NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Diabetes in children and young people: diagnosis and management of type 1 and type 2 diabetes in children and young people

1.1 Short title

Diabetes in children and young people

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 for children and young people. 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.

The guideline is also being extended to cover type 2 diabetes in children and young people.

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

3.1.1 Type 1 diabetes

a) Type 1 diabetes is an autoimmune disorder resulting in the destruction of insulin-producing cells in the pancreas. It is predominantly diagnosed in children and young people and inevitably needs insulin replacement treatment.

b) Around 26,500 children and young people in the UK are estimated to have type 1 diabetes needing insulin replacement therapy.

c) Most children and young people diagnosed with type 1 diabetes do not have a family member with the condition, although there may be related disorders such as thyroid or rheumatoid disease in the family. However, a family history of type 1 diabetes does increase a child's risk of developing type 1 diabetes. For children with an identical twin with type 1 diabetes, the risk of developing the disorder is 1 in 3, for children with a father with type 1 diabetes the risk is 1 in 16, and for children with a mother with type 1 diabetes the risk is 1 in 40. By comparison, the population risk is roughly 1 in 500, although this varies with geographical location.

d) Children and young people with type 1 diabetes have poorer glucose control and the higher rates of acute metabolic complications such as diabetic ketoacidosis in comparison with children and young people with type 2 diabetes. Nine per cent of children and young people with diabetes experienced at least 1 episode of diabetic ketoacidosis in 2009–2010.

e) Systems of surveillance for the early detection of complications in children and young people with type 1 diabetes are important, as is effective management of late complications when they occur.

f) Good blood glucose control is known to prevent or delay the long-term complications of both type 1 and type 2 diabetes.

3.1.2 Type 2 diabetes

g) In 2011, around 300 children and young people in the UK had a confirmed diagnosis of type 2 diabetes.

h) 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 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.

i) Obesity is the most common risk factor for type 2 diabetes. Type 2 diabetes is more common in people of South Asian, Chinese, black African and African–Caribbean origin. In Europeans, type 2 diabetes in children is associated with the most severe degrees of obesity.

j) People from the most deprived socioeconomic backgrounds are 2.5 times more likely than average to have type 2 diabetes at any given age.

3.2 Current practice

a) Fewer than 20% of children and young people with diabetes receive the basic care recommended by NICE guidelines.

b) Current standard care for children and young people with diabetes includes patient education, dietary advice, psychological support and management of complications.

c) Standard care for children and young people with type 1 diabetes also includes insulin therapy.

d) For children and young people with type 2 diabetes, first-line care often includes advice on the need for weight loss and the importance of adopting a healthy lifestyle. Metformin may also be used to improve glycaemic control by increasing insulin sensitivity. If good glycaemic control is not achieved then additional insulin or other agents may be needed.

e) The aim of patient education is to enable children and young people and their parents or carers to live a normal life and minimise the risk of complications. It includes advice on diet, improving glycaemic control and how complications are managed.

f) Management of hypoglycaemia depends on its severity. Hospital care may be needed if the child or young person is unresponsive or unconscious, but some children and young people can be cared for at home.

g) It is considered good practice that children and young people with diabetes receive an integrated package of care and that this is delivered by a multidisciplinary care team with expertise in paediatric diabetes, including its clinical, educational, dietetic, lifestyle and psychological management.

h) Children and young people with type 1 diabetes are monitored for growth and pubertal development, blood pressure, injection site

complications, thyroid disease and coeliac disease. Long-term glycaemic control is monitored using haemoglobin A_{1c} (HbA_{1c}). From the age of 12 years they are also monitored for retinopathy and nephropathy by the measurement of microalbuminuria. Rare associated conditions (juvenile cataracts, necrobiosis lipoidica, rheumatoid disease and Addison's disease, among others) may also be considered.

i) Children and young people with type 1 or type 2 diabetes receive annual foot care reviews from the age of 12 years. Minor problems (ingrown toenails or verrucas) are common and may be treated by a chiropodist. Serious foot problems are very rare in children and young people.

j) Psychological and social issues are also important to consider at each clinic visit, and treatment or advice is given where necessary.

k) There is a process of transition so that from the age of 13 years, young people are prepared for eventual transfer to adult care. This includes agreed protocols and joint clinics if possible. Young people are given time to familiarise themselves with this process and it is only completed when they are ready to move to adult services. The timing of transition depends on the young person's physical development, emotional maturity, stability of health, other life changes and local circumstances.

l) Since the publication of Type 1 diabetes (NICE clinical guideline 15), new evidence has been published (or is anticipated) to warrant reconsideration of the following areas of care for children and young people with type 1 diabetes:

- structured education programmes
- behavioural interventions to improve adherence
- insulin regimens (multiple daily injections versus mixed insulin injections)
- strategies for glucose and ketone monitoring

- dietetic advice
- recognition and management of diabetic ketoacidosis
- recognition of complications and comorbidities.

m) Consideration is also being given to the following areas of care for children and young people with type 2 diabetes based on clinical priorities and likely availability of evidence:

- structured education programmes
- behavioural interventions to improve adherence
- dietetic advice
- weight management
- metformin monotherapy
- targets for HbA_{1c}
- recognition and management of diabetic ketoacidosis
- recognition of complications and comorbidities.

