

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## SCOPE

### 1 Guideline title

Type 2 diabetes: management of type 2 diabetes in adults

#### 1.1 *Short title*

Type 2 diabetes

### 2 The remit

This is an update of [Type 2 diabetes](#) (NICE clinical guideline 66) and [Type 2 diabetes: newer agents](#) (NICE clinical guideline 87). It will also incorporate [Type 2 diabetes: prevention and management of foot problems](#) (NICE clinical guideline 10), [Diabetic foot problems: inpatient management of diabetic foot problems](#) (NICE clinical guideline 119). See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all the recommendations to ensure that they comply with NICE's duties under equality legislation.

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

### 3 Clinical need for the guideline

#### 3.1 *Epidemiology*

- a) Type 2 diabetes is initially an insulin-resistant state, the primary treatment for which is weight loss and exercise. Pharmacological measures to increase insulin sensitivity or to increase insulin release can be added to lifestyle interventions, but insulin therapy may be needed because of the continuing failure of insulin secretion. Like type 1 diabetes, type 2 diabetes has a significant impact on lifestyle in the short term, and is associated with major

long-term complications and reduced life expectancy. There are 2.9 million people known to be diagnosed with diabetes in the UK, with an average prevalence of approximately 4.45%. Currently, it is thought that more than 1 in 20 of the UK population has diagnosed or undiagnosed diabetes and incidence rates are increasing. Approximately 90% of adults currently diagnosed with diabetes have type 2 diabetes.

- b) Type 2 diabetes mainly develops in people aged over 40 years, although it is usually diagnosed earlier in people of South Asian family origin. It can occur in all age groups and is increasingly being diagnosed in children. People who are overweight or obese, have inactive lifestyles or have a family history of diabetes are at risk. It is more prevalent in less-affluent populations and in people of South Asian, African or African-Caribbean family origin.
- c) Type 2 diabetes can lead to acute metabolic disturbances such as hyperglycaemia (high blood glucose). If prolonged, hyperglycaemia can cause irreversible complications. These can include microvascular complications such as diabetic retinopathy (eye damage), nephropathy (kidney damage) and neuropathy, (nerve damage) and macrovascular complications such as cardiovascular disease (for example, coronary heart disease, cerebrovascular disease and peripheral vascular disease).
- d) It is estimated that approximately 10% of NHS expenditure goes on diabetes care. The presence of diabetic complications can lead to a 5-fold increase in a patient's NHS costs and people with diabetes can experience prolonged stays in hospital. Life-expectancy for people with type 2 diabetes is reduced by an average of 5 to 7 years, and the impact on quality of life can be considerable.

### **3.2 Current practice**

- a) Initial management of type 2 diabetes typically involves lifestyle interventions, although as the condition progresses oral glucose-

lowering agents may be needed to control blood glucose levels. Many people start on metformin therapy, but some may also need insulin therapy because of the continuing failure of insulin secretion. Regular monitoring of blood glucose levels can help people with diabetes to manage their risk of developing complications. The NICE–recommended target for blood glucose control is haemoglobin A1c (HbA<sub>1c</sub>) of 59 mmol/mol or lower, or below 7.5%. However, specific targets may be individualised to meet people's needs, taking into consideration their risk of hypoglycaemia, cardiovascular risk and other comorbidities<sup>1</sup>.

- b) Good management of blood pressure (including the use of angiotensin-converting enzyme [ACE] inhibitors, calcium-channel blockers and diuretics) and the management of blood lipid levels (including the use of statins and fibrates) can help to prevent or delay the onset of microvascular or macrovascular complications.
- c) The 2011 review of NICE clinical guidelines 66 and 87 identified new evidence in a number of areas and recommended that the guidelines should be updated. In particular, new evidence was found relating to the pharmacological management of blood glucose. This includes the effect of drugs coming off patent and newly licensed combinations, as well as their health-economic impacts.
- d) There are new members of the dipeptidyl peptidase 4 (DPP-4) inhibitor class of drugs and new indications for licensed class members. New evidence has also arisen relating to the use of aspirin in the primary prevention of cardiovascular disease.

