



PRACTICE

GUIDELINES

Diagnosis and management of type 1 diabetes in adults: summary of updated NICE guidance

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This is one of a series of BMJ summaries of new guidelines based on the best available evidence; they highlight important recommendations for clinical practice, especially where uncertainty or controversy exists.

Having type 1 diabetes reduces the life expectancy of adults in the United Kingdom by as much as 13 years.¹ Despite incontrovertible evidence that good care reduces the risk of complications such as blindness, renal failure, and premature cardiovascular disease and death,² as well as complications of treatment such as severe hypoglycaemia,³ fewer than 30% of UK adults with type 1 diabetes achieve current national treatment targets for glucose control.⁴ The challenges of managing type 1 diabetes do not lessen after the age of 18 years. Since the publication of the 2004 National Institute for Health and Care Excellence (NICE) guideline, new technologies to achieve diabetic control have become available—for example, insulin analogues, new glucose meters, and real time subcutaneous continuous glucose monitoring systems. The recent updated NICE guidance aims to support healthcare professionals and adults with type 1 diabetes to use these technologies optimally and to individualise targets and treatment regimens for greater lifestyle flexibility, with clear advice on education programmes, glucose monitoring, and insulin preparations.

This article summarises the most recent recommendations from NICE on the diagnosis and management of type 1 diabetes in adults.⁵

Recommendations

NICE recommendations are based on systematic reviews of best available evidence and explicit consideration of cost effectiveness. When minimal evidence is available, recommendations are based on the Guideline Development

Group's experience and opinion of what constitutes good practice. Evidence levels for the recommendations based on the GRADE method⁶ are given in italics in square brackets.

Diagnosis

- Diagnose type 1 diabetes on clinical grounds:
 - Ketosis
 - Rapid weight loss
 - Age of onset below 50 years
 - Body mass index (BMI) below 25
 - Personal or family history of autoimmune disease. (New recommendation.)
- However, do not discount a diagnosis of type 1 diabetes in people aged 50 years or more or those with a BMI of 25 or above. (New recommendation.)
- In any person of any age or BMI presenting with thirst and excessive micturition in whom diabetes is suspected, particularly those with weight loss or nausea, check random blood glucose and blood or urinary ketones. The presence of ketonuria or ketonaemia should raise suspicion of type 1 diabetes. Diabetic ketoacidosis (ketonaemia ≥ 3 mmol/L, or $>2+$ ketonuria on strip testing; venous bicarbonate <15 mmol/L, or venous pH <7.3 , or a combination thereof) is a medical emergency.⁷ Lesser degrees of ketosis with hyperglycaemia (>11 mmol/L) will probably also require urgent institution of insulin therapy.
- Consider further investigation (measurement of C peptide or diabetes specific autoimmune antibodies, or both) if there are atypical features (age ≥ 50 years, BMI ≥ 25 , slow evolution of hyperglycaemia, or long prodrome) or

The bottom line

- Offer all adults with type 1 diabetes a structured education programme in self management of diabetes six to 12 months after diagnosis or, if this was not achieved, at any time that is clinically appropriate and suitable for the person
- Support adults to aim for a target glycated haemoglobin 48 mmol/mol (6.5%) or lower, to minimise risk of vascular complications; ensure that aiming for the target is not accompanied by problematic hypoglycaemia, and support four to 10 daily self monitoring blood tests as routine
- Offer all adults daily basal-bolus insulin injection regimens, with twice daily insulin detemir as basal insulin therapy and rapid acting insulin analogues injected before meals for mealtime insulin "boluses"
- Assess awareness of hypoglycaemia at least annually using a scoring system

How patients were involved in the creation of this article

Patients were involved at every stage of creating the guideline. Patient groups and individuals contributed to the scoping of the update and at the consultation stage. Lay members were active in the Guideline Development Group, contributing to the formulation of the recommendations summarised here, and were instrumental in setting the new treatment targets.

uncertainty exists about the type of diabetes. (New recommendation.)

- *[Based on evidence from cross sectional observational studies and case series and the opinion of the Guideline Development Group (GDG).]*