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) Children and young people (younger than 18 years) with type 1 diabetes.

b) Children and young people (younger than 18 years) with type 2 diabetes (new 2012).

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

- children and young people with an ethnicity associated with a high prevalence of diabetes
- disabilities (including learning disabilities)
- children and young people with comorbidities (medical or psychological conditions)
- children and young people with poor educational achievement.

4.1.2 Groups that will not be covered

a) Young women with diabetes who wish to conceive or who are pregnant.

b) Children and young people with other forms of diabetes mellitus (for example, monogenic diabetes and cystic fibrosis-related diabetes) (new 2012).

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

d) Adults (aged 18 years and older) with type 2 diabetes.

4.2 Healthcare setting

All settings in which NHS care is received or commissioned.

The guideline will address the support and advice that the NHS should offer to crèches, nurseries, schools and other institutions.

The guideline will also be relevant to the work, but will not cover the practice, of:

- social services and the voluntary sector

- services supplied by secondary and tertiary specialties for late complications of diabetes (for example, renal, cardiology, urology and ophthalmology services) to which patients have been referred
- the education sector.

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

a) The role of c-peptide and antibody testing in the diagnosis of type 1 and type 2 diabetes.

b) Structured education programmes for children and young people with type 1 diabetes.

c) Behavioural interventions to improve adherence in children and young people with type 1 diabetes.

d) Multiple daily injections versus mixed insulin injections in children and young people with type 1 diabetes.

e) HbA_{1c} targets for children and young people with type 1 diabetes.

f) Glucose monitoring strategies in children and young people with type 1 diabetes, including:

- blood glucose targets
- frequency of intermittent testing (finger-prick read by meter)
- continuous glucose monitoring with retrospective (intermittent) versus real-time (long-term) adjustment of treatment.

g) Blood ketone monitoring compared with urine ketone monitoring in children and young people with type 1 diabetes.

h) Dietetic advice, including carbohydrate counting and glycaemic index, for children and young people with type 1 diabetes.

i) Recognition and management of diabetic ketoacidosis in children and young people with type 1 diabetes:

- recognition based on symptoms, signs and biochemical abnormalities
- immediate management at presentation (for example, maintenance of airway, breathing and circulation or the potential need for a nasogastric tube to prevent pulmonary aspiration)
- clinical assessment and investigations at presentation to guide management
- fluid management, including:
  - assessment of dehydration
  - route of administration
  - rate and volume of administration
  - choice of fluid
  - other additives (for example, glucose, potassium and bicarbonate)
- insulin therapy, including:
  - timing
  - route of administration
  - dosage
- anticoagulant prophylaxis to prevent venous thrombosis
- clinical monitoring (to assess the response to treatment and to look for evidence of cerebral oedema), including:
  - general observations (for example, heart and respiratory rate and blood pressure)
  - body weight
  - hydration status

  - fluid balance
  - neurological observations
  - electrocardiographic (ECG) monitoring
- laboratory monitoring (to assess the response to treatment and to look for evidence of hypokalaemia), including:
  - blood glucose
  - blood or urine ketones
  - serum urea and electrolytes
  - acid/base status.

j) Recognition of complications and comorbidities in children and young people with type 1 diabetes (retinopathy and nephropathy).

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

k) Structured education programmes for children and young people with type 2 diabetes.

l) Behavioural interventions to improve adherence in children and young people with type 2 diabetes.

m) Dietetic advice to optimise glycaemic control in children and young people with type 2 diabetes.

n) Weight management in children and young people with type 2 diabetes who are overweight or obese to improve glycaemic control.

o) Metformin monotherapy for children and young people with type 2 diabetes.

p) HbA_{1c} targets for children and young people with type 2 diabetes.

q) Recognition and management of diabetic ketoacidosis in children and young people with type 2 diabetes (the specific aspects to be

covered for this area will be the same as those in section 4.3.1, point h)).

r) Recognition of complications and comorbidities in children and young people with type 2 diabetes (hypertension, dyslipidaemia, retinopathy and nephropathy).