## **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.

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 2 diabetes.
- b)       Specific patient sub-groups for whom the management of type 2 diabetes may vary. These may include (but are not restricted to):
  - older adults
  - people with renal impairment
  - people in specific ethnic groups
  - people in specific cardiovascular risk groups.

### **4.1.2    Groups that will not be covered**

- a)       Children and young people with type 1 or type 2 diabetes (this will be addressed in a separate guideline).
- b)       Adults (aged 18 years and older) with type 1 diabetes (this will be addressed in a separate guideline).
- c)       Diabetes in pregnancy (this will be addressed in a separate guideline).

## **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 guidelines that will be updated by an evidence review**

- a) Pharmacological management of blood glucose levels. This includes the following glucose-control therapies, either alone or in combination with other glucose-control therapies:
- DPP-4 inhibitors:
    - sitagliptin, vildagliptin, linagliptin, saxagliptin and alogliptin
  - glucagon-like peptide-1 (GLP-1) mimetics:
    - exenatide (conventional formula) and lixisenatide
  - thiazolidinediones:
    - pioglitazone
  - sulphonylureas
  - metformin
  - insulin
  - acarbose.
- b) Target values for blood glucose control. This includes:
- HbA<sub>1c</sub>
  - fasting blood glucose
  - post-prandial blood glucose
  - oral glucose tolerance.
- c) The effectiveness of self monitoring of blood-glucose levels for blood-glucose control.

- d) Antithrombotic therapy:
- the effectiveness of anti-platelet therapy and aspirin for the prevention of macrovascular complications.

#### **Areas not in the original guidelines that will be included in the update**

- e) The effectiveness of testosterone therapy for the management of erectile dysfunction in men with type 2 diabetes.

#### **4.3.2 Clinical issues that will not be covered**

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

- a) Patient education (including structured education).
- b) Dietary advice.
- c) Management of depression.
- d) Pharmacological management of blood glucose levels:
- SGLT-2 Inhibitors (canagliflozin, dapagliflozin and empagliflozin)
    - it is intended that these drugs will be covered by a technology appraisal(s) (TA). The clinical guideline intends to use these drugs as comparators but will not make new recommendations on their use
  - glucagon-like peptide-1 (GLP-1) mimetics:
    - exenatide (prolonged release) and liraglutide
  - thiazolidinediones:
    - rosiglitazone (original recommendations removed following European Medicines Agency [EMA] safety warning, September 2010)
  - meglitinides.
- e) Blood pressure control (including target values and pharmacological management).

- f) Pharmacological and non-pharmacological management of blood lipid levels (an update of [Lipid modification](#) [NICE clinical guideline 67] is in progress).
- g) Cardiovascular risk estimation (an update of [Lipid modification](#) [NICE clinical guideline 67] is in progress).
- h) The diagnosis and management of kidney disease (an update of [Chronic kidney disease](#) [NICE clinical guideline 73] is in progress).
- i) The diagnosis and management of diabetic neuropathic pain (an update of [Neuropathic pain](#) [NICE clinical guideline 96] is in progress).
- j) Prevention and management of diabetic foot problems.
- k) The effectiveness of phosphodiesterase type 5 (PDE-5) inhibitors for the management of erectile dysfunction.

#### **Areas from the original guidelines that will be removed**

- l) No areas from the original guidelines will be removed.

#### **Areas not covered by the original guidelines or the update**

- m) Diagnosis of type 2 diabetes.
- n) Primary prevention of type 2 diabetes.
- o) Ketone testing.
- p) The management of hypoglycaemia, unless this is as a consequence of pharmacological interventions for hyperglycaemia.
- q) The diagnosis and management of diabetic retinopathy.
- r) Peripheral arterial disease comprising peripheral vascular neuropathy (PVD) and peripheral sensory neuropathy (PSN).

- s) Surgical interventions: the use and effectiveness of bariatric surgery for the management of type 2 diabetes (this is covered in clinical guideline 43: Obesity).

#### **4.4 Main outcomes**

- a) Changes in blood glucose levels (including HbA<sub>1c</sub>).
- b) Changes in weight or body mass index (BMI).
- c) Frequency and severity of hypoglycaemic episodes.
- d) Adverse events.
- e) The development of microvascular and macrovascular complications.
- f) Mortality.
- g) Health-related quality of life.
- h) Resource use and cost.