Education and information

- Offer all adults with type 1 diabetes a structured education programme in the self management of flexible insulin therapy (for example the DAFNE (dose adjustment for normal eating) programme⁸) six to 12 months after diagnosis or at any time that is clinically appropriate and suitable for the person, regardless of duration of type 1 diabetes. Such programmes aim to transfer skills of insulin dose adjustment to the person with diabetes, enabling diabetic control with minimal risk of acute complications of therapy (diabetic ketoacidosis and hypoglycaemia)⁹ and long term vascular complications (visual loss, renal failure, nerve damage, and vascular disease),¹⁰ while allowing flexibility of lifestyle and good quality of life.¹¹ They fulfil the requirements of structured therapeutic education, which include evidence of the programme's efficacy, a written curriculum, delivery by trained educators, and a quality assurance programme to ensure consistency and regular audit of its outcomes.¹² (New recommendation.)
- Provide an alternative of equal standard for those not able to participate in group education and ensure that this includes the components of structured therapeutic education. (New recommendation.)
- Carry out a formal review of patients' ability to manage their insulin regimen annually, and their need for support from healthcare professionals, including assessment of their achievement of glucose targets, their freedom from problematic hypoglycaemia, and the management of their risk of complications. (Amended recommendation.)
- *[Based on very low to moderate and high quality evidence from randomised controlled trials (RCTs), the experience and opinion of the GDG, and a cost-utility study with potentially serious limitations and direct applicability.]*

Dietary management and physical activity

- Offer carbohydrate counting training to adults with type 1 diabetes as part of structured education programmes. (New recommendation.)
- *[Based on very low to moderate quality evidence from RCTs, observational studies, and the opinion of the GDG.]*

- Offer dietary advice about matters other than blood glucose control, such as weight control and cardiovascular risk management, as indicated clinically. (New recommendation.)

- *[Based on the opinion and experience of the GDG.]*

- Do not advise adults to follow a low glycaemic index diet for blood glucose control. The GDG found no evidence of benefit for glycaemic control, frequency of hypoglycaemia, or quality of life. (New recommendation.)

- *[Based on very low to low quality evidence from randomised and non-randomised controlled trials.]*

- Advise adults with type 1 diabetes that physical activity can reduce their increased cardiovascular risk in the medium and longer term.

- *[Based on evidence from randomised and non-randomised controlled trials and observational studies in the 2004 NICE guideline (GRADE assessment not performed).]*

Blood glucose management

- Measure glycated haemoglobin (HbA_{1c}) every three to six months, or more often if blood glucose control might be changing rapidly, and ensure that the result is available at the time of consultation. (New recommendation.)
- Support adults with type 1 diabetes to aim for a target HbA_{1c} of 48 mmol/mol (6.5%) or lower to minimise the risk of vascular complications. (New recommendation.)
- Agree an individualised target based on daily activities, aspirations, likelihood of complications, comorbidities, occupation, and history of hypoglycaemia. Most adults should be supported to aim for the recommended target, but adjust the numerical value in, for example, frail elderly patients, and those with limited life expectancy or advanced vascular complications. Take care to help people in occupations with a high risk of accidents to avoid hypoglycaemia; this can be achieved by good education and, where indicated, use of newer technologies for insulin delivery and glucose monitoring, although some people may also need the target to be modified. (New recommendation.)
- Ensure that aiming for the target is not accompanied by problematic hypoglycaemia. (New recommendation.)
- *[Based on evidence from RCTs, prospective case series studies, cross sectional observational studies, and an original economic analysis with potentially serious limitations but direct applicability.]*

Self monitoring of blood glucose

- Advise routine monitoring at least four times a day, before each meal and before bed. (New recommendation.)
- Support self monitoring up to 10 times a day and enable more than this if necessitated by the person's lifestyle. (New recommendation.)
- Advise patients to aim for a fasting plasma glucose of 5-7 mmol/L before breakfast; 4-7 mmol/L before meals at other times of day, and, if patients chose to test after meals, 5-9 mmol/L at least 90 minutes after eating. Agree a bedtime target that accounts for the time of the last meal. (New recommendation.)
- *[Based on low quality evidence from RCTs, non-comparative observational studies, and an original economic analysis with potentially serious limitations but direct applicability.]*
- Teach self monitoring skills at diagnosis and educate patients to interpret and use the results, reviewing their skills at least annually. (Amended recommendation.)
- Do not recommend routine use of sites other than the fingertips for testing. (Amended recommendation.)
- Do not routinely offer real time continuous glucose monitoring (use of subcutaneous sensors for measuring glucose continuously), but consider it for patients willing to use it at least 70% of the time if they are experiencing problematic hypoglycaemia despite optimised use of insulin (multiple daily injections of insulin or pump therapy) and conventional monitoring. (New recommendation.)
- *[Based on very low to moderate quality evidence from RCTs, cost-utility studies with potentially serious limitations and partial applicability, and an original economic analysis with potentially serious limitations but direct applicability.]*