4.3.2 Clinical issues that will not be covered

Areas from the original guideline that will not be updated

The following areas addressed in Type 1 diabetes (NICE clinical guideline 15) will not be updated (the existing recommendations will remain as current guidance):

a) All aspects of diagnosis and initial management in children and young people other than those listed in section 4.3.1, including:

- location of initial management after diagnosis
- advice on the natural history of type 1 diabetes.

b) All aspects of ongoing management other than those listed in section 4.3.1, including:

- insulin preparations, including new short- and long-acting insulins
- methods of delivering insulin
- metformin in addition to insulin for type 1 diabetes
- exercise
- advice on alcohol, smoking and recreational drugs
- long-distance travel
- immunisation.

c) All aspects of complications and associated conditions other than those listed in section 4.3.1, including:

- hypoglycaemia
- care during surgery

- monitoring for complications and comorbidities of type 1 diabetes other than those specified.

d) All aspects of psychological and social issues other than those listed in section 4.3.1, including:

- emotional and behavioural problems, anxiety, depression and eating disorders
- cognitive disorders
- behavioural and conduct disorders
- psychosocial support
- adolescence.

e) Continuity of care, including:

- communication between organisations
- transition from paediatric to adult care.

Areas not covered by the original guideline or the update

f) Management of hypoglycaemia unawareness in children and young people with type 1 diabetes.

g) Glycaemic monitoring strategies for children and young people with type 2 diabetes.

h) Treatment for children and young people with type 2 diabetes in whom glycaemic control is not maintained with metformin.

i) Bariatric surgery for children and young people with type 2 diabetes.

j) Monitoring for complications and comorbidities of type 2 diabetes other than those specified in section 4.3.1.

k) Management of complications and comorbidities of type 1 or type 2 diabetes.

l) Contraceptive, pre-pregnancy and conception advice for children and young people with type 1 or type 2 diabetes.

m) Foot care for children and young people with type 1 or type 2 diabetes.

4.4 Main outcomes

a) Glycaemic control.

b) Any adverse effects of interventions used to manage type 1 or type 2 diabetes.

c) Health-related quality of life (validated questionnaire), for example, diabetes-specific health-related quality of life.

d) Complications of diabetes.

e) Mortality.

f) Psychological outcomes.

g) Patient satisfaction.

4.5 Review questions

These are draft review questions and the final questions will be agreed by the Guideline Development Group during development.

Type 1 diabetes

- What is the effectiveness of c-peptide and antibody tests to distinguish type 1 and type 2 diabetes?
- What is the effectiveness of structured education programmes in improving clinical and patient outcomes in children and young people with type 1 diabetes?
- What is the effectiveness of behavioural interventions to improve outcomes in children and young people with type 1 diabetes?

- What is the effectiveness of multiple daily injections of insulin when compared with mixed insulin injections in improving glycaemic control in children and young people with type 1 diabetes?
- What is the optimal HbA_{1c} target for children and young people with type 1 diabetes?
- What are the optimal blood glucose targets for children and young people with type 1 diabetes?
- How frequently should finger-prick blood glucose testing be performed in children and young people with type 1 diabetes?
- What is the effectiveness of continuous glucose monitoring performed intermittently compared with continuous glucose monitoring performed in real-time in children and young people with type 1 diabetes?
- What is the effectiveness of blood ketone monitoring compared with urine ketone monitoring for the prevention of diabetic ketoacidosis?
- What is the effectiveness of dietetic advice using carbohydrate counting in maintaining glycaemic control in children and young people with type 1 diabetes?
- What is the effectiveness of dietetic advice using glycaemic index in maintaining glycaemic control in children and young people with type 1 diabetes?
- What is the predictive value of symptoms, signs and biochemical abnormalities as indicators of diabetic ketoacidosis in children and young people?
- What routine assessments and investigations should be used to guide management in children and young people who present with diabetic ketoacidosis?
- What is the appropriate route of administration for fluids in children and young people with diabetic ketoacidosis?
- At what rate should children and young people with diabetic ketoacidosis be rehydrated?
- What is the optimal fluid composition (including glucose, potassium and bicarbonate additives) for rehydrating children and young people with diabetic ketoacidosis?

- When should intravenous insulin therapy be started and stopped in children and young people with diabetic ketoacidosis?
- How should the dosage of insulin be calculated for children and young people with diabetic ketoacidosis?
- What is the effectiveness of routine anticoagulant prophylaxis to prevent venous thrombosis in children and young people with diabetic ketoacidosis?
- Which of the following should be performed as clinical monitoring during treatment of diabetic ketoacidosis in children and young people:
  - general observations (for example, heart and respiratory rate and blood pressure)
  - body weight
  - hydration status
  - fluid balance
  - neurological observations
  - ECG monitoring?