#### **4.5 Review questions**

##### **Pharmacological management of blood glucose levels**

- What pharmacological interventions should be used to control blood glucose levels in people with type 2 diabetes? When should pharmacological interventions be used?
- What are the long-term safety issues associated with the use of pharmacological interventions to control blood glucose in people with type 2 diabetes?

##### **Target values for glucose control**

- What are the optimal target values for HbA<sub>1c</sub>, fasting blood glucose, post-prandial blood glucose and oral glucose tolerance in people with type 2 diabetes?

### **Self monitoring of plasma glucose**

- Should self monitoring be used to control blood glucose levels in people with type 2 diabetes?

### **Antithrombotic therapy**

- Does aspirin prevent macrovascular complications in people with type 2 diabetes?
- Does anti-platelet therapy prevent macrovascular complications in people with type 2 diabetes?

### **Erectile dysfunction**

- Should testosterone therapy be used to manage erectile dysfunction in men with type 2 diabetes?

## **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 consultation draft of the scope. The consultation dates are 4 July to 29 August 2012.

### **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 2 diabetes: newer agents](#). NICE clinical guideline 87 (2009)
- [Type 2 diabetes](#). NICE clinical guideline 66 (2008)

#### 5.1.2 NICE guidance to be incorporated

This guideline will incorporate the following NICE guidance:

- TA248 (exenatide prolonged-release) and TA203 (liraglutide) - to be incorporated into the clinical guideline subject to guideline consultation and technology appraisal review consultation on both TA248 and TA203.
- [Diabetic foot problems: inpatient management of diabetic foot problems](#). NICE clinical guideline 119 (2011) - incorporation under discussion.
- [Type 2 diabetes: prevention and management of foot problems](#). NICE clinical guideline 10 (2004) - incorporation under discussion.

#### 5.1.3 Other related NICE guidance

- [Patient experience in adult NHS services](#). NICE clinical guideline 138 (2012).
- [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 guidance 237 (2011).
- [Dexamethasone intravitreal implant for the treatment of macular oedema secondary to retinal vein occlusion](#). NICE technology appraisal guidance 229 (2011).

- [Preventing type 2 diabetes: population and community-level interventions in high-risk groups and the general population](#). NICE public health guidance 35 (2011).
- [Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events](#). NICE technology appraisal guidance 210 (2010).
- [Neuropathic pain](#). NICE clinical guideline 96 (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).
- [Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus](#). NICE technology appraisal guidance 151 (2008).
- [Smoking cessation services](#). NICE public health guidance 10 (2008).
- [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).
- [Type 1 diabetes](#). NICE clinical guideline 15 (2004).

## **5.2 Guidance under development**

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

- Preventing type 2 diabetes: risk identification and interventions for individuals at high risk. NICE Public Health guidance. Publication expected July 2012.
- Lower limb peripheral arterial disease. NICE clinical guideline. Publication expected August 2012.

- Fluocinolone acetonide intravitreal implant for the treatment of diabetic macular oedema. NICE technology appraisal guidance. Publication expected November 2012.
- Obesity – working with local communities. NICE public health guidance. Publication expected 2013.
- Type 1 diabetes (update). NICE clinical guideline. Publication expected 2014.
- Diabetes in children (update). NICE clinical guideline. Publication expected 2014.
- Diabetes in pregnancy. NICE clinical guideline. Publication expected 2014.
- Chronic kidney disease (update). NICE clinical guideline. Publication date to be confirmed.
- Lipid modification (update). NICE clinical guideline. Publication date to be confirmed.
- Buccal insulin for the management of type 1 diabetes. NICE technology appraisal guidance. Publication date to be confirmed.
- Pegaptanib sodium for the treatment of diabetic macular oedema. NICE technology appraisal guidance. Publication date to be confirmed.
- Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion. NICE technology appraisal guidance. Publication date to be confirmed.
- Canagliflozin for the treatment of type 2 diabetes. NICE technology appraisal guidance. Publication date to be confirmed.
- Dapagliflozin in combination with metformin for the fixed dose treatment of type 2 diabetes. NICE technology appraisal guidance. Publication date to be confirmed.
- Empagliflozin for type 2 diabetes. NICE technology appraisal guidance. 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](#).