Insulin therapy

- Offer multiple daily insulin injection basal-bolus regimens, rather than twice daily mixed insulin regimens. Such regimens control endogenous glucose production with slow acting insulins ("basal" insulin), to which fast acting insulin "boluses" are added before a meal or snack. In flexible therapy, doses of basal insulin are based on fasting glucose readings and readings made five or more hours after eating; doses for meal insulin are based on the current blood glucose test result and the amount of carbohydrate the patient plans to eat. All doses can be adjusted prospectively, after reviewing the effectiveness of doses taken in the past few days, or to accommodate exercise or other predicted changes in insulin requirement. Bolus doses of fast acting insulin can also be used to correct a glucose reading that is over target.
- Do not offer newly diagnosed patients non-basal-bolus regimens. (New recommendation.)
- Basal-bolus regimens include:
Basal insulin to control endogenous glucose production:
-Offer twice daily insulin detemir as basal insulin therapy (New recommendation.)
-As an alternative, consider an existing regimen that is delivering agreed glucose targets or once daily glargine or detemir, if the twice daily regimen is not acceptable to the patient

-Consider other regimens only if the above do not deliver agreed targets (New recommendation.)

-For guidance on use of continuous subcutaneous insulin ("pump") therapy, refer to the NICE technology appraisal.¹³ (New recommendation.)

- *[Based on very low to high quality evidence from RCTs, a network meta-analysis, cost-utility studies with minor to very serious limitations and partial or direct applicability, and an original economic analysis with potentially serious limitations and direct applicability.]*

Bolus insulin to cover ingestion of food (primarily carbohydrate):

-Offer rapid acting insulin analogues injected before meals for mealtime insulin replacement (New recommendation.)

-Do not advise routine use of rapid acting insulin analogues after meals. Delayed injection increases the risk of high blood glucose immediately after eating (because the glucose from the food is absorbed before the insulin is active) and of late hypoglycaemia (because the insulin continues to act after the food related glucose has gone) (New recommendation.)

Respect the wishes of the patient in choosing a rapid acting insulin. (New recommendation.)

- *[Based on very low to moderate quality evidence from RCTs and cost-utility studies with potentially serious limitations and partial or direct applicability.]*

Awareness and management of hypoglycaemia

- Assess awareness of hypoglycaemia at least annually, using a scoring system. For example, ask patients to rate their awareness from 1 (always aware of their hypoglycaemia) to 7 (never aware of their hypoglycaemia) and consider a score of 4 or more to indicate impaired awareness with high risk of severe hypoglycaemia.¹⁴
- Ensure that people with impaired hypoglycaemia awareness receive structured education in flexible insulin therapy using basal-bolus regimens, and offer additional education around avoidance and treatment of hypoglycaemia if needed. (New recommendation.)
- *[Based on low quality evidence from observational studies and the opinion of the GDG.]*
- Avoid raising agreed blood glucose targets as a treatment for impaired awareness of hypoglycaemia and reinforce recommended targets if the person prefers lower ones. (New recommendation.)
- First reinforce principles of structured education, then offer "pump" therapy, and then offer real time glucose monitoring if impaired awareness of hypoglycaemia persists. (New recommendation.)
- *[Based on very low to moderate quality evidence from RCTs, cohort studies, and low quality case series.]*

Overcoming barriers

Implementing the recommendations will require adequate resourcing and training of the healthcare workforce to help healthcare professionals and people with diabetes understand the importance of glycaemic control; to deliver the mandated structured education programmes in flexible insulin therapy; to support glucose self monitoring; and to identify and help patients

who need additional support, including enhanced techniques of insulin delivery and glucose monitoring (pumps and glucose sensors). The aim is to help people achieve their targets for glycaemic control and thereby reduce long term complications, while avoiding asymptomatic, severe hypoglycaemia, and acute emergencies, while also optimising quality of life. Solutions may include creating skilled teams that can deliver education and psychological support across wide geographical areas, and greater use of communication technology in delivering structured education “refresher” courses and accessing specialist advice on regimen change. More effective monitoring for, and treatment of, risk factors for long term complications also require stronger engagement between primary and specialist care, ideally with access to shared data systems.

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Contributors: SAA, NP, and BH contributed to the conception of this article. SAA, NP, and DD contributed to the acquisition, analysis, and interpretation of data. All authors contributed to drafting and critical revision of this article. All authors approved the final version for publication. NP is guarantor.

Funding: NP, BH, and DD are employed by the Royal College of Physicians, London at the National Clinical Guideline Centre, which is commissioned and funded by NICE to develop clinical guidelines. No authors received specific funding to write this summary.

Competing interests: We declare the following interests based on NICE's policy on conflicts of interests (available at www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/code-of-practice-for-declaring-and-managing-conflicts-of-interest.pdf): BH is employed by the Royal College of Physicians, London and Newcastle upon Tyne Hospitals NHS Foundation Trust. NP is employed by the Royal College of Physicians, London. SAA is employed by King's College London. DD is employed by the Royal College of Physicians, London. The authors'

full statements can be viewed at www.bmj.com/content/351/bmj.h4188/related#datasupp.