- Which of the following laboratory investigations should be performed to monitor children and young people during treatment for diabetic ketoacidosis:
  - blood glucose
  - blood or urine ketones
  - serum urea or electrolytes
  - acid/base status?

- What is the optimal monitoring strategy for identifying retinopathy in children and young people with type 1 diabetes?
- What is the optimal monitoring strategy for identifying nephropathy in children and young people with type 1 diabetes?

Type 2 diabetes

- What is the effectiveness of structured education programmes in improving clinical and patient outcomes in children and young people with type 2 diabetes?

- What is the effectiveness of behavioural interventions to promote engagement with clinical services in children and young people with type 2 diabetes?
- What is the effectiveness of behavioural interventions to improve outcomes in children and young people with type 2 diabetes?
- What is the effectiveness of dietetic advice to optimise glycaemic control in children and young people with type 2 diabetes?
- Does weight loss in children and young people with type 2 diabetes who are overweight or obese improve glycaemic control as measured by HbA_{1c}?
- What is the effectiveness of metformin in improving glycaemic control in children and young people with type 2 diabetes when compared with usual care or placebo?
- What is the optimal HbA_{1c} target for children and young people with type 2 diabetes?
- What is the predictive value of symptoms, signs and biochemical abnormalities as indicators of diabetic ketoacidosis in children and young people?
- What routine assessments and investigations should be used to guide management in children and young people who present with diabetic ketoacidosis?
- What is the appropriate route of administration for fluids in children and young people with diabetic ketoacidosis?
- At what rate should children and young people with diabetic ketoacidosis be rehydrated?
- What is the optimal fluid composition (including glucose, potassium and bicarbonate additives) for rehydrating children and young people with diabetic ketoacidosis?
- When should intravenous insulin therapy be started and stopped in children and young people with diabetic ketoacidosis?
- How should the dosage of insulin be calculated for children and young people with diabetic ketoacidosis?

- What is the effectiveness of routine anticoagulant prophylaxis to prevent venous thrombosis in children and young people with diabetic ketoacidosis?
- Which of the following should be performed as clinical monitoring during treatment of diabetic ketoacidosis in children and young people:
  - general observations (for example, heart and respiratory rate and blood pressure)
  - body weight
  - hydration status
  - fluid balance
  - neurological observations
  - ECG monitoring?

- Which of the following laboratory investigations should be performed to monitor children and young people during treatment for diabetic ketoacidosis:
  - blood glucose
  - blood or urine ketones
  - serum urea or electrolytes
  - acid/base status?

- What is the optimal monitoring strategy for identifying hypertension in children and young people with type 2 diabetes?
- What is the optimal monitoring strategy for identifying dyslipidaemia in children and young people with type 2 diabetes?
- What is the optimal monitoring strategy for identifying retinopathy in children and young people with type 2 diabetes?
- What is the optimal monitoring strategy for identifying nephropathy in children and young people 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

Scope

This is the final scope.

Timing

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

5 Related NICE guidance

5.1 Published guidance

Related NICE guidance

- Preventing type 2 diabetes: risk identification and interventions for individuals at high risk. NICE public health guidance 38 (2012).
- Anxiety. NICE clinical guideline 113 (2011).
- Preventing type 2 diabetes: population and community interventions. NICE public health guidance 35 (2011).
- Depression with a chronic physical health problem. NICE clinical guideline 91 (2010).
- Type 2 diabetes. NICE clinical guideline 87 (2009).
- Coeliac disease. NICE clinical guideline 86 (2009).
- Medicines adherence. NICE clinical guideline 76 (2009).
- Promoting physical activity for children and young people. NICE public health guidance 17 (2009).
- Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal guidance 151 (2008).

- Obesity. NICE clinical guideline 43 (2006).
- Four commonly used methods to increase physical activity. NICE public health guidance 2 (2006).
- Type 2 diabetes: footcare. NICE clinical guideline 10 (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).

5.2 Guidance under development

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

- Obesity – working with local communities. NICE public health guidance. Publication expected November 2012.
- Overweight and obese children and young people – lifestyle weight management services. NICE public health guidance. Publication expected October 2013.
- Type 1 diabetes in adults (update). NICE clinical guideline. Publication expected July 2014.
- Type 2 diabetes in adults (update). NICE clinical guideline. Publication expected July 2014.
- Diabetes in pregnancy (update). NICE clinical guideline. Publication expected June 2014.
- 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.

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.