



Type 1 diabetes in adults: diagnosis and management

NICE guideline

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

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

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

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This guideline replaces TA53, TA60 and ESNM24.

This guideline partially replaces CG15.

This guideline is the basis of QS109 and QS6.

Overview

This guideline covers care and treatment for adults (aged 18 and over) with type 1 diabetes. It includes advice on diagnosis, education and support, blood glucose management, cardiovascular risk, and identifying and managing long-term complications.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- Adults with type 1 diabetes, and their families and carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care.

<u>Making decisions using NICE guidelines</u> explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

Blood glucose and plasma glucose

'Blood glucose' is the more commonly used term. However, a lot of the evidence this guideline is based on uses 'plasma' rather than 'blood' glucose, and patient-held glucose meters and monitoring systems are calibrated to plasma glucose equivalents. Because of this, in this guideline we use the term 'blood glucose', except when referring to specific concentration values.

1.1 Diagnosis and early care plan

Initial diagnosis

- 1.1.1 Make an initial diagnosis of type 1 diabetes on clinical grounds in adults presenting with hyperglycaemia. Bear in mind that people with type 1 diabetes typically (but not always) have 1 or more of:
 - ketosis
 - rapid weight loss
 - age of onset under 50 years
 - BMI below 25 kg/m²
 - personal and/or family history of autoimmune disease. [2015, amended 2022]
- 1.1.2 Do not use age or BMI alone to exclude or diagnose type 1 diabetes in adults. [2022]

- 1.1.3 Take into consideration the possibility of other diabetes subtypes and revisit the diagnosis at subsequent clinical reviews. Carry out further investigations if there is uncertainty (see <u>recommendations 1.1.7 and 1.1.8</u>). [2022]
- 1.1.4 Measure diabetes-specific autoantibodies in adults with an initial diagnosis of type 1 diabetes, taking into account that:
 - the false negative rate of diabetes-specific autoantibody tests is lowest at the time of diagnosis
 - the false negative rate can be reduced by carrying out quantitative tests for 2 different diabetes-specific autoantibodies (with at least 1 being positive). [2022]
- 1.1.5 Do not routinely measure serum C-peptide to confirm type 1 diabetes in adults. [2022]
- 1.1.6 In people with a negative diabetes-specific autoantibody result, and if diabetes classification remains uncertain, consider measuring non-fasting serum C-peptide (with a paired blood glucose). [2022]

Revisiting initial diagnosis

- 1.1.7 At subsequent clinical reviews, consider using serum C-peptide to revisit the diabetes classification if there is doubt that type 1 diabetes is the correct diagnosis. [2022]
- 1.1.8 Take into account that the discriminative value of serum C-peptide to diagnose type 1 diabetes increases the longer the test is done after initial diagnosis of diabetes. [2022]
- 1.1.9 For people aged 60 and over presenting with weight loss and new-onset diabetes, follow recommendations on assessing for pancreatic cancer in the section on pancreatic cancer in the NICE guideline on suspected cancer: recognition and referral. [2022]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on diagnosis</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review C</u>: <u>diagnosis</u> of diabetes.

Early care plan

- 1.1.10 At diagnosis (or, if necessary, after managing critically decompensated metabolism), the diabetes professional team should work with adults with type 1 diabetes to develop a plan for their early care. This will generally require:
 - medical assessment to:
 - ensure the diagnosis is accurate (see recommendations 1.1.1 to 1.1.5)
 - ensure appropriate acute care is given when needed
 - review medicines and detect potentially associated disease
 - detect adverse vascular risk factors
 - environmental assessment to understand:
 - the social, home, work and recreational circumstances of the person and their carers
 - their lifestyle (including diet and physical activity)
 - other relevant factors, such as substance use
 - cultural and educational assessment to:
 - find out what they know about diabetes
 - help with tailoring advice, and with planning treatments and diabetes education programmes
 - assessment of their emotional wellbeing to decide how to pace diabetes education.
 [2004]
- 1.1.11 Use the results of the initial diabetes assessment to agree a future care plan.

This assessment should include:

- acute medical history
- social, cultural and educational history, and lifestyle review
- complications history and symptoms
- diabetes history (recent and long term)
- other medical history
- family history of diabetes and cardiovascular disease
- medication history
- vascular risk factors
- smoking
- general examination
- weight and BMI
- foot, eye and vision examination
- urine albumin:creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR)
- psychological wellbeing
- attitudes to medicine and self-care
- immediate family and social relationships, and availability of informal support. [2004, amended 2021]
- 1.1.12 Include the following in an individualised and culturally appropriate diabetes plan:
 - when and where they will have their diabetes education, including their dietary advice (see the <u>sections on education and information</u> and <u>dietary management</u>)
 - initial treatment, including guidance on insulin injection and insulin regimens (see the sections on insulin therapy and insulin delivery)

- self-monitoring and targets (see the <u>section on blood glucose management</u>)
- symptoms, and the risk of hypoglycaemia and how it is treated
- management of special situations, such as driving
- communicating with the diabetes professional team (how often and how to contact them)
- management of cardiovascular risk factors (see the <u>section on control of</u> cardiovascular risk)
- implications for pregnancy and family planning advice (see NICE's guideline on diabetes in pregnancy)
- how often they will have follow-up appointments, and what these will cover (including review of HbA1c levels, experience of hypoglycaemia, and annual reviews). [2004, amended 2015]
- 1.1.13 After the initial plan is agreed, implement it without inappropriate delay. Based on discussion with the adult with type 1 diabetes, modify the plan as needed over the following weeks. [2004]

1.2 Support and individualised care

- 1.2.1 Take account of any disabilities, including visual impairment, when planning and delivering care for adults with type 1 diabetes. [2015]
- 1.2.2 Advice to adults with type 1 diabetes should be provided by a range of professionals with skills in diabetes care, working together in a coordinated approach. [2004, amended 2021]
- 1.2.3 Provide adults with type 1 diabetes with:
 - access to services by different methods (including phone and email) during working hours
 - information about out-of-hours services staffed by people with diabetes expertise. [2004]
- 1.2.4 View each adult with type 1 diabetes as an individual, rather than as a member

of any cultural, economic or health-affected group (also see recommendations 1.4.5 and 1.4.14 on cultural preferences in the section on dietary advice). [2004, amended 2015]

- 1.2.5 Jointly agree an individual care plan with the adult with type 1 diabetes. Review this plan annually and amend it as needed, taking into account changes in the person's wishes, circumstances and medical findings. [2004, amended 2015]
- 1.2.6 Individual care plans should include:
 - diabetes education, including dietary advice (see the <u>sections on education and</u> <u>information</u> and <u>dietary management</u>)
 - insulin therapy, including dosage adjustment (see the <u>sections on insulin therapy</u> and <u>insulin delivery</u>)
 - self-monitoring (see the <u>section on blood glucose management</u>)
 - avoiding hypoglycaemia and maintaining hypoglycaemia awareness
 - family planning, contraception and pregnancy planning (see <u>NICE's guideline on diabetes in pregnancy</u>)
 - cardiovascular risk factor monitoring and management (see the <u>section on control of</u> cardiovascular risk)
 - complications monitoring and management (see the <u>section on managing</u> complications)
 - communicating with the diabetes professional team (how often and how to contact them)
 - how often they will have follow-up appointments, and what these will cover (including review of HbA1c levels, experience of hypoglycaemia, and annual reviews). [2004, amended 2015]
- 1.2.7 Use population, practice-based and clinic diabetes registers (as specified by the Department of Health and Social Care's national service framework for diabetes) to assist programmed recall for annual reviews and assessments of complications and cardiovascular risk. [2004]

1.2.8 At diagnosis and periodically after this, give adults with type 1 diabetes up-to-date information about diabetes support groups (local and national), how to contact them and their benefits. [2004]

