# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

# SCOPE

## 1 Guideline title

Type 1 diabetes: diagnosis and management of type 1 diabetes in adults

### *1.1 Short title*

Type 1 diabetes in adults

## 2 The remit

This is an update of Type 1 diabetes (NICE clinical guideline 15). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

This is the scope for 1 of 4 NICE clinical guidelines being developed that address diabetes care. Included below is a summary of the content for each guideline and of the NICE steering committee.

Guideline 1 – **Diabetes in children and young people** (developed by the National Collaborating Centre for Women's and Children's Health)

This guideline will update Type 1 diabetes in children, young people and adults (NICE clinical guideline 15). It will cover the diagnosis and management of type 1 and type 2 diabetes in children and young people (younger than 18 years). It will include: structured education programmes, behavioural interventions to improve adherence, glucose monitoring strategies, ketone monitoring, insulin regimens for type 1 diabetes and metformin monotherapy for type 2 diabetes.

**Guideline 2 – Diabetes in pregnancy** (developed by the National Collaborating Centre for Women's and Children's Health)

This guideline will update Diabetes in pregnancy (NICE clinical guideline 63). It will cover women of reproductive age who have pre-existing diabetes or who develop diabetes during pregnancy and it will also cover their newborn babies. It will include: target glucose ranges in the preconception period and during pregnancy, glucose monitoring strategies during pregnancy, screening, diagnosis and treatment of gestational diabetes, and postnatal testing for type 2 diabetes.

**Guideline 3 – Type 1 diabetes in adults** (developed by the National Clinical Guideline Centre)

This guideline will update Type 1 diabetes in children, young people and adults (NICE clinical guideline 15). It will cover adults (18 years or older) with type 1 diabetes. It will include: tests to differentiate type 1 diabetes from type 2 diabetes, structured education programmes, clinical monitoring of glucose control, insulin regimens, ketone monitoring, dietary advice on carbohydrate counting and glycaemic index, and treatment and monitoring of specific complications.

**Guideline 4 –Type 2 diabetes in adults** (developed by the Internal Clinical Guidelines Programme, Centre for Clinical Practice, NICE)

This guideline will update Type 2 diabetes (NICE clinical guideline 66) and Type 2 diabetes: newer agents (NICE clinical guideline 87). It will cover adults (18 years or older) with type 2 diabetes. It will include: pharmacological management of blood glucose levels, target values for blood glucose control, self-monitoring of blood glucose levels for blood glucose control, antithrombotic therapy and drug therapy for erectile dysfunction.

**NICE steering committee**

NICE has set up a steering committee to oversee the production of these clinical guidelines. The group, which includes the Guideline Development Groups' chairs, together with staff from the 3 guidance-producing centres and NICE, will identify and act on any gaps or overlaps across the different guidance topics to ensure that the final guidelines are complementary and consistent. It is intended that the guidance-producing centres will share systematic reviews and cross-refer to recommendations in the other guidelines where appropriate. This update is being undertaken as part of the guideline review cycle.

# 3 Clinical need for the guideline

## *3.1 Epidemiology*

a) Type 1 diabetes is a long-term hormonal deficiency disorder, in which there is loss of insulin secretion. This results in high blood glucose concentrations and other metabolic and haematological abnormalities. It is usually caused by autoimmune destruction of the insulin-secreting beta cells of the pancreas. In the short term, people with type 1 diabetes may face significant challenges to daily living, for example, hyperglycaemia (high blood glucose) and hypoglycaemia (low blood glucose), the need for daily administration of insulin and frequent self-monitoring of blood glucose, and to plan daily activities such as eating and exercising. Over the long term, type1 diabetes is associated with major complications and reduced life expectancy. The condition is treated with insulin replacement therapy and at present there is no cure.

b) Approximately 10% of adults diagnosed with diabetes have type 1 diabetes. Currently, it is estimated that 0.34-0.55% of the population of England and Wales are known to have type 1

diabetes. Among people aged between 10 and 80 years, there is little difference in prevalence across age groups.

c) Type 1 diabetes can present at any age. Although it commonly presents in children and adolescents, the condition persists into and can start in adult life. Treatment regimens used to manage diabetes and the demands of living with diabetes are as complex in adults as in younger people.

d) Effective insulin management requires detailed knowledge of its actions.

e) Life expectancy for people with type 1 diabetes has increased. In one study from the USA, life expectancy among people diagnosed with type 1 diabetes between 1965 and 1980 improved by 15 years compared with people diagnosed between 1950 and 1964. Nevertheless, having type 1 diabetes typically reduces life expectancy in the UK by 20 years. People with type 1 diabetes in England are 2.6 times more likely to die than people without diabetes of the same age. Most of the deaths are due to chronic complications, although death in acute hypoglycaemia or diabetic ketoacidosis may occur.

f) The Diabetes Control and Complications Trial Research Group[1] confirmed that strict blood glucose control reduces risk of long-term complications and is associated with increased life expectancy among people with type 1 diabetes. Effective insulin management requires detailed knowledge of its actions. The insulin user needs to acquire skill in insulin management. Control of blood pressure also reduces risk of complications in people with type 1 diabetes. Controlling lipids within recommended targets for other forms of diabetes is expected to reduce excess cardiovascular risk associated with type 1 diabetes.

[1] The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993;329:977-986.

g) Early detection and effective management of type 1 diabetes and its complications are important to prevent or limit disability in people with type1 diabetes.

## *3.2 Current practice*

a) People with type 1 diabetes manage many aspects of their own care, including administering insulin by injection or infusion, monitoring their blood glucose levels, and adjusting insulin doses accordingly. Glucose levels should be assessed regularly to guide insulin dose adjustment and to ensure they remain within target levels known to minimise risk of complications, while avoiding problems such as hypoglycaemia or ketosis.

b) People with type 1 diabetes need education and support from healthcare professionals with expertise in insulin physiology and therapeutics to manage their diabetes effectively. Hypoglycaemia remains a problem for people using insulin.

c) Fewer than 1 third of people with type 1 diabetes achieve the NICE-recommended target for blood glucose control, which is haemoglobin A1c ($HbA_{1c}$) of 59 mmol/mol or lower, or below 7.5%. In the last 4 audit cycles, there has been no significant improvement in the proportion of people who meet this target.

d) People with type 1 diabetes need regular monitoring for complications of diabetes. Where these occur, active management is needed. However, only 31.9% of people with type 1 diabetes in England and Wales have records of receiving all 9 of the care processes recommended by NICE. More than 30% of people with type 1 diabetes miss their annual eye and foot checks for early complications and almost 1 half miss screening appointments for kidney complications.

e) Two thirds of people with type 1 diabetes achieve the NICE-recommended target for blood pressure control. Among people

who are morbidly obese this figure is 45%. Approximately 1 third of people with type 1 diabetes achieve the current stringent target for total cholesterol, which is below 4 mmol/litre.

f) Rates of diabetic ketoacidosis appear to be increasing in the UK. There has also been an increase in the number of people with type 1 diabetes needing treatment for end-stage kidney disease.

g) Diabetes management in hospitals and other places for professional health care remains suboptimal. Insulin regimens are the most common cause of drug errors in inpatient prescribing

h) People with type 1 diabetes have traditionally received care primarily from specialist services. However, 15–20% of adults with type 1 diabetes have little or no contact with secondary care services, or are offered only infrequent appointments focussed on annual review.

i) A small number of people with type 1 diabetes experiencing life-threatening episodes of hypoglycaemia undergo pancreatic transplant or islet cell transplantation. Around 200 pancreas transplants are performed in the UK each year[2]. Around 95 islet transplants have been performed in 65 people in the UK to date[3].

# 4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

[2] NHS Choices http://www.nhs.uk/conditions/pancreastransplant/Pages/Introduction.aspx (accessed 23 July 2013)
[3] Diabetes UK http://www.diabetes.org.uk/Guide-to-diabetes/Treatments/Islet-transplants/ (accessed 23 July 2013)

The areas that will be addressed by the guideline are described in the following sections.

## *4.1 Population*

### 4.1.1 Groups that will be covered

a) Adults (aged 18 years and older) with type 1 diabetes.

b) Where the evidence supports it, the following subgroups will be given special consideration

- Ethnic groups
- People who are unable to inject themselves for whatever reason
- People whose religious beliefs may affect the management of their diabetes
- People with literacy or numeracy difficulties

### 4.1.2 Groups that will not be covered

a) Children and young people with type 1 diabetes (this will be addressed in a separate guideline).

b) Adults with type 2 diabetes (this will be addressed in a separate guideline).

c) Diabetes in pregnancy (this will be addressed in a separate guideline).

d) Monogenic and other rarer forms of diabetes

## *4.2 Healthcare setting*

a) All settings in which NHS care is received or commissioned.

## *4.3 Clinical management*

### 4.3.1 Key clinical issues that will be covered

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use

outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

**Areas from the original guideline that will be updated by an evidence review**

a) Diagnosis of type 1 diabetes: differentiation from type 2 diabetes and other forms of diabetes using c-peptides and antibody testing.

b) Education programmes and self-care: structured educational programmes.

c) Clinical monitoring of glucose control:

- $HbA_{1c}$:
  - targets
  - frequency of monitoring.
- Self-monitoring of blood glucose (finger pricks):
  - targets
  - frequency of monitoring
  - timing
  - benefit of technologies (bolus calculators and downloads).
- Continuous glucose monitoring (CGM):
  - self-monitoring blood glucose versus real-time CGM
  - self-monitoring blood glucose versus retrospective CGM
  - intermittent real-time monitoring versus continuous real-time monitoring.
- Ketone monitoring (see 4.3.1.m).

d) Insulin regimens, particularly rapid-acting insulins and new background insulins (see also 4.3.1.j).

- Detemir versus degludec versus degludec-aspart combinations versus glargine versus NPH.
- Once-daily basal versus twice-daily basal.

- Rapid-acting insulins for meal times: analogues versus human soluble.

e) Non-insulin pharmacological agents in combination with insulin (specifically, metformin).

f) Needle length and injection site for insulin administration.

g) Aspirin for the primary prevention of cardiovascular disease.

h) Treatment of specific late-stage complications:

- Insulin-induced neuritis.
- Gastroparesis.
- Erectile dysfunction.

i) Inpatient management in relation to insulin replacement:

- Intravenous regimens.
- Dose-adjustment devices.

**Areas not in the original guideline that will be included in the update**

j) New insulin formulations, including insulin degludec, insulin degludec-aspart combinations and insulin detemir (see 4.3.1.d).

k) Hypoglycaemia unawareness.

l) Monitoring for thyroid disease.

m) The role of ketone monitoring:

- Self-monitoring for the prevention of diabetic ketoacidosis.
- Monitoring of diabetic ketoacidosis

n) Carbohydrate counting and glycaemic index taking into account balancing protein and lipid intake

o) Referral criteria for pancreas transplant and islet cell transplantation.

### 4.3.2 Clinical issues that will not be covered

**Areas from the original guideline that will not be updated by an evidence review**

a) The care process and support: topics such as multidisciplinary support, individual care plans, use of technology, and support groups will not be included.

b) Aspects of education programmes and self-management not listed in section 4.3.1: topics such as physical activity, cultural and individual lifestyle and dietary management (with the exception of carbohydrate counting) will not be included.

c) Aspects of blood glucose control and insulin therapy not listed in section 4.3.1: topics such as the management of symptomatic hypoglycaemia will not be included.

d) Arterial risk control, with the exception of aspirin.

e) Management of late complications: topics such as diabetic eye disease, diabetic kidney disease, diabetes foot, diabetic nerve damage (other than erectile dysfunction, insulin-induced neuritis and gastroparesis) will not be included.

f) Management of special situations not listed in section 4.3.1: topics such as the management of diabetic ketoacidosis (with the exception of blood ketone measurement), management of intercurrent illness, and psychological problems will not be included.

g) Inpatient management not listed in section 4.3.1.i.

**Areas not covered by the original guideline or the update**

h) Preconception care in women with type 1 diabetes (this will be addressed by the diabetes in pregnancy guideline).

i) Contraceptive advice in women with type 1 diabetes (this will be addressed by the diabetes in pregnancy guideline).

**The following NICE guidance will be cross referred to**

j) Insulin pumps:

- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal 151 (2008).

k) Identification of arterial risk, interventions to reduce risk (with the exception of aspirin), and blood pressure management:

- Hypertension. NICE clinical guideline 127 (2011).
- Lipid modification. NICE clinical guideline 67 (2007). (An update of this guideline is currently in progress)
- Statins for the prevention of cardiovascular events. NICE technology appraisal 94 (2006).

l) Painful neuropathy:

- Neuropathic pain. NICE clinical guideline 96 (2010). (An update of this guideline is currently in progress)
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE technology appraisal 159 (2008).

m) Diabetic kidney disease:

- Chronic kidney disease (update). NICE clinical guideline 73 (2008). (An update of this guideline is currently in progress)

n) Diabetic foot problems:

- Diabetic foot problems - inpatient management. NICE clinical guideline 119 (2011).
- Type 2 diabetes - footcare. NICE clinical guideline 10 (2004).

o) Monitoring and management of special situations including eating disorders, depression, or other psychological problems:

- Anxiety. NICE clinical guideline 113 (2011).
- Depression with a chronic physical health problem. NICE clinical guideline 91 (2009).
- Depression in adults (update). NICE clinical guideline 90 (2009).
- Nutrition support in adults. NICE clinical guideline 32 (2006).
- Eating disorders. NICE clinical guideline 9 (2004).

## *4.4 Main outcomes*

a) Health-related quality of life.

b) Adverse events and complications.

c) Mortality.

d) $HbA_{1c.}$

e) Hypoglycaemia.

## *4.5 Review questions*

**Diagnosis**

- In adults and young people with diabetes, what is the best diagnostic test(s) (c-peptides plus or minus antibodies) to distinguish between a diagnosis of type 1 diabetes, type 2 diabetes and other forms of diabetes?

**Education programmes and self-care**

- In adults with type 1 diabetes, what is the most effective structured education programme?

**Clinical monitoring of glucose control**

- $HbA_{1c}$
  - In adults with type 1 diabetes, what is the optimum target $HbA_{1c}$ level that should be achieved to reduce the risk of complications?

  - In adults with type 1 diabetes, what is optimum frequency of $HbA_{1c}$ monitoring for effective diabetic control?
- Self-monitoring of blood glucose (finger pricks)
  - In adults with type 1 diabetes, what is the optimum glucose target for self-monitoring of blood glucose for effective diabetic control?
  - In adults with type 1 diabetes, what is optimum timing and frequency to self-monitor blood glucose for effective diabetic control?
  - In adults with type 1 diabetes, what are the benefits of technologies (bolus calculators,downloads and smartphone apps) for self-monitoring of blood glucose?
- Continuous glucose monitoring (CGM)
  - In adults with type 1 diabetes, is real-time CGM more effective than self-monitoring blood glucose for optimal diabetic control?
  - In adults with type 1 diabetes, is retrospective CGM more effective than care without CGM (with SMBG) for improving diabetic control?
  - In adults with type 1 diabetes, is continuous real-time monitoring more effective than intermittent real-time monitoring for optimal diabetic control?
- Ketone monitoring
  - In adults with T1D (including atypical ketosis-prone diabetes), does patient self-monitoring of blood (and urine) ketones reduce the incidence of diabetic ketoacidosis and hospital admissions?
  - In adults with type 1 diabetes does inpatient monitoring of blood ketones by the healthcare professional reduce the length of hospital stay, exposure to iv insulin and the development of in-hospital complications : a) in patients with suspected diabetic ketoacidosis; b) in patients admitted with diabetic ketoacidosis and / or those who get it in hospital

**Insulin regimens**

- In adults with type 1 diabetes, what are the most effective long-acting insulins (detemir versus degludec versus glargine versus NPH) for optimal diabetic control?

- In adults with type 1 diabetes, is once-daily basal insulin more effective than twice-daily basal insulin for optimal diabetic control?
- In adults with type 1 diabetes, what are the most effective mixed insulins (degludec-aspart versus glargine versus NPH) for optimal diabetic control?
- In adults with type 1 diabetes, which are the most effective rapid-acting insulins for meal times: analogues versus human (intermediate NPH), for optimal diabetic control?

**Insulin combination with non-insulin pharmacological agents**

- In adults with type 1 diabetes, aremetformin (with or without insulin) or GLP1-agonists (with or without insulin) as effective as insulin alone for optimal diabetic control?

**Insulin administration**

- In adults with type 1 diabetes, what is the optimum needle length for insulin delivery?
- In adults with type 1 diabetes, what is the optimum injection site and rotation for insulin delivery?

**Prevention of cardiovascular disease (aspirin)**

- In adults with type 1 diabetes, is aspirin an effective anti-platelet agent for the primary prevention of cardiovascular events?

**Treatment of specific late-stage complications**

- In adults with type 1 diabetes, what is the most effective treatment for insulin-induced neuropathy?
- In adults with type 1 diabetes, what is the most effective treatment for gastroparesis?

**Inpatient management (in relation to insulin replacement)**

- In adults with type 1 diabetes who have been admitted to hospital, what is the most effective intravenous insulin regimen for optimal diabetic control?
- In adults with type 1 diabetes who have been admitted to hospital, what are the most effective dose-adjustment devices for optimal diabetic control?

**Hypoglycaemia unawareness**

- In adults with type 1 diabetes, what is the most effective strategy for recovering hypoglycaemia awareness?
- In adults with type 1 diabetes, how is problematic hypoglycaemia identified and quantified?

**Monitoring for thyroid disease**

- Should adults with type 1 diabetes be monitored for thyroid disease, and if so, for how long?

**Carbohydrate counting and glycaemic index**

- In adults with type 1 diabetes, what is the clinical and cost-effectiveness of a diet based on carbohydrate counting or restriction for optimal diabetic control?
- In adults with type 1 diabetes, what is the clinical and cost-effectiveness of a diet based on the glycaemic index for optimal diabetic control?

**Referral criteria for pancreas transplant and pancreatic islet cell transplantation**

- In adults with type 1 diabetes, what are the referral criteria that indicate a person should be considered for a pancreas transplant, or pancreatic islet cell transplantation?

## *4.6 Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

## *4.7 Status*

### 4.7.1 Scope

This is the final version of the scope.

### 4.7.2 Timing

The development of the guideline recommendations will begin in October 2012.

# 5 Related NICE guidance

## *5.1 Published guidance*

### 5.1.1 NICE guidance to be updated

Depending on the evidence, this guideline might update and replace parts of the following NICE guidance:

- Type 1 diabetes. NICE clinical guideline 15 (2004).
- Guidance on the use of patient-education models for diabetes. NICE technology appraisal guidance 60 (2003).
- Guidance on the use of long-acting insulin analogues for the treatment of diabetes – insulin glargine. NICE technology appraisal guidance 53 (2002).

### 5.1.2 Other related NICE guidance

- Patient experience in adult NHS services. NICE clinical guideline 138 (2012).
- Lower limb peripheral arterial disease. NICE clinical guideline 147 (2012).
- Preventing type 2 diabetes: population and community-level interventions. NICE public health guidance 35 (2011).
- Hyperglycaemia in acute coronary syndromes. NICE clinical guideline 130 (2011).
- Hypertension. NICE clinical guideline 127 (2011).
- Ranibizumab for the treatment of diabetic macular oedema. NICE technology appraisal 237 (2011).

- Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion. NICE technology appraisal 229 (2011).
- Ranibizumab for the treatment of diabetic macular oedema. NICE technology appraisal 237 (2011).
- Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events. NICE technology appraisal guidance 210 (2010).
- Depression with a chronic physical health problem. NICE clinical guideline 91 (2009).
- Depression in adults. NICE clinical guideline 90 (2009).
- Medicines adherence. NICE clinical guideline 76 (2009).
- Coeliac disease. NICE clinical guideline 86 (2009).
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal 151 (2008).
- Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus. NICE interventional procedure guideline 257 (2008).
- Inhaled insulin for the treatment of type 1 and type 2 diabetes. NICE technology appraisal 113 (2006).
- Smoking cessation services. NICE public health guidance 1 (2006).
- Obesity. NICE clinical guideline 43 (2006).
- Nutrition support in adults. NICE clinical guideline 32 (2006).
- Four commonly used methods to increase physical activity. NICE public health guidance 2 (2006).
- Statins for the prevention of cardiovascular events. NICE technology appraisal 94 (2006).
- Gastroelectrical stimulation for gastroparesis. NICE interventional procedure guide 103 (2004).

### *5.2 Guidance under development*

NICE is currently developing the following related guidance (details available from the NICE website):

- Diabetic macular oedema - fluocinolone acetonide intravitreal implant. NICE technology appraisal. Publication expected November 2012.
- Type 2 diabetes (update). NICE clinical guideline. Publication date to be confirmed.
- Diabetes in children (update). NICE clinical guideline. Publication date to be confirmed.
- Diabetes in pregnancy. NICE clinical guideline. Publication date to be confirmed.
- Diabetes - buccal insulin. NICE technology appraisal. Publication date to be confirmed.
- Macular oedema (diabetic) - pegaptanib sodium. NICE technology appraisal. Publication date to be confirmed.
- Macular oedema (diabetic) ranibizumab. NICE technology appraisal. Publication date to be confirmed.
- Lipid modification (update). NICE clinical guideline. Publication date to be confirmed.
- Chronic kidney disease (update). NICE clinical guideline. Publication date to be confirmed.

## 6 Further information

Information on the guideline development process is provided in the following documents, available from the NICE website:

- How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS
- The guidelines manual

Information on the progress of the guideline will also be available from the NICE website.