1.14">section 1.14</a>).[2004]
- 1.2.8 At the time of diagnosis and periodically thereafter, provide adults with type 1 diabetes with up-to-date information about diabetes support groups (local and national), how to contact them and the benefits of membership. [2004]

## 1.3 Education and information

Recommendations in this section update and replace the NICE technology appraisal guidance on the use of patient-education models for diabetes for adults with type 1 diabetes.

- 1.3.1 Offer all adults with type 1 diabetes a structured education programme of proven benefit, for example the <u>DAFNE (dose-adjustment for normal eating)</u> programme. Offer this programme 6–12 months after diagnosis. [new 2015]
- 1.3.2 If a structured education programme has not been undertaken by an adult with type 1 diabetes by 12 months after diagnosis, offer it at any time that is clinically appropriate and suitable for the person, regardless of duration of type 1 diabetes. [new 2015]
- 1.3.3 Provide an alternative of equal standard for any adult with type 1 diabetes unable or unwilling to participate in group education. [new 2015]
- 1.3.4 Ensure that any structured education programme for adults with type 1 diabetes includes the following components:

- It is evidence-based, and suits the needs of the person.
- It has specific aims and learning objectives, and supports the person and their family members and carers in developing attitudes, beliefs, knowledge and skills to self-manage diabetes.
- It has a structured curriculum that is theory-driven, evidence-based and resource-effective, has supporting materials, and is written down.
- It is delivered by trained educators who have an understanding of educational theory appropriate to the age and needs of the person, and who are trained and competent to deliver the principles and content of the programme.
- It is quality assured, and reviewed by trained, competent, independent assessors who measure it against criteria that ensure consistency.
- The outcomes are audited regularly. [new 2015]
- 1.3.5 Explain to adults with type 1 diabetes that structured education is an integral part of diabetes care. [new 2015]
- 1.3.6 Provide information about type 1 diabetes and its management to adults with type 1 diabetes at all opportunities from diagnosis onwards. Follow the principles in the NICE guideline on <u>patient experience in adult NHS services</u>. [new 2015]
- 1.3.7 Consider the Blood Glucose Awareness Training (BGAT) programme for adults with type 1 diabetes who are having recurrent episodes of hypoglycaemia (see also <u>section 1.10</u>). [new 2015]
- 1.3.8 Carry out more formal review of self-care and needs annually in all adults with type 1 diabetes. Vary the agenda addressed each year according to the priorities agreed between the healthcare professional and the adult with type 1 diabetes. [2004, amended 2015]

## 1.4 Dietary management

#### Carbohydrate counting

- 1.4.1 Offer carbohydrate-counting training to adults with type 1 diabetes as part of structured education programmes for self-management (see <a href="section 1.3">section 1.3</a>). [new 2015]
- 1.4.2 Consider carbohydrate-counting courses for adults with type 1 diabetes who are waiting for a more detailed structured education programme or are unable to take part in a stand-alone structured education programme. [new 2015]

#### Glycaemic index diets

1.4.3 Do not advise adults with type 1 diabetes to follow a low glycaemic index diet for blood glucose control. [new 2015]

## Dietary advice

- 1.4.4 Offer dietary advice to adults with type 1 diabetes about issues other than blood glucose control, such as weight control and cardiovascular risk management, as indicated clinically. [new 2015]
- 1.4.5 Provide nutritional information sensitive to personal needs and culture from the time of diagnosis of type 1 diabetes. [2004]
- 1.4.6 Provide nutritional information individually and as part of a diabetes education programme (see section 1.3). Include advice from professionals with specific and approved training and continuing accredited education in delivering nutritional advice to people with health conditions. Offer opportunities to receive nutritional advice at intervals agreed between adults with type 1 diabetes and their advising professionals. [2004]
- 1.4.7 Discuss the hyperglycaemic effects of different foods an adult with type 1 diabetes wishes to eat in the context of the insulin preparations chosen to match those food choices. [2004]
- 1.4.8 Make programmes available to adults with type 1 diabetes to enable them to make:

- optimal choices about the variety of foods they wish to consume
- insulin dose changes appropriate to reduce glucose excursions when taking different quantities of those foods. [2004, amended 2015]
- 1.4.9 Agree the choice of content, timing and amount of snacks between meals or at bedtime available to the adult with type 1 diabetes, based on informed discussion about the extent and duration of the effects of eating different food types and the insulin preparations available to match them. Modify those choices based on discussion of the results of self-monitoring tests. [2004]
- 1.4.10 Make information available on:
  - effects of different alcohol-containing drinks on blood glucose excursions and calorie intake
  - use of high-calorie and high-sugar 'treats'. [2004, amended 2015]
- 1.4.11 Make information available about the benefits of healthy eating in reducing cardiovascular risk as part of dietary education in the period after diagnosis, and according to need and interest at intervals thereafter. Include information about fruit and vegetables, types and amounts of fat, and ways of making the appropriate nutritional changes. [2004, amended 2015]
- 1.4.12 Modify nutritional recommendations to adults with type 1 diabetes to take account of associated features of diabetes, including:
  - excess weight and obesity
  - underweight
  - eating disorders
  - hypertension
  - renal failure. [2004]
- 1.4.13 Be aware of appropriate nutritional advice on common topics of concern and interest to adults living with type 1 diabetes, and be prepared to seek advice from colleagues with more specialised knowledge. Suggested common topics include:

- body weight, energy balance and obesity management
- cultural and religious diets, feasts and fasts
- foods sold as 'diabetic'
- sweeteners
- dietary fibre intake
- protein intake
- vitamin and mineral supplements
- alcohol
- matching carbohydrate, insulin and physical activity
- salt intake in hypertension
- comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders
- use of peer support groups. [2004, amended 2015]

# 1.5 Physical activity

- 1.5.1 Advise adults with type 1 diabetes that physical activity can reduce their enhanced cardiovascular risk in the medium and longer term. [2004]
- 1.5.2 Give adults with type 1 diabetes who choose to integrate increased physical activity into a more healthy lifestyle information about:
  - appropriate intensity and frequency of physical activity
  - role of self-monitoring of changed insulin and/or nutritional needs
  - effect of activity on blood glucose levels (likely fall) when insulin levels are adequate
  - effect of exercise on blood glucose levels when hyperglycaemic and hypoinsulinaemic (risk of worsening of hyperglycaemia and ketonaemia)
  - appropriate adjustments of insulin dosage and/or nutritional intake for exercise and post-exercise periods, and the next 24 hours

- interactions of exercise and alcohol
- further contacts and sources of information. [2004]

## 1.6 Blood glucose management

#### HbA1c measurement and targets

#### Measurement

- 1.6.1 Measure HbA1c levels every 3-6 months in adults with type 1 diabetes. [new 2015]
- 1.6.2 Consider measuring HbA1c levels more often in adults with type 1 diabetes if the person's blood glucose control is suspected to be changing rapidly; for example, if the HbA1c level has risen unexpectedly above a previously sustained target. [new 2015]
- 1.6.3 Use methods to measure HbA1c that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. [new 2015]
- 1.6.4 Inform adults with type 1 diabetes of their HbA1c results after each measurement and ensure that their most recent result is available at the time of consultation. Follow the principles in the NICE guideline on <u>patient experience</u> in adult NHS services about communication. [new 2015]
- 1.6.5 If HbA1c monitoring is invalid because of disturbed erythrocyte turnover or abnormal haemoglobin type, estimate trends in blood glucose control using one of the following:
  - fructosamine estimation
  - quality-controlled blood glucose profiles
  - total glycated haemoglobin estimation (if abnormal haemoglobins). [2015]

#### **Targets**

- 1.6.6 Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications.
  [new 2015]
- 1.6.7 Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia. [new 2015]
- 1.6.8 Ensure that aiming for an HbA1c target is not accompanied by problematic hypoglycaemia in adults with type 1 diabetes. [new 2015]
- 1.6.9 Diabetes services should document the proportion of adults with type 1 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower. [new 2015]

#### Self-monitoring of blood glucose

## Frequency of self-monitoring of blood glucose

- 1.6.10 Advise routine self-monitoring of blood glucose levels for all adults with type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed. [new 2015]
- 1.6.11 Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply:
  - the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved
  - the frequency of hypoglycaemic episodes increases
  - there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] At a glance guide to the current medical standards of fitness to drive)
  - during periods of illness

- before, during and after sport
- when planning pregnancy, during pregnancy and while breastfeeding (see the NICE guideline on <u>diabetes in pregnancy</u>)
- if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, impaired awareness of hypoglycaemia, high-risk activities). [new 2015]
- 1.6.12 Enable additional blood glucose testing (more than 10 times a day) for adults with type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia. [new 2015]

#### Blood glucose targets

- 1.6.13 Advise adults with type 1 diabetes to aim for:
  - a fasting plasma glucose level of 5–7 mmol/litre on waking and
  - a plasma glucose level of 4–7 mmol/litre before meals at other times of the day. [new 2015]
- 1.6.14 Advise adults with type 1 diabetes who choose to test after meals to aim for a plasma glucose level of 5–9 mmol/litre at least 90 minutes after eating. (This timing may be different in pregnancy for guidance on plasma glucose targets in pregnancy, see the NICE guideline on diabetes in pregnancy.) [new 2015]
- 1.6.15 Agree bedtime target plasma glucose levels with each adult with type 1 diabetes that take into account timing of the last meal and its related insulin dose, and are consistent with the recommended fasting level on waking (see recommendation 1.6.13). [new 2015]

## Empowering people to self-monitor blood glucose

- 1.6.16 Teach self-monitoring skills at the time of diagnosis and initiation of insulin therapy. [2004, amended 2015]
- 1.6.17 When choosing blood glucose meters:

- take the needs of the adult with type 1 diabetes into account
- ensure that meters meet current ISO standards. [new 2015]
- 1.6.18 Educate adults with type 1 diabetes about how to measure their blood glucose level, interpret the results and know what action to take. Review these skills at least annually. [new 2015]
- 1.6.19 Support adults with type 1 diabetes to make the best use of data from self-monitoring of blood glucose through structured education (see recommendations 1.3.1 and 1.3.2). [new 2015]

#### Sites for self-monitoring of blood glucose

1.6.20 Monitoring blood glucose using sites other than the fingertips cannot be recommended as a routine alternative to conventional self-monitoring of blood glucose. [2004, amended 2015]

#### Continuous glucose monitoring

- 1.6.21 Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes. [new 2015]
- 1.6.22 Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:
  - More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
  - Complete loss of awareness of hypoglycaemia.
  - Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
  - Extreme fear of hypoglycaemia.
  - Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below

53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more. [new 2015]

- 1.6.23 For adults with type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy. [new 2015]
- 1.6.24 Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes. [new 2015]

# 1.7 Insulin therapy

## Insulin regimens

- 1.7.1 Offer multiple daily injection basal-bolus insulin regimens, rather than twice-daily mixed insulin regimens, as the insulin injection regimen of choice for all adults with type 1 diabetes. Provide the person with guidance on using multiple daily injection basal-bolus insulin regimens. [new 2015]
- 1.7.2 Do not offer adults newly diagnosed with type 1 diabetes non-basal-bolus insulin regimens (that is, twice-daily mixed, basal only or bolus only). [new 2015]

## Long-acting insulin

Recommendations in this section update and replace the NICE technology appraisal guidance on the use of long-acting insulin analogues for the treatment of diabetes – insulin glargine, in relation to adults with type 1 diabetes.

- 1.7.3 Offer twice-daily insulin detemir as basal insulin therapy for adults with type 1 diabetes. [new 2015]
- 1.7.4 Consider, as an alternative basal insulin therapy for adults with type 1 diabetes:
  - an existing insulin regimen being used by the person that is achieving their agreed targets

- once-daily insulin glargine or insulin detemir if twice-daily basal insulin injection is not acceptable to the person, or once-daily insulin glargine if insulin detemir is not tolerated. [new 2015]
- 1.7.5 Consider other basal insulin regimens for adults with type 1 diabetes only if the regimens in recommendations 1.7.3 and 1.7.4 do not deliver agreed targets.
   When choosing an alternative insulin regimen, take account of the person's preferences and acquisition cost. [new 2015]

## Continuous subcutaneous insulin infusion (CSII or insulin pump) therapy

1.7.6 For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, see <u>continuous</u> subcutaneous insulin infusion for the treatment of diabetes mellitus (NICE technology appraisal guidance 151). [new 2015]

#### Rapid-acting insulin

- 1.7.7 Offer rapid-acting insulin analogues injected before meals, rather than rapid-acting soluble human or animal insulins, for mealtime insulin replacement for adults with type 1 diabetes. [new 2015]
- 1.7.8 Do not advise routine use of rapid-acting insulin analogues after meals for adults with type 1 diabetes. [new 2015]
- 1.7.9 If an adult with type 1 diabetes has a strong preference for an alternative mealtime insulin, respect their wishes and offer the preferred insulin. [new 2015]

#### Mixed insulin

- 1.7.10 Consider a twice-daily human mixed insulin regimen for adults with type 1 diabetes if a multiple daily injection basal-bolus insulin regimen is not possible and a twice-daily mixed insulin regimen is chosen. [new 2015]
- 1.7.11 Consider a trial of a twice-daily analogue mixed insulin regimen if an adult using a twice-daily human mixed insulin regimen has hypoglycaemia that affects their quality of life. [new 2015]

#### Optimising insulin therapy

- 1.7.12 For adults with erratic and unpredictable blood glucose control (hyperglycaemia and hypoglycaemia at no consistent times), rather than a change in a previously optimised insulin regimen, the following should be considered:
  - injection technique
  - injection sites
  - self-monitoring skills
  - knowledge and self-management skills
  - nature of lifestyle
  - psychological and psychosocial difficulties
  - possible organic causes such as gastroparesis. [2004, amended 2015]
- 1.7.13 Give clear guidelines and protocols ('sick-day rules') to all adults with type 1 diabetes to help them to adjust insulin doses appropriately during periods of illness. [2004]

#### **Adjuncts**

1.7.14 Consider adding metformin<sup>[1]</sup> to insulin therapy if an adult with type 1 diabetes and a BMI of 25 kg/m<sup>2</sup> (23 kg/m<sup>2</sup> for people from South Asian and related minority ethnic groups) or above wants to improve their blood glucose control while minimising their effective insulin dose. [new 2015]

# 1.8 Insulin delivery

- 1.8.1 Adults with type 1 diabetes who inject insulin should have access to the insulin injection delivery device they find allows them optimal wellbeing, often using one or more types of insulin injection pen. [2004]
- 1.8.2 Provide adults with type 1 diabetes who have special visual or psychological needs with injection devices or needle-free systems that they can use independently for accurate dosing. [2004]

- 1.8.3 Offer needles of different lengths to adults with type 1 diabetes who are having problems such as pain, local skin reactions and injection site leakages. [new 2015]
- 1.8.4 After taking clinical factors into account, choose needles with the lowest acquisition cost to use with pre-filled and reusable insulin pen injectors. [new 2015]
- 1.8.5 Advise adults with type 1 diabetes to rotate insulin injection sites and avoid repeated injections at the same point within sites. [new 2015]
- 1.8.6 Provide adults with type 1 diabetes with suitable containers for collecting used needles and other sharps. Arrangements should be available for the suitable disposal of these containers. See also section 1.1.4 of the NICE guideline on infection control. [2004, amended 2015]
- 1.8.7 Check injection site condition at least annually and if new problems with blood glucose control occur. [2004, amended 2015]
- 1.9 Referral for islet or pancreas transplantation
- 1.9.1 Consider referring adults with type 1 diabetes who have recurrent severe hypoglycaemia that has not responded to other treatments (see <u>section 1.10</u>) to a centre that assesses people for islet and/or pancreas transplantation. [new 2015]
- 1.9.2 Consider islet or pancreas transplantation for adults with type 1 diabetes with suboptimal diabetes control who have had a renal transplant and are currently on immunosuppressive therapy. [new 2015]
- 1.10 Awareness and management of hypoglycaemia

## Identifying and quantifying impaired awareness of hypoglycaemia

1.10.1 Assess awareness of hypoglycaemia in adults with type 1 diabetes at each annual review. [new 2015]

- 1.10.2 Use the Gold score or Clarke score to quantify awareness of hypoglycaemia in adults with type 1 diabetes, checking that the questionnaire items have been answered correctly. [new 2015]
- 1.10.3 Explain to adults with type 1 diabetes that impaired awareness of the symptoms of plasma glucose levels below 3 mmol/litre is associated with a significantly increased risk of severe hypoglycaemia. [new 2015]

#### Strategies for managing impaired awareness of hypoglycaemia

- 1.10.4 Ensure that adults with type 1 diabetes with impaired awareness of hypoglycaemia have had structured education in flexible insulin therapy using basal-bolus regimens and are following its principles correctly. [new 2015]
- 1.10.5 Offer additional education focusing on avoiding and treating hypoglycaemia to adults with type 1 diabetes who continue to have impaired awareness of hypoglycaemia after structured education in flexible insulin therapy. [new 2015]
- 1.10.6 Avoid relaxing individualised blood glucose targets as a treatment for adults with type 1 diabetes with impaired awareness of hypoglycaemia. [new 2015]
- 1.10.7 If target blood glucose levels preferred by adults with type 1 diabetes who have impaired awareness of hypoglycaemia are lower than recommended, reinforce the recommended targets (see <u>recommendations 1.6.13–1.6.15</u>). [new 2015]
- 1.10.8 Review insulin regimens and doses and prioritise strategies to avoid hypoglycaemia in adults with type 1 diabetes with impaired awareness of hypoglycaemia, including:
  - reinforcing the principles of structured education
  - offering continuous subcutaneous insulin infusion (CSII or insulin pump) therapy
  - offering real-time continuous glucose monitoring. [new 2015]
- 1.10.9 If impaired awareness of hypoglycaemia is associated with recurrent severe hypoglycaemia in an adult with type 1 diabetes despite these interventions, consider referring the person to a specialist centre. [new 2015]

#### Preventing and managing hypoglycaemia

- 1.10.10 Explain to adults with type 1 diabetes that a fast-acting form of glucose is needed for the management of hypoglycaemic symptoms or signs in people who are able to swallow. [2004, amended 2015]
- 1.10.11 Adults with type 1 diabetes with a decreased level of consciousness as a result of hypoglycaemia and so are unable to take oral treatment safely should be:
  - given intramuscular glucagon by a family member or friend who has been shown how to use it (intravenous glucose may be used by healthcare professionals skilled in obtaining intravenous access)
  - monitored for response at 10 minutes, and then given intravenous glucose if their level of consciousness is not improving significantly
  - then given oral carbohydrate when it is safe to administer it, and placed under continued observation by a third party who has been warned of the risk of relapse. [2004, amended 2015]
- 1.10.12 Explain to adults with type 1 diabetes that some hypoglycaemic episodes are an inevitable consequence of insulin therapy in most people using any insulin regimen, and that it is advisable that they should use a regimen that avoids or reduces the frequency of hypoglycaemic episodes while maintaining as optimal a level of blood glucose control as is feasible. Make advice available to all adults with type 1 diabetes to assist in obtaining the best such balance from any insulin regimen. (See sections 1.7 and 1.8.) [2004]
- 1.10.13 If hypoglycaemia becomes unusually problematic or of increased frequency, review the following possible contributory causes:
  - inappropriate insulin regimens (incorrect dose distributions and insulin types)
  - meal and activity patterns, including alcohol
  - injection technique and skills, including insulin resuspension if necessary
  - injection site problems
  - possible organic causes including gastroparesis

- changes in insulin sensitivity (including drugs affecting the renin-angiotensin system and renal failure)
- psychological problems
- previous physical activity
- lack of appropriate knowledge and skills for self-management. [2004]
- 1.10.14 Manage nocturnal hypoglycaemia (symptomatic or detected on monitoring) by:
  - reviewing knowledge and self-management skills
  - reviewing current insulin regimen, evening eating habits and previous physical activity
  - choosing an insulin type and regimen that is less likely to induce low glucose levels at night. [2004, amended 2015]
- 1.10.15 If early cognitive decline occurs in adults on long-term insulin therapy, supplement normal investigations by the consideration or investigation of possible brain damage resulting from overt or covert hypoglycaemia, and the need to ameliorate this. [2004]
- 1.11 Ketone monitoring and management of diabetic ketoacidosis (DKA)

## Ketone self-monitoring for prevention of DKA

1.11.1 Consider ketone monitoring (blood or urine) as part of 'sick-day rules' for adults with type 1 diabetes, to facilitate self-management of an episode of hyperglycaemia. [new 2015]

## Ketone monitoring in hospital

- 1.11.2 In adults with type 1 diabetes presenting to emergency services, consider capillary blood ketone testing if:
  - DKA is suspected or
  - the person has uncontrolled diabetes with a period of illness, and urine ketone testing is positive. [new 2015]

1.11.3 Consider capillary blood ketone testing for inpatient management of DKA in adults with type 1 diabetes that is incorporated into a formal protocol. [new 2015]

#### Management of DKA

- 1.11.4 Professionals managing DKA in adults should be adequately trained, including regular updating, and be familiar with all aspects of its management which are associated with mortality and morbidity. These topics should include:
  - fluid balance
  - acidosis
  - cerebral oedema
  - electrolyte imbalance
  - disturbed interpretation of familiar diagnostic tests (white cell count, body temperature, ECG)
  - respiratory distress syndrome
  - cardiac abnormalities
  - precipitating causes
  - infection management, including opportunistic infections
  - gastroparesis
  - use of high dependency and intensive care units
  - recommendations 1.11.5 to 1.11.12 in this guideline.

Management of DKA in adults should be in line with local clinical governance. [2004]

- 1.11.5 For primary fluid replacement in adults with DKA, use isotonic saline, not given too rapidly except in cases of circulatory collapse. [2004]
- 1.11.6 Do not generally use bicarbonate in the management of DKA in adults. [2004, amended 2015]

- 1.11.7 Give intravenous insulin by infusion to adults with DKA. [2004]
- 1.11.8 In the management of DKA in adults, once the plasma glucose concentration has fallen to 10–15 mmol/litre, give glucose-containing fluids (not more than 2 litres in 24 hours) in order to allow continued infusion of insulin at a sufficient rate to clear ketones (for example, 6 units/hour monitored for effect). [2004, amended 2015]
- 1.11.9 Begin potassium replacement early in DKA in adults, with frequent monitoring for the development of hypokalaemia. [2004]
- 1.11.10 Do not generally use phosphate replacement in the management of DKA in adults. [2004, amended 2015]
- 1.11.11 In adults with DKA whose conscious level is impaired, consideration should be given to inserting a nasogastric tube, monitoring urine production using a urinary catheter and giving heparin. [2004]
- 1.11.12 To reduce the risk of catastrophic outcomes in adults with DKA, ensure that monitoring is continuous and that review covers all aspects of clinical management at frequent intervals. [2004, amended 2015]

#### 1.12 Associated illness

- 1.12.1 In adults with type 1 diabetes who have a low BMI or unexplained weight loss, assess markers of coeliac disease. For guidance on testing for coeliac disease, see the NICE guideline on coeliac disease. [2004, amended 2015]
- 1.12.2 Be alert to the possibility of the development of other autoimmune disease in adults with type 1 diabetes (including Addison's disease and pernicious anaemia). For advice on monitoring for thyroid disease, see <a href="recommendation 1.15.40">recommendation 1.15.40</a>. [2004, amended 2015]

## 1.13 Control of cardiovascular risk

## **Aspirin**

1.13.1 Do not offer aspirin for the primary prevention of cardiovascular disease to adults with type 1 diabetes. [new 2015]

#### Identifying cardiovascular risk

- 1.13.2 Assess cardiovascular risk factors annually, including:
  - albuminuria
  - smoking
  - blood glucose control
  - blood pressure
  - full lipid profile (including HDL and LDL cholesterol and triglycerides)
  - age
  - family history of cardiovascular disease
  - abdominal adiposity. [2004, amended 2015]
- 1.13.3 For guidance on tools for assessing risk of cardiovascular disease in adults with type 1 diabetes, see recommendation 1.1.9 in the NICE guideline on <u>lipid</u> modification. [new 2015]

## Interventions to reduce risk and manage cardiovascular disease

- 1.13.4 For guidance on the primary prevention of cardiovascular disease in adults with type 1 diabetes, see the NICE guideline on <u>lipid modification</u>. [new 2015]
- 1.13.5 Give adults with type 1 diabetes who smoke advice on smoking cessation and use of smoking cessation services, including NICE guidance-recommended therapies. Reinforce these messages annually for people who currently do not plan to stop smoking, and at all clinical contacts if there is a prospect of the person stopping. [2004]

- 1.13.6 Advise young adult non-smokers never to start smoking. [2004]
- 1.13.7 Provide intensive management for adults who have had myocardial infarction or stroke, according to relevant non-diabetes guidelines. In the presence of angina or other ischaemic heart disease, beta-adrenergic blockers should be considered. (For use of insulin in these circumstances, see <a href="section 1.14">section 1.14</a>.) For guidance on secondary prevention of myocardial infarction, see the NICE guideline on <a href="MI">MI secondary prevention</a>. [2004, amended 2015]

#### Blood pressure management

- 1.13.8 Intervention levels for recommending blood pressure management should be 135/85 mmHg unless the adult with type 1 diabetes has albuminuria or 2 or more features of metabolic syndrome, in which case it should be 130/80 mmHg. See also recommendations 1.15.14–1.15.16. [2004]
- 1.13.9 To allow informed choice by the person with hypertension, discuss the following with them:
  - reasons for choice of intervention level
  - substantial potential gains from small improvements in blood pressure control
  - possible negative consequences of therapy.

See also recommendations <u>1.15.14</u> and <u>1.15.15</u>. [2004, amended 2015]

- 1.13.10 Start a trial of a renin–angiotensin system blocking drug as first-line therapy for hypertension in adults with type 1 diabetes. [2004, amended 2015]
- 1.13.11 Provide information to adults with type 1 diabetes on the potential for lifestyle changes to improve blood pressure control and associated outcomes, and offer assistance in achieving their aims in this area. [2004]
- 1.13.12 Do not allow concerns over potential side effects to inhibit advising and offering the necessary use of any class of drugs, unless the side effects become symptomatic or otherwise clinically significant. In particular:
  - do not avoid selective beta-adrenergic blockers where indicated in adults on insulin

- low-dose thiazides may be combined with beta-blockers
- when calcium channel antagonists are prescribed, use only long-acting preparations
- use direct questioning to detect the potential side effects of erectile dysfunction, lethargy and orthostatic hypotension with different drug classes. [2004, amended 2015]
- 1.13.13 For guidance on blood pressure management in adults with type 1 diabetes and evidence of renal involvement, see recommendations 1.6.2–1.6.4 in the NICE guideline on chronic kidney disease. [new 2015]

## 1.14 Care of adults with type 1 diabetes in hospital

## Blood glucose control

- 1.14.1 Aim for a target plasma glucose level of 5–8 mmol/litre for adults with type 1 diabetes during surgery or acute illness. [new 2015]
- 1.14.2 Establish a local protocol for controlling blood glucose levels in adults with type 1 diabetes during surgery or acute illness to achieve the target level. [new 2015]
- 1.14.3 Use intravenous in preference to subcutaneous insulin regimens for adults with type 1 diabetes if:
  - the person is unable to eat or is predicted to miss more than 1 meal or
  - an acute situation is expected to result in unpredictable blood glucose levels for example, major surgery, high-dose steroid treatment, inotrope treatment or sepsis or
  - insulin absorption is expected to be unpredictable, for example because of circulatory compromise. [new 2015]
- 1.14.4 Consider continuing the person's existing basal insulin regimen (including basal rate if they are using continuous subcutaneous insulin infusion [CSII or insulin pump] therapy) together with protocol-driven insulin delivery for controlling blood glucose levels in adults with type 1 diabetes during surgery or acute illness. [new 2015]

- 1.14.5 Use subcutaneous insulin regimens (including rapid-acting insulin before meals) if an adult with type 1 diabetes and acute illness is eating. [new 2015]
- 1.14.6 Enable adults with type 1 diabetes who are hospital inpatients to self-administer subcutaneous insulin if they are willing and able and it is safe to do so. [new 2015]

#### Delivery of care

- 1.14.7 From the time of admission, the adult with type 1 diabetes and the team caring for him or her should receive, on a continuing basis, advice from a trained multidisciplinary team with expertise in diabetes. [2004]
- 1.14.8 Throughout the course of an inpatient admission, respect the personal expertise of adults with type 1 diabetes (in managing their own diabetes) and routinely integrate this into ward-based blood glucose monitoring and insulin delivery.

  [2004, amended 2015]
- 1.14.9 Throughout the course of an inpatient admission, the personal knowledge and needs of adults with type 1 diabetes regarding their dietary requirements should be a major determinant of the food choices offered to them, except when illness or medical or surgical intervention significantly disturbs those requirements. [2004]
- 1.14.10 Members of care teams caring for adults with type 1 diabetes in institutions, such as nursing homes, residential homes and prisons, should follow the recommendations in this section. [2004]
- 1.14.11 Provide optimal insulin therapy, which can be achieved by the use of intravenous insulin and glucose, to all adults with type 1 diabetes with threatened or actual stroke. Critical care and emergency departments should have a protocol for such management. [2004, amended 2011]

## 1.15 Managing complications

## Eye disease

1.15.1 On diagnosis, GPs should immediately refer adults with type 1 diabetes to the local eye screening service. Perform screening as soon as possible and no later

than 3 months from referral. Arrange repeat structured eye screening annually. [2004, amended 2016]

- 1.15.2 Depending on the findings, follow structured eye screening by:
  - routine review annually or
  - earlier review or
  - referral to an ophthalmologist. [2004, amended 2015]
- 1.15.3 Explain the reasons and success of eye screening systems to adults with type 1 diabetes, so that attendance is not reduced by lack of knowledge or fear of outcome. [2004]
- 1.15.4 Offer digital retinopathy screening annually to adults with type 1 diabetes. [2004, amended 2015]
- 1.15.5 Use mydriasis with tropicamide when photographing the retina, after prior agreement with the adult with type 1 diabetes after discussion of the advantages and disadvantages, including appropriate precautions for driving. [2004]
- 1.15.6 Make visual acuity testing a routine part of eye screening programmes. [2004, amended 2015]
- 1.15.7 Ensure that emergency review by an ophthalmologist occurs for:
  - sudden loss of vision
  - rubeosis iridis
  - pre-retinal or vitreous haemorrhage
  - retinal detachment. [2004, amended 2015]
- 1.15.8 Ensure that rapid review by an ophthalmologist occurs for new vessel formation. [2004, amended 2015]
- 1.15.9 Refer to an ophthalmologist for:

- referable maculopathy:
  - exudate or retinal thickening within 1 disc diameter of the centre of the fovea
  - circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, of a diameter the distance between the temporal border of the optic disc and the fovea)
  - any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea, only if associated with a best visual acuity of 6/12 or worse
- referable pre-proliferative retinopathy:
  - any venous beading
  - any venous reduplication
  - any intraretinal microvascular abnormalities (IRMA)
  - multiple deep, round or blot haemorrhages

(If cotton wool spots are present, look carefully for the above features, but cotton wool spots themselves do not define pre proliferative retinopathy)

any large sudden unexplained drop in visual acuity. [2004, amended 2015]

## Diabetic kidney disease

- 1.15.10 For guidance on managing kidney disease in adults with type 1 diabetes, see the NICE guideline on <u>chronic kidney disease</u>. [new 2015]
- 1.15.11 Ask all adults with type 1 diabetes with or without detected nephropathy to bring in the first urine sample of the day ('early morning urine') once a year. Send this for estimation of albumin:creatinine ratio. Estimation of urine albumin concentration alone is a poor alternative. Serum creatinine should be measured at the same time. [2004]
- 1.15.12 Suspect other renal disease:
  - in the absence of progressive retinopathy
  - if blood pressure is particularly high

- if proteinuria develops suddenly
- if significant haematuria is present
- in the presence of systemic ill health. [2004]
- 1.15.13 Discuss the significance of a finding of albuminuria with the person concerned. [2004, amended 2015]
- 1.15.14 Start angiotensin-converting enzyme (ACE) inhibitors and, with the usual precautions, titrate to full dose in all adults with confirmed nephropathy (including those with moderately increased albuminuria ['microalbuminuria'] alone) and type 1 diabetes. [2004, amended 2015]
- 1.15.15 If ACE inhibitors are not tolerated, substitute angiotensin 2 receptor antagonists. Combination therapy is not recommended. [2004, amended 2015]
- 1.15.16 Maintain blood pressure below 130/80 mmHg by addition of other anti-hypertensive drugs if necessary. [2004]
- 1.15.17 Advise adults with type 1 diabetes and nephropathy about the advantages of not following a high-protein diet. [2004]
- 1.15.18 Referral criteria for tertiary care should be agreed between local diabetes specialists and nephrologists. [2004]

## Chronic painful diabetic neuropathy

1.15.19 For guidance on managing chronic painful diabetic neuropathy in adults with type 1 diabetes, see the NICE guideline on <a href="mainto:neuropathic pain">neuropathic pain</a> – <a href="pharmacological">pharmacological</a> <a href="mainto:management">management</a>. [new 2015]

## Autonomic neuropathy

- 1.15.20 In adults with type 1 diabetes who have unexplained diarrhoea, particularly at night, the possibility of autonomic neuropathy affecting the gut should be considered. [2004]
- 1.15.21 Take care when prescribing antihypertensive medicines not to expose people to the risks of orthostatic hypotension as a result of the combined effects of

sympathetic autonomic neuropathy and blood pressure lowering medicines. [2004]

- 1.15.22 In adults with type 1 diabetes who have bladder emptying problems, investigate the possibility of autonomic neuropathy affecting the bladder, unless other explanations are adequate. [2004]
- 1.15.23 When managing the symptoms of autonomic neuropathy, include standard interventions for the manifestations encountered (for example, for abnormal sweating and postural hypotension). [2004, amended 2015]
- 1.15.24 Anaesthetists should be aware of the possibility of parasympathetic autonomic neuropathy affecting the heart in adults with type 1 diabetes who are listed for procedures under general anaesthetic and who have evidence of somatic neuropathy or other manifestations of autonomic neuropathy. [2004]

#### Gastroparesis

- 1.15.25 Advise a small-particle-size diet (mashed or pureed food) for symptomatic relief for adults with type 1 diabetes who have vomiting caused by gastroparesis<sup>[2]</sup>. [new 2015]
- 1.15.26 Consider continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes who have gastroparesis. [new 2015]
- 1.15.27 For adults with type 1 diabetes who have vomiting caused by gastroparesis, explain that:
  - there is no strong evidence that any available antiemetic therapy is effective
  - some people have had benefit with domperidone<sup>[s]</sup>, erythromycin<sup>[s]</sup> or metoclopramide<sup>[s]</sup>
  - the strongest evidence for effectiveness is for domperidone<sup>[3]</sup>, but prescribers must take into account its safety profile, in particular its cardiac risk and potential interactions with other medicines. [new 2015]
- 1.15.28 For treating vomiting caused by gastroparesis in adults with type 1 diabetes:

- $\bullet$  consider alternating use of erythromycin  $^{^{\bowtie}}$  and metoclopramide  $^{^{\bowtie}}$
- consider domperidone<sup>[3]</sup> only in exceptional circumstances (that is, when it is the only effective treatment) and in accordance with MHRA guidance. [new 2015]
- 1.15.29 Refer adults with type 1 diabetes who have gastroparesis for specialist advice if the interventions in recommendations 1.15.25, 1.15.26 and 1.15.28 are not beneficial or not appropriate. [new 2015]

## Acute painful neuropathy of rapid improvement of blood glucose control

- 1.15.30 Reassure adults with type 1 diabetes that acute painful neuropathy resulting from rapid improvement of blood glucose control is a self-limiting condition that improves symptomatically over time. [new 2015]
- 1.15.31 Explain to adults with type 1 diabetes that the specific treatments for acute painful neuropathy resulting from rapid improvement of blood glucose control:
  - have the aim of making the symptoms tolerable until the condition resolves
  - may not relieve pain immediately and may need to be taken regularly for several weeks to be effective. [new 2015]
- 1.15.32 Use of simple analgesics (paracetamol, aspirin) and local measures (bed cradles) are recommended as a first step, but if trials of these measures are ineffective, discontinue them and try other measures. [2004]
- 1.15.33 Do not relax diabetes control to address acute painful neuropathy resulting from rapid improvement of blood glucose control in adults with type 1 diabetes. [new 2015]
- 1.15.34 If simple analgesia does not provide sufficient pain relief for adults with type 1 diabetes who have acute painful neuropathy resulting from rapid improvement of blood glucose control, offer treatment as described in the NICE guideline on neuropathic pain pharmacological management. Simple analgesia may be continued until the effects of additional treatments have been established. [new 2015]

1.15.35 When offering medicines for managing acute painful neuropathy resulting from rapid improvement of blood glucose control to adults with type 1 diabetes, be aware of the risk of dependency associated with opioids. [new 2015]

#### Diabetic foot problems

1.15.36 For guidance on preventing and managing foot problems in adults with type 1 diabetes, see the NICE guideline on <u>diabetic foot problems</u>. [new 2015]

## **Erectile dysfunction**

- 1.15.37 Offer men with type 1 diabetes the opportunity to discuss erectile dysfunction as part of their regular review. [new 2015]
- 1.15.38 Offer a phosphodiesterase-5 inhibitor to men with type 1 diabetes with isolated erectile dysfunction unless contraindicated. Choose the phosphodiesterase-5 inhibitor with the lowest acquisition cost. [new 2015]
- 1.15.39 Consider referring men with type 1 diabetes to a service offering further assessment and other medical, surgical or psychological management of erectile dysfunction if phosphodiesterase-5 inhibitor treatment is unsuccessful or contraindicated. [new 2015]

## Thyroid disease monitoring

1.15.40 Measure blood thyroid-stimulating hormone (TSH) levels in adults with type 1 diabetes at annual review. [new 2015]

## Psychological problems

- 1.15.41 Members of diabetes professional teams providing care or advice to adults with type 1 diabetes should be alert to the development or presence of clinical or subclinical depression and/or anxiety, in particular if someone reports or appears to be having difficulties with self-management. [2004]
- 1.15.42 Diabetes professionals should:
  - ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds

• be familiar with appropriate counselling techniques and drug therapy, while arranging prompt referral to specialists of those people in whom psychological difficulties continue to interfere significantly with wellbeing or diabetes self-management.

See also the NICE guidelines on <u>common mental health disorders</u>, <u>generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults and depression in adults with a chronic health problem</u>. [2004, amended 2015]

#### Eating disorders

- 1.15.43 Members of diabetes professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and insulin dose manipulation in adults with type 1 diabetes with:
  - over-concern with body shape and weight
  - low BMI
  - hypoglycaemia
  - suboptimal overall blood glucose control.

See also the NICE guideline on <u>eating disorders</u>. [2004, amended 2015]

- 1.15.44 The risk of morbidity from the complications of poor metabolic control suggests that consideration should be given to early, and occasionally urgent, referral of adults with type 1 diabetes to local eating disorder services. [2004]
- 1.15.45 Make provision for high-quality professional team support at regular intervals with regard to counselling about lifestyle issues and particularly dietary behaviour for all adults with type 1 diabetes from the time of diagnosis (see sections 1.3 and 1.4). [2004]

At the time of publication (August 2015), metformin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Prescribing guidance</u>: <u>prescribing unlicensed medicines</u> for further information.

<sup>[2]</sup> Diagnosis of gastroparesis needing specific therapy can only be made in the absence of hyperglycaemia at the time of testing, because hyperglycaemia induces a physiological delay in gastric emptying.

Medicines and Healthcare Products Regulatory Agency (MHRA) guidance (2014) notes that domperidone is associated with a small increased risk of serious cardiac side effects. Domperidone is now contraindicated in certain groups in whom the risk of cardiac effects is higher; its marketing authorisations have also been restricted to its use in the relief of nausea and vomiting only, at the lowest effective dose and for the shortest possible time (usually not more than 1 week): see the MHRA guidance and summaries of product characteristics. The MHRA advises that prescribers should take into account the overall safety profile of domperidone, and in particular its cardiac risk and potential interactions with other medicines (such as erythromycin), if there is a clinical need to use it at doses or durations greater than those authorised. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Prescribing guidance</u>: <u>prescribing unlicensed medicines</u> for further information.

At the time of publication (August 2015), erythromycin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's <u>Prescribing guidance: prescribing unlicensed medicines</u> for further information. NICE has published an evidence summary: unlicensed or off-label medicine on <u>oral erythromycin for gastroparesis in adults</u>, including a version for the public.

Medicines and Healthcare Products Regulatory Agency (MHRA) guidance (2013) notes that metoclopramide has well-known risks of neurological effects such as short-term extrapyramidal disorders and tardive dyskinesia. It advises that metoclopramide should be prescribed only for short-term use (up to 5 days) at a maximum dose of 30 mg in 24 hours (usual dose of 10 mg up to 3 times a day).

#### 2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in the <u>full guideline</u>.

## 2.1 Improved methods and interventions for achieving HbA1c targets in adults with type 1 diabetes

What methods and interventions are effective in increasing the number of adults with type 1 diabetes who achieve the recommended HbA1c targets without risking severe hypoglycaemia or weight gain?

#### Why this is important

The evidence that sustained near-normoglycaemia substantially reduces the risk of long-term complications in adults with type 1 diabetes is unequivocal. Current methods for achieving such blood glucose control require skills in glucose monitoring and insulin dose adjustment, injection technique and site management, and the ability to use such self-management skills on a day-to-day basis life-long. Fear of hypoglycaemia and of weight gain are major barriers to success, as is fitting diabetes self-management into busy lifestyles. Everyone struggles to meet optimised targets and some are more successful in achieving them than others. Research into new interventions ranging from more effective education and support, through improved technologies in terms of insulin replacement and glucose monitoring, and including use of cell-based therapies, is urgently needed. It is also important to ensure that adults with type 1 diabetes are able to engage with such methodologies.

## 2.2 Continuous glucose monitoring for adults with type 1 diabetes

In adults with type 1 diabetes who have chronically poor control of blood glucose levels, what is the clinical and cost effectiveness of continuous glucose monitoring technologies?

#### Why this is important

Current continuous glucose monitoring systems were found not to be cost-effective in the de novo analysis carried out for this guideline, even in people who had impaired awareness of hypoglycaemia. In adults with type 1 diabetes who have high HbA1c values, there still may be some

value in using continuous glucose monitoring systems, and further research is needed to determine whether newer technologies would prove to be cost-effective, particularly in this group.

## 2.3 Structured education programmes for adults with type 1 diabetes

In adults with type 1 diabetes, what methods can be used to increase the uptake of structured education programmes and to improve their clinical outcomes (particularly achieving and sustaining blood glucose control targets)?

#### Why this is important

Structured education programmes in flexible insulin therapy have been shown to improve diabetes control (lower HbA1c and less hypoglycaemia), but achieving and sustaining optimal diabetes control for avoidance of complications remains challenging. Some people do not achieve ideal targets for blood glucose control, others achieve but are not able to maintain them, and still others are not offered or do not access structured education at all. There is therefore a need to develop and test (1) more effective ways of engaging adults with type 1 diabetes in education; (2) improvements in the delivery of education to increase the number of people achieving targets for diabetic control and (3) enhanced support for adults with type 1 diabetes to sustain good diabetic control over time. If the uptake and delivery of clinically and cost-effective education and support for adults with type 1 diabetes can be improved, it should be possible to achieve a reduction in the short-term and long-term complications of the condition.

## 2.4 Risk stratification tool for HbA1c targets for adults with type 1 diabetes

Can a risk stratification tool be used to aid the setting of individualised HbA1c targets for adults with type 1 diabetes?

#### Why this is important

Strict blood glucose control early in the history of type 1 diabetes has been shown to reduce the development and progression of long-term complications, but it is not possible to determine who is at particular risk of glucose-driven poor outcomes. Furthermore, there is a dearth of evidence of the risk:benefit ratio of strict blood glucose control in people who already have diabetes complications. Since achieving and maintaining near-normal blood glucose concentrations is complicated, a risk stratification tool to calculate the modifiable individual risk of complications will allow blood glucose targets to be tailored for each person and appropriate support to be provided.

## 2.5 Technologies for preventing and treating impaired awareness of hypoglycaemia in adults with type 1 diabetes

For adults with type 1 diabetes, what are the optimum technologies (such as insulin pump therapy and/or continuous glucose monitoring, partially or fully automated insulin delivery, and behavioural, psychological and educational interventions) and how are they best used, in terms of clinical and cost effectiveness, for preventing and treating impaired awareness of hypoglycaemia?

#### Why this is important

Impaired awareness of hypoglycaemia renders adults with type 1 diabetes susceptible to sudden unexpected deteriorations of conscious level and irrational behaviour, and increases their risk of severe hypoglycaemia 6-fold. Impaired awareness of hypoglycaemia and severe hypoglycaemia creates barriers to many aspects of daily living, and can cause enormous stress for family and friends. Severe hypoglycaemia can also cause fear of hypoglycaemia great enough to prevent a person achieving the glucose targets that are associated with minimal risk of complications. Impaired awareness of hypoglycaemia results from overexposure to hypoglycaemia in daily life, and awareness can be much improved by avoidance of hypoglycaemia. Developing technologies in glucose monitoring and insulin delivery have not been rigorously tested in adults with type 1 diabetes and impaired awareness of hypoglycaemia. Research is needed formally to document the extent to which existing technologies can help the adult with type 1 diabetes and impaired awareness of hypoglycaemia to avoid hypoglycaemic episodes and regain awareness for occasional episodes. Research is also needed to develop new technologies. Research is also needed into how to engage adults with type 1 diabetes and impaired awareness of hypoglycaemia with treatment strategies designed to improve awareness.

## 3 Other information

## 3.1 Scope and how this guideline was developed

NICE guidelines are developed in accordance with a <u>scope</u> that defines what the guideline will and will not cover.

#### How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see <a href="section 4">section 4</a>), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in <u>the</u> guidelines manual.

## 3.2 Related NICE guidance

Details are correct at the time of publication of the guideline (August 2015). Further information is available on the NICE website.

#### **Published**

#### General

- Medicines optimisation (2015) NICE guideline NG5
- Patient experience in adult NHS services (2012) NICE guideline CG138
- Medicines adherence (2009) NICE guideline CG76

### Condition-specific

- Diabetic foot problems (2015) NICE guideline NG19
- Diabetes in children and young people (2015) NICE guideline NG18
- Diabetes in pregnancy (2015) NICE guideline NG3
- Obesity (2014) NICE guideline CG189
- Chronic kidney disease (2014) NICE guideline CG182

- Gastroelectrical stimulation for gastroparesis (2014) NICE interventional procedures guidance 489
- <u>Lipid modification</u> (2014) NICE guideline CG181
- Neuropathic pain pharmacological management (2013) NICE guideline CG173
- Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy (2013) NICE technology appraisal guidance 301
- Lower limb peripheral arterial disease (2012) NICE guideline CG147
- Ranibizumab for the treatment of diabetic macular oedema (2011) NICE technology appraisal guidance 237
- Hyperglycaemia in acute coronary syndromes (2011) NICE guideline CG130
- Hypertension (2011) NICE guideline CG127
- <u>Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion</u> (2011) NICE technology appraisal guidance 229
- <u>Depression in adults</u> (2009) NICE guideline CG90
- Depression with a chronic physical health problem (2009) NICE guideline CG91
- Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus (2008) NICE interventional procedure guidance 257
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (2008) NICE technology appraisal guidance 151

## Under development

NICE is <u>developing</u> the following guidance:

- Type 2 diabetes in adults (update). NICE guideline. Publication expected October 2015.
- Type 1 diabetes: Integrated sensor-augmented pump therapy systems for managing blood glucose levels (The MiniMed Paradigm Veo System and the Vibe and G4 PLATINUM CGM system). NICE diagnostics guidance. Publication expected January 2016.

## 4 The Guideline Development Group, National Collaborating Centre and NICE project team, and declarations of interests

## 4.1 Guideline Development Group

The Guideline Development Group members listed are those for the 2015 update. For the composition of the previous Guideline Development Group, see the <u>full guideline</u>.

### Stephanie Amiel

Professor of Diabetic Medicine, King's College London

#### **Augustin Brooks**

Consultant Diabetologist, Bournemouth Hospital

#### **Arthur Durrant**

Patient member

#### Michael Flynn

Consultant Physician, Kent and Canterbury Hospital

#### Roger Gadsby

Visiting Professor, Institute of Diabetes in Older People, University of Bedfordshire; GP; and Principal Teaching Fellow, University of Warwick

#### Peter Hammond

Consultant Physician, Harrogate District Hospital

#### Michael Kendall

Patient member

#### Vibhuti Mistry

Lead Diabetes and Obesity Dietitian, Homerton University NHS Foundation Trust

#### Henrietta Mulnier

Lecturer in Diabetes Nursing, King's College London

#### Victoria Ruszala

Specialist Pharmacist, Diabetes and Endocrinology, North Bristol NHS Trust

#### Stuart Smellie

Consultant in Chemical Pathology, Durham and Darlington NHS Foundation Trust

#### Perdy van den Berg

Clinical Lead, Oxfordshire Diabetes Service

## 4.2 National Clinical Guideline Centre

#### Jill Cobb

Information Scientist

#### Dalia Dawoud

**Health Economist** 

#### **Bernard Higgins**

Clinical Director

#### Elisabetta Fenu

Health Economics Lead

#### **Bethany King**

Document Editor/Process Assistant

#### Rachel O'Mahony

Senior Research Fellow

#### **Nancy Pursey**

Senior Project Manager

## 4.3 NICE project team

#### **Christine Carson**

Guideline Lead

#### Phil Alderson

Clinical Adviser

#### Clifford Middleton

Guideline Commissioning Manager

#### Jennifer Wells

**Guideline Coordinator** 

#### Nichole Taske

Technical Lead

#### **Bhash Naidoo**

Health Economist

#### Lyn Knott

Editor

## 4.4 Declarations of interests

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare. The conflicts of interest policy (2007) was followed until September 2014, when an <u>updated policy</u> was published.

Committee member	Interest declared	Type of interest	Decision taken
Stephanie	Co-head of a Clinical Academic Group and	Non-personal,	Declare and participate
Amiel	an academic division at King's College	specific,	
(Chair)	London and King's College Hospital	pecuniary	
Stephanie	Member of the Juvenile Diabetes	Personal,	Declare and participate
Amiel	Research Foundation and Diabetes UK	specific,	
(Chair)	advisory boards	non-pecuniary	
Stephanie Amiel (Chair)	Member of the Diabetes and Wellness Foundation editorial board	Personal, specific, non-pecuniary	Declare and participate
Stephanie	Academic representative of the Executive	Personal,	Declare and participate
Amiel	Committee of the Association of British	specific,	
(Chair)	Clinical Diabetologists	non-pecuniary	

Stephanie Amiel (Chair)	Chairman of the National dose adjustment for normal eating (DAFNE) executive	Personal, specific, non-pecuniary	Declare and participate
Stephanie Amiel (Chair)	Member of the International Hypoglycaemia Study Group, run and funded by the Six Degrees Academy, which is supported by multiple sponsors including Novo Nordisk	Personal, specific, non-pecuniary	Declare and participate
Stephanie Amiel (Chair)	Chairman of the EFSD/China Diabetes Society/Lilly Programme	Non-personal, specific, pecuniary	Declare and participate
Stephanie Amiel (Chair)	Editor of the International Diabetes Federation's journal, Diabetes Voice	Non-personal, specific, pecuniary	Declare and participate
Stephanie Amiel (Chair)	Member of the Juvenile Diabetes Research Foundations' international scientific advisory board	Non-personal, specific, pecuniary	Declare and participate
Arthur Durrant	Chair of the Sheffield Teaching Hospitals' Lay Panel for Diabetes & Endocrinology Research	Personal, specific, non-pecuniary	Declare and participate
Roger Gadsby	Member of the MSD (sitagliptin), NovoNordisk (insulin degludec) and Janssen (canagliflozin) advisory boards	Personal, specific, pecuniary	Declare and withdraw from discussions of all types of insulin
Roger Gadsby	Part of the team that developed Warwick Diabetes Care (WDC)	Non-personal, specific, pecuniary	Declare and participate
Roger Gadsby	Chairman of the Trustees of Pregnancy Sickness Support Trust (Registered Charity No. 1094788)	Non-personal, specific, pecuniary	Declare and participate
Roger Gadsby	Member of the NovoNordisk Diabetes Primary Care Advisory Board for Degludec	Personal, specific, pecuniary	Declare and withdraw from discussions on insulin

Peter Hammond	Part of the team that delivered a video-workshop on diabetes and pregnancy Medtronic to various centres in Eastern Europe	Personal, specific, non-pecuniary	Declare and participate
Henrietta Mulnier	Member of the Novo Nordisk nursing advisory board	Personal, specific, pecuniary	Declare and withdraw from discussions about insulin and needle lengths
Henrietta Mulnier	Part of the team that developed a new education and support programme for Novo Nordisk	Personal, specific, non-pecuniary	Declare and participate at chair's discretion (pending expiry of prior conflict for insulin)
Victoria Ruszala	Pharmacy lead for the NHS England Endocrinology clinical reference group	Personal, non-specific, non-pecuniary	Declare and participate
Victoria Ruszala	Member of the Sanofi advisory board	Personal, specific, pecuniary	Declare and withdraw from discussions on insulin
Stuart Smellie	Clinical Director of the Association of Clinical Biochemists	Personal, non-specific, pecuniary	Declare and participate
Stuart Smellie	Vice President of the Association of Clinical Pathologists	Personal, non-specific, pecuniary	Declare and participate

## **Update information**

July 2016: Recommendation 1.15.1 has been reworded to clarify the role of GPs in referring people for eye screening and also to add information on when this should happen.

November 2015: A footnote has been added to recommendation 1.7.14, to state that metformin does not have a UK marketing authorisation for the recommended indication. A link to the NICE guideline on coeliac disease has been added to recommendation 1.12.1.

September 2015: 'that is' has been added to the wording of recommendation 1.7.2, to clarify that these regimens should not be offered.

August 2015: This guidance is an update of NICE guideline CG15 (published July 2004) and replaces the guidance for adults. It also updates and replaces NICE technology appraisal guidance 53 and NICE technology appraisal guidance 60.

It has not been possible to update all recommendations in this update of the guideline. Areas for review and update were identified and prioritised through the scoping process and stakeholder feedback. Areas that have not been reviewed in this update may be addressed in 2 years' time when NICE next considers updating this guideline. NICE is currently considering setting up a standing update committee for diabetes, which would enable more rapid update of discrete areas of the diabetes guidelines, as and when new and relevant evidence is published.

Recommendations are marked as [new 2015], [2015], [2004] or [2004, amended 2015]:

- [new 2015] indicates that the evidence has been reviewed and the recommendation has been added or updated
- [2015] indicates that the evidence has been reviewed but no change has been made to the recommended action
- [2004] indicates that the evidence has not been reviewed since 2004
- [2004, amended 2015] or [2004, amended 2016] indicates that the evidence has not been reviewed since 2004, but either changes have been made to the recommendation wording that change the meaning or NICE has made editorial changes to the original wording to clarify the action to be taken (see below).

## Recommendations from NICE guideline CG15 that have been amended

Recommendations are labelled [2004, amended 2015] or [2004, amended 2016] if the evidence has not been reviewed but either:

- changes have been made to the recommendation wording (indicated by highlighted text) that change the meaning **or**
- NICE has made editorial changes to the original wording to clarify the action to be taken.

Recommendation in	Recommendation in	Reason for change
2004 guideline	current guideline	

Elements of an individualised and culturally appropriate plan will include:

 management of arterial risk factors (see 'Control of arterial risk', Section 1.10). (1.12.1.2) Elements of an individualised and culturally appropriate plan will include:

- sites and timescales of diabetes education, including nutritional advice (see sections 1.3 and 1.4)
- initial treatment modalities, including guidance on insulin injection and insulin regimens (see sections 1.7 and 1.8)
- means of self-monitoring and targets (see section 1.6)
- symptoms, risk and treatment of hypoglycaemia
- management of special situations, such as driving
- means and frequency of communication with the diabetes professional team

Additional elements have been included to make this recommendation comprehensive.

- management of cardiovascular risk factors (see section 1.13)
- for women of childbearing potential, implications for pregnancy and family planning advice (see the NICE guideline on diabetes in pregnancy)
- frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and annual review [2004, amended 2015] (1.1.7)

An individual care plan should be set up and reviewed annually, modified according to changes in wishes, circumstances and medical findings, and the details recorded. The plan should include aspects of:

Set up an individual care plan jointly agreed with the adult with type 1 diabetes, review it annually and modify it taking into account changes in the person's wishes, circumstances and medical findings, and record the details. The plan should include aspects of:

- diabetes education, including nutritional advice (see sections 1.3 and 1.4)
- insulin therapy, including dose adjustment (see sections 1.8 and 1.9)
- self-monitoring (see section 1.6)
- avoiding
   hypoglycaemia and
   maintaining
   awareness of
   hypoglycaemia
- for women of childbearing potential, family planning,

The word 'late' has been deleted (with respect to complications) because it implies advanced complications and takes the focus away from prevention. Some crucial aspects of a care plan have been added for completeness as they were not covered in the 2004 recommendation.

contraception and pregnancy planning (see the NICE guideline on diabetes in pregnancy)

- cardiovascular risk factor monitoring and management (see section 1.13)
- complications monitoring and management (see section 1.15)
- means and frequency of communicating with the diabetes professional team
- frequency and content of follow-up consultations, including review of HbA1c levels and experience of hypoglycaemia, and next annual review.
   [2004, amended 2015] (1.2.5)

# Information should also be made available on:

• use of foods of high glycaemic index. (1.8.3.6) Make information available on:

- effects of different alcohol-containing drinks on blood glucose excursions and calorie intake
- use of high-calorie and high-sugar 'treats'. [2004, amended 2015] (1.4.10)

There is no evidence of benefit for a low glycaemic index diet (see recommendation 1.4.3), so the reference to giving information about foods of high glycaemic index has been deleted.

Information about the benefits of healthy eating in reducing arterial risk should be made available as part of dietary education in the period after diagnosis, and according to need and interest at intervals thereafter. This should include information about low glycaemic index foods, fruit and vegetables, and types and amounts of fat, and ways of making the appropriate nutritional changes. (1.8.3.7)

Make information available about the benefits of healthy eating in reducing cardiovascular risk as part of dietary education in the period after diagnosis, and according to need and interest at intervals thereafter. Include information about fruit and vegetables, types and amounts of fat, and ways of making the appropriate nutritional changes. [2004, amended 2015] (1.4.11)

There is no evidence of benefit for a low glycaemic index diet (see recommendation 1.4.3), so the reference about giving information about foods of low glycaemic index has been deleted.

All healthcare professionals providing advice on the management of type 1 diabetes should be aware of appropriate nutritional advice on common topics of concern and interest to adults living with type 1 diabetes, and should be prepared to seek advice from colleagues with more specialised knowledge. Suggested common topics include:

- glycaemic index of specific foods
- body weight, energy balance and obesity management
- cultural and religious diets, feasts and fasts
- foods sold as 'diabetic'
- sweeteners
- dietary fibre intake

Be aware of appropriate nutritional advice on common topics of concern and interest to adults living with type 1 diabetes, and be prepared to seek advice from colleagues with more specialised knowledge. Suggested common topics include:

- body weight, energy balance and obesity management
- cultural and religious diets, feasts and fasts
- foods sold as 'diabetic'
- sweeteners
- dietary fibre intake
- protein intake
- vitamin and mineral supplements
- alcohol
- matching carbohydrate, insulin and physical activity

There is no evidence of benefit for a low glycaemic index diet (see recommendation 1.4.3), so the reference about giving information about the glycaemic index of foods has been deleted.

• protein intake	• salt intake in	
<ul> <li>protein intake</li> <li>vitamin and mineral supplements</li> <li>alcohol</li> <li>matching carbohydrate, insulin and physical activity</li> <li>salt intake in hypertension</li> <li>co-morbidities including nephropathy and renal failure,</li> <li>coeliac disease,</li> </ul>	<ul> <li>salt intake in hypertension</li> <li>comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders</li> <li>use of peer support groups. [2004, amended 2015] (1.4.13)</li> </ul>	
cystic fibrosis or eating disorders		
<ul><li>use of peer support groups.</li></ul>		
(1.8.3.9)		
Self-monitoring skills should be taught close to the time of diagnosis and initiation of insulin	Teach self-monitoring skills at the time of diagnosis and initiation of insulin therapy.  [2004, amended 2015]	The GDG stated that it is important that self-monitoring skills are taught as soon as type 1 diabetes is diagnosed.
therapy. (1.8.2.2)	(1.6.16)	

Monitoring using sites other than the fingertips (often the forearm, using meters that require small volumes of blood and devices to obtain those small volumes) cannot be recommended as a routine alternative to conventional self-blood glucose monitoring. (1.8.2.8)

Monitoring blood glucose using sites other than the fingertips cannot be recommended as a routine alternative to conventional self-monitoring of blood glucose. [2004, amended 2015] (1.6.20) Blood glucose has been stated for clarity. The statements about small volumes and special devices for alternative site monitoring have been removed because (1) the 2015 guideline supports the 2004 view that alternative site monitoring is not recommended, so the comment is redundant and (2) all meters now use small volumes.

For adults with erratic and unpredictable blood glucose control (hyper- and hypoglycaemia at no consistent times), rather than a change in a previously optimised insulin regimen, the following should be considered:

- resuspension of insulin and injection technique
- injection sites
- self-monitoring skills
- knowledge and self-management skills
- nature of lifestyle
- psychological and psychosocial difficulties
- possible organic causes such as gastroparesis. (1.9.3.12)

For adults with erratic and unpredictable blood glucose control (hyperglycaemia and hypoglycaemia at no consistent times), rather than a change in a previously optimised insulin regimen, the following should be considered:

- injection technique
- injection sites
- self-monitoring skills
- knowledge and self-management skills
- nature of lifestyle
- psychological and psychosocial difficulties
- possible organic causes such as gastroparesis.
   [2004, amended 2015] (1.7.12)

Reference to resuspension of insulin is out of date and so has been deleted.

Adults with diabetes should be provided with suitable containers for the collection of used needles. Arrangements should be available for the suitable disposal of these containers. (1.9.4.7)	Provide adults with type 1 diabetes with suitable containers for collecting used needles and other sharps.  Arrangements should be available for the suitable disposal of these containers. See also section 1.1.4 of the NICE guideline on infection control.  [2004, amended 2015] (1.8.6)	Mention of other sharps and cross-reference to the NICE guideline on infection control added to the recommendation.
The injection-site condition should be checked annually and if new problems with blood glucose control occur. (1.9.4.8)	Check injection site condition at least annually and if new problems with blood glucose control occur. [2004, amended 2015] (1.8.7)	The GDG clarified that injection site condition can be checked more frequently than annually if appropriate.

Adults with type 1 diabetes should be informed that any available glucose/ sucrose-containing fluid is suitable for the management of hypoglycaemic symptoms or signs in people who are able to swallow. Glucose-containing tablets or gels are also suitable for those able to dissolve or disperse these in the mouth and swallow the products. (1.9.5.1)

Explain to adults with type 1 diabetes that a fast-acting form of glucose is needed for the management of hypoglycaemic symptoms or signs in people who are able to swallow. [2004, amended 2015] (1.10.10)

The GDG clarified that a fast-acting form of glucose can be used for managing hypoglycaemia. The text specifying tablets or gels has been deleted. Glucogel is no longer listed in the BNF. The BNF also advises that other suitable forms of glucose can be used and therefore we did not want to state that only gels and tablets are appropriate..

Adults with decreased level of consciousness due to hypoglycaemia who are unable to take oral treatment safely should be:

- given intramuscular glucagon by a trained user (intravenous glucose may be used by professionals skilled in obtaining intravenous access)
- monitored for response at 10 minutes, and then given intravenous glucose if the level of consciousness is not improving significantly
- then given oral carbohydrate when it is safe to administer it, and placed under continued observation by a third party who has been warned

Adults with type 1 diabetes with a decreased level of consciousness as a result of hypoglycaemia and so are unable to take oral treatment safely should be:

- given intramuscular member or friend who has been (intravenous glucose may be used by healthcare professionals skilled in obtaining intravenous access)
- monitored for response at 10 minutes, and then given intravenous glucose if their level of consciousness is not improving significantly
- then given oral carbohydrate when it is safe to administer it, and placed under continued observation by a third party who has

The GDG clarified that this recommendation relates to people who are unable to protect their airway because of a decreased level of consciousness.

Glucagon can be administered in an emergency situation. The Human Medicines Regulations 2012 schedule 19 lists glucagon as a medicine that can be administered in an emergency without a prescription. The MHRA states that 'Regulation 238 of the glucagon by a family Human Medicines Regulations 2012 allows for certain prescription only medicines to be administered by anyone for the purpose of shown how to use it saving life in an emergency. The medicines this concerns are covered in Schedule 19 and are listed below.' Therefore the recommendation has been changed to reflect that intramuscular glucagon does not have to be given by a trained user.

of the risk of relapse. (1.9.5.3)	been warned of the risk of relapse.
	[2004, amended 2015] (1.10.11)

Nocturnal hypoglycaemia (symptomatic or detected on monitoring) should be managed by:

- reviewing knowledge and self-management skills
- reviewing current insulin regimen and evening eating habits and previous physical activity.
- choosing an insulin type and regimen with less propensity to induce low glucose levels in the night hours, such as:
  - isophane (NPH) insulin at bedtime
  - rapid-acting analogue with the evening meal

Manage nocturnal hypoglycaemia (symptomatic or detected on monitoring) by:

- reviewing knowledge and self-management skills
- reviewing current insulin regimen, evening eating habits and previous physical activity
- choosing an insulin type and regimen that is less likely to induce low glucose levels at night.
   [2004, amended 2015] (1.10.14)

Details about insulin types have been deleted because the information is out of date and inconsistent with other recommendations in this guideline.

<ul> <li>long-acting insulin analogues (insulin glargine)</li> <li>insulin pump. (1.9.5.8)</li> </ul>		
In adults with type 1 diabetes who have a low body mass index or unexplained weight loss, markers of coeliac disease, should be assessed. (1.12.4.1)	In adults with type 1 diabetes who have a low BMI or unexplained weight loss, assess markers of coeliac disease. For guidance on testing for coeliac disease, see the NICE guideline on coeliac disease. [2004, amended 2015] (1.12.1)	Cross-reference to relevant NICE guideline added.
Healthcare professionals should be alert to the possibility of the development of other autoimmune disease in adults with type 1 diabetes (including Addison's disease, pernicious anaemia and thyroid disorders). (1.12.4.2)	Be alert to the possibility of the development of other autoimmune disease in adults with type 1 diabetes (including Addison's disease and pernicious anaemia). For advice on monitoring for thyroid disease, see recommendation 1.15.40. [2004, amended 2015] (1.12.2)	Mention of thyroid disorders has been deleted because thyroid disease is now covered by a separate recommendation to measure TSH levels at annual review.

Adults who have had myocardial infarction or stroke should be managed intensively, according to relevant non-diabetes guidelines. In the presence of angina or other ischaemic heart disease, beta-adrenergic blockers should be considered. (For use of insulin in these circumstances, see 'Hospital administration and intercurrent disease', Section 1.12.3.) (1.10.2.8)

Provide intensive management for adults who have had myocardial infarction or stroke, according to relevant non-diabetes guidelines. In the presence of angina or other ischaemic heart disease. beta-adrenergic blockers should be considered. (For use of insulin in these circumstances, see section 1.14). For guidance on secondary prevention of myocardial infarction, see the NICE guideline on MI - secondary prevention. [2004, amended 2015]

(1.13.7)

Cross-reference to relevant NICE guideline added.

A trial of a low-dose thiazide diuretic should be started as first-line therapy for raised blood pressure, unless the person with type 1 diabetes is already taking a renin-angiotensin system blocking drug for nephropathy (see 'Nephropathy', Section 1.1 1.2). Multiple drug therapy will often be required. (1.10.3.3)

Start a trial of a renin-angiotensin system blocking drug as first-line therapy for hypertension in adults with type 1 diabetes. [2004, amended 2015] (1.13.10)

The GDG did not review the evidence for this recommendation. However, the NICE guidance on hypertension has changed since CG15 was published in 2004, and thiazides are no longer first-line therapy for any age group. Thiazides can elevate blood glucose. The GDG recommend renin-angiotensin system blockers as first-line therapy. They are recommended in NICE's hypertension guideline as first-line therapy for people under 55 years, which accounts for most adults with type 1 diabetes and hypertension. For people over 55 years who do not have renal impairment, the NICE hypertension guideline recommends calcium channel blockers. As soon as renal impairment or albuminuria is detected, a renin-angiotensin system blocker is recommended for renal protection. Therefore it is sensible to recommend a renin-angiotensin blocker as first-line therapy for all adults with type 1 diabetes if they have hypertension. Mention of nephropathy has been removed; guidance on nephropathy is given in recommendation 1.15.19.

Throughout the course of an inpatient admission, the personal expertise of adults with type 1 diabetes (in managing their own diabetes) should be respected and routinely integrated into ward-based blood glucose monitoring and insulin delivery, using the person with type 1 diabetes' own system. This should be incorporated into the nursing care plan. (1.12.3.2)

Throughout the course of an inpatient admission, respect the personal expertise of adults with type 1 diabetes (in managing their own diabetes) and routinely integrate this into ward-based blood glucose monitoring and insulin delivery. [2004, amended 2015] (1.14.8)

The GDG advised removing 'using the person's own systems', because hospitals increasingly use monitoring systems that are quality controlled and recorded automatically into electronic patient records that can be reviewed remotely by the diabetes professional team. The updated recommendation does not preclude the person using their own system in addition to the hospital system if they wish to do so. Use of such hospital monitoring systems improves patient care.

Concerns over potential side effects should not be allowed to inhibit advising and offering the necessary use of any class of drugs, unless the side effects become symptomatic or otherwise clinically significant. In particular:

- selective
   beta-adrenergic
   blockers should
   not be avoided in
   adults on insulin
- low-dose thiazides may be combined with beta-blockers
- when calcium channel antagonists are prescribed, only long-acting preparations should be used
- direct questioning should be used to detect the potential side effects of erectile dysfunction, lethargy and

Do not allow concerns over potential side effects to inhibit advising and offering the necessary use of any class of drugs, unless the side effects become symptomatic or otherwise clinically significant. In particular:

- do not avoid selective beta-adrenergic blockers where indicated in adults on insulin
- low-dose thiazides may be combined with beta-blockers
- when calcium channel antagonists are prescribed, use only long-acting preparations
- use direct
   questioning to
   detect the potential
   side effects of
   erectile
   dysfunction,
   lethargy and
   orthostatic
   hypotension with

The GDG added 'where indicated' because the indications for beta blockers in pure hypertension are much more reduced now than in 2004.

orthostatic hypotension with different drug classes. [1.10.3.5]	different drug classes. (1.13.12)	
Depending on the findings, structured eye surveillance should be followed by:  • routine review in 1 year, or  • earlier review, or  • referral to an ophthalmologist. (1.11.1.2)	Depending on the findings, follow structured eye screening by:  • routine review annually or  • earlier review or  • referral to an ophthalmologist. [2004, amended 2015] (1.15.2)	The recommendation has been amended to clarify that review should be annual.
Digital retinal photography should be implemented for eye surveillance programmes for adults with type 1 diabetes. (1.11.1.5)	Offer digital retinopathy screening annually to adults with type 1 diabetes. [2004, amended 2015] (1.15.4)	The recommendation has been amended in line with the National Screening Programme.

1.11.1.10 Referral to an ophthalmologist should occur for:

- referable maculopathy:
- exudate or retinal thickening within 1 disc diameter of the centre of the fovea
- circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, of a diameter the distance between the temporal border of the optic disc and the fovea)
- any
   microaneurysm or
   haemorrhage
   within 1 disc
   diameter of the
   centre of the
   fovea, only if
   associated with a
   best visual acuity
   of 6/12 or worse

Refer to an ophthalmologist for:

- referable maculopathy:
- exudate or retinal thickening within 1 disc diameter of the centre of the fovea
- circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, of a diameter the distance between the temporal border of the optic disc and the fovea)
- any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea, only if associated with a best visual acuity of 6/12 or worse
- referable pre-proliferative retinopathy:
- any venous beading

The recommendations on eye disease were reviewed by the National Screening Programme and were amended to make them consistent with the current practice of the diabetes eye screening programme.

- referable pre-proliferative retinopathy:
- any venous beading
- any venous loop or reduplication
- any intraretinal microvascular abnormalities (IRMA)
- multiple deep, round or blot haemorrhages (If cotton wool spots are present, look carefully for the above features, but cotton wool spots themselves do not define pre-proliferative retinopathy)
- any unexplained drop in visual acuity. (1.11.1.10)

- any venous reduplication
- any intraretinal microvascular abnormalities (IRMA)
- multiple deep, round or blot haemorrhages

(If cotton wool spots are present, look carefully for the above features, but cotton wool spots themselves do not define pre-proliferative retinopathy)

 any large sudden unexplained drop in visual acuity. [2004, amended 2015] (1.15.9)

ACE inhibitors should be started and, with the usual precautions, titrated to full dose in all adults with confirmed nephropathy (including those with microalbuminuria alone) and type 1 diabetes. (1.11.2.5)	Start angiotensin-converting enzyme (ACE) inhibitors and, with the usual precautions, titrate to full dose in all adults with confirmed nephropathy (including those with moderately increased albuminuria ['microalbuminuria'] alone) and type 1 diabetes. [2004, amended 2015] (1.15.14)	The term 'moderately increased albuminuria' has been added, for consistency with the classification used in the NICE guideline on chronic kidney disease.
If ACE inhibitors are not tolerated, angiotensin 2 receptor antagonists should be substituted. Combination therapy is not recommended at present. (1.11.2.6)	If ACE inhibitors are not tolerated, substitute angiotensin 2 receptor antagonists. Combination therapy is not recommended. [2004, amended 2015] (1.15.15)	'at present' has been removed in view of evidence known to the GDG that the combination can be harmful, increasing risk of hyperkalaemia and acute renal injury.
The management of the symptoms of autonomic neuropathy should include standard interventions for the manifestations encountered (for example, for erectile dysfunction or abnormal sweating). (1.11.4.9)	When managing the symptoms of autonomic neuropathy, include standard interventions for the manifestations encountered (for example, for abnormal sweating and postural hypotension). [2004, amended 2015] (1.15.23)	The GDG added postural hypertension because this is an important manifestation of autonomic neuropathy. There are now separate recommendations about managing erectile dysfunction (1.15.30–1.15.32) and gastroparesis (1.15.1–1.15.4).

**Diabetes** professionals should ensure that they have appropriate skills in the detection and basic management of non-severe psychological disorders in people from different cultural backgrounds. They should be familiar with appropriate counselling techniques and appropriate drug therapy, while arranging prompt referral to specialists of those people in whom psychological difficulties continue to interfere significantly with well-being or diabetes self-management. (1.12.5.2)

Diabetes professionals should:

- ensure that they
  have appropriate
  skills in the
  detection and basic
  management of
  non-severe
  psychological
  disorders in people
  from different
  cultural
  backgrounds
- be familiar with appropriate counselling techniques and drug therapy, while arranging prompt referral to specialists of those people in whom psychological difficulties continue to interfere significantly with wellbeing or diabetes

See also the NICE guidelines on common mental health disorders, generalised anxiety disorder and panic disorder (with or without agoraphobia)

self-management.

Cross-references to relevant NICE guidelines have been added for information.

	in adults and depression in adults with a chronic health problem. [2004, amended 2015] (1.15.42)	
Members of multidisciplinary professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and insulin dose manipulation in adults with type 1 diabetes with:  • over-concern with body shape and weight  • low body mass index  • poor overall blood glucose control. (1.12.6.1)	Members of diabetes professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and insulin dose manipulation in adults with type 1 diabetes with:  • over-concern with body shape and weight  • low BMI  • hypoglycaemia  • suboptimal overall blood glucose control.  See also the NICE guideline on eating disorders. [2004, amended 2015] (1.15.43)	The GDG stated that hypoglycaemia is another possible indicator of eating disorders. Cross-reference to the relevant NICE guideline has been added for information.
	1.13.2, 1.13.9, 1.15.13	Change made from '[abnormal] albumin excretion rate' to 'albuminuria' for accuracy.

1.11.6, 1.11.8, 1.11.10,	NICE has made editorial changes to the original wording to clarify the action to be taken (no change to meaning): a verb has been added, the verb used has been changed or
	other wording has changed for clarification.

## About this guideline

# Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also <u>patient-centred care</u>).

#### Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

#### Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

### Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2004] (see <u>update information</u> for details about how recommendations are labelled). In particular, for recommendations labelled [2004] and [2004, amended 2015] or [2004, amended 2016] the word 'consider' may not necessarily be used to denote the strength of the recommendation.

ISBN: 978-1-4731-1389-3

#### Accreditation