1.3 Education and information

- 1.3.1 Offer all adults with type 1 diabetes a structured education programme of proven benefit, for example, the <u>DAFNE (dose adjustment for normal eating)</u> programme. [2015]
- 1.3.2 Offer the structured education programme 6 to 12 months after diagnosis. For adults who have not had a structured education programme by 12 months, offer it at any time that is clinically appropriate and suitable for the person, regardless of how long they have had type 1 diabetes. [2015]
- 1.3.3 For adults with type 1 diabetes who are unable or prefer not to take part in group education, provide an alternative of equal standard. [2015]
- 1.3.4 Ensure that any structured education programme for adults with type 1 diabetes:
 - is evidence-based, and suits the needs of the person
 - has specific aims and learning objectives, and supports the person and their family members and carers in developing attitudes, beliefs, knowledge and skills to self-manage diabetes
 - has a structured curriculum that is theory driven, evidence-based and resource effective and has supporting materials, and is written down
 - is delivered by trained educators who:
 - have an understanding of educational theory appropriate to the age and needs of the person and
 - are trained and competent to deliver the principles and content of the programme
 - is quality assured, and reviewed by trained, competent, independent assessors who measure it against criteria that ensure consistency
 - has outcomes that are audited regularly. [2015]

- 1.3.5 Explain to adults with type 1 diabetes that structured education is an integral part of diabetes care. [2015]
- 1.3.6 Provide information about type 1 diabetes and its management to adults with type 1 diabetes at all opportunities from diagnosis onwards. Follow the principles in NICE's guideline on patient experience in adult NHS services.
 [2015]
- 1.3.7 Consider the Blood Glucose Awareness Training (BGAT) programme for adults with type 1 diabetes who are having recurrent episodes of hypoglycaemia (see also the section on hypoglycaemia awareness and management). [2015]
- 1.3.8 Carry out an annual review of self-care and needs for all adults with type 1 diabetes. Decide what to cover each year by agreeing priorities with the adult with type 1 diabetes. [2004, amended 2015]

1.4 Dietary management

Carbohydrate counting

- 1.4.1 Offer carbohydrate-counting training to adults with type 1 diabetes as part of structured education programmes for self-management (see the <u>section on education and information</u>). [2015]
- 1.4.2 Consider carbohydrate-counting courses for adults with type 1 diabetes who are waiting for a more detailed structured education programme or who are unable to take part in a standalone structured education programme. [2015]

Glycaemic index diets

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

Dietary advice

1.4.4 Offer dietary advice to adults with type 1 diabetes about issues other than blood glucose control (such as managing weight and cardiovascular risk), as needed. [2015]

- 1.4.5 From diagnosis, provide nutritional information that is sensitive to the personal needs and culture of each adult with type 1 diabetes. [2004]
- 1.4.6 Provide nutritional information individually and as part of a structured education programme (see the <u>section on education and information</u>). Include advice from professionals who are trained and accredited to provide dietary advice to people with health conditions. [2004]
- 1.4.7 Offer opportunities to receive dietary advice at intervals agreed between adults with type 1 diabetes and their healthcare professionals. [2004]
- 1.4.8 Discuss the hyperglycaemic effects of the different foods the adult with type 1 diabetes wants to eat in the context of the insulin regimens chosen to match those food choices. [2004]
- 1.4.9 Provide education programmes for adults with type 1 diabetes to help them with:
 - · healthy eating and a balanced diet
 - changing their insulin dosage to reduce glucose excursions when varying their diet.
 [2004, amended 2015]
- 1.4.10 Discuss snacks with the adult with type 1 diabetes:
 - Cover the choice of snack, the quantity, and when to eat them.
 - Explain the effects of eating different food types, and how long these effects last.
 - Explain which insulin regimens are available to match different food types.
 - Discuss changes in choice of snack if needed, based on the results of self-monitoring tests. [2004]
- 1.4.11 Provide information on:
 - the effects of different alcohol-containing drinks on blood glucose excursions and calorie intake
 - high-calorie and high-sugar 'treats'. [2004, amended 2015]

- 1.4.12 As part of dietary education after diagnosis (and as needed after this), provide information on how healthy eating can reduce cardiovascular risk. Include information about fruit and vegetables, types and amounts of fat, and how to make the appropriate dietary changes. [2004, amended 2015]
- 1.4.13 Modify nutritional recommendations to adults with type 1 diabetes to take account of associated features of diabetes, including:
 - excess weight and obesity
 - underweight
 - disordered eating
 - hypertension
 - renal failure. [2004, amended 2021]
- 1.4.14 Healthcare professionals giving dietary advice to