Provenance and peer review: Commissioned; not externally peer reviewed.

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Cite this as: *BMJ* 2015;351:h4188

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Further information on the guidance

The National Diabetes Audit showed that targets for glycaemic control were not being met and that regional variations existed in the proportions of patients achieving these targets, the use of currently available insulins, the availability of accredited structured education programmes, and the proportion of patients using insulin pumps.⁴

Some recommendations in the updated guideline may seem aspirational but are necessary to improve clinical outcomes for adults with type 1 diabetes. The tighter targets for glycaemic control require adequate resourcing and a culture shift in the health service, so that the workforce believes in the importance of achieving these targets and can support people with diabetes to do so comfortably and safely. The National Institute for Health and Care Excellence (NICE) has developed an educational tool for healthcare professionals.¹³ However, even where good structured education has been delivered,⁵ people may struggle to sustain the strategies they have learnt.¹¹ Techniques to help deliver sustainable behaviour change may be the key to greater long term success.¹²

Hypoglycaemia and fear of hypoglycaemia, as well as fear of weight gain, remain barriers to optimal insulin therapy. Yet the evidence is that structured education programmes reduce severe hypoglycaemia risk even more than glycated haemoglobin (HbA_{1c}).¹⁴ Technologies such as pumps and sensors can be beneficial and their cost effectiveness enhanced if properly used within a care pathway that starts with structured education and adds these technologies as needed to people who already know how to adjust insulin doses. This ensures that the technologies go first to people who need them most.

Services should document the proportion of patients achieving an HbA_{1c} of 53 mmol/mol (7%) or lower (new recommendation). In the major randomised controlled trial of intensified versus conventional insulin therapy in people with type 1 diabetes, this is the approximate HbA_{1c} value that was associated with long term benefit (fewer complications and reduced premature mortality).¹⁵ It should be noted that the target for control in this study was 42.6 mmol/mol (6.05%).

What's new

- Reduction of the HbA_{1c} target from 53 mmol/mol to 48 mmol/mol, with an audit standard of the proportion of people achieving 53 mmol/mol rather than 58 mmol/mol, based on evidence that achieved glycated haemoglobin is always higher than the target set^{15,4}
- Twice daily detemir as the basal insulin regimen of choice, based on a network meta-analysis,⁵ audit data,¹⁶ and original economic analysis⁵ showing its effectiveness and cost effectiveness, especially with structured education programmes
- Annual assessment of awareness of hypoglycaemia, based on growing recognition of the increased risk of severe hypoglycaemia in people with impaired awareness
- More frequent daily routine glucose self monitoring with strips, based on evidence showing better glycated haemoglobin with increased self testing
- Appropriate use of continuous glucose monitoring

Methods

The updated guideline was developed in accordance with NICE guideline methodology (<http://publications.nice.org.uk/the-guidelines-manual-pmg6>). The Guideline Development Group (GDG) included diabetologists, nurse and dietitian diabetes educators, patient representatives, a general practitioner, a chemical pathologist, and a pharmacist, as well as the research and technical staff from NICE. It developed clinical questions and protocols a priori, undertook systematic literature searching, appraised the evidence, and evaluated cost effectiveness of interventions through review of published evaluations and economic modelling. The quality of the evidence was assessed using the GRADE methodology (www.gradeworkinggroup.org). The guideline was subject to a rigorous validation process, during which stakeholder organisations were invited to comment. All comments were considered in producing the final version.

The guideline is available in three formats: a short version; a full version (including all evidence; www.nice.org.uk/guidance/ng17/evidence); and information for the public for people with type 1 diabetes, their families and carers, and the general public (www.nice.org.uk/guidance/ng17/informationforpublic).

Implementation and costing tools have been developed and are available at the NICE website (www.nice.org.uk/guidance/ng17/resources.)

Further updates of the guidance will be produced as part of NICE's guideline development programme.

Future research

The GDG prioritised these five research recommendations:

- What methods and interventions are effective in increasing the number of adults with type 1 diabetes who achieve the recommended HbA_{1c} targets without risking severe hypoglycaemia or weight gain?
- In adults who have chronically poor control of blood glucose levels, what is the clinical and cost effectiveness of continuous glucose monitoring technologies?
- What methods can increase the uptake of structured education programmes and improve their clinical outcomes (particularly achieving and sustaining blood glucose control targets)?
- Could a risk stratification tool help set individualised HbA_{1c} targets?
- In preventing and treating impaired awareness of hypoglycaemia, what are the most clinically and cost effective technologies (such as insulin pump therapy or continuous glucose monitoring (or both); partially or fully automated insulin delivery; and behavioural, psychological and educational interventions)? How are they best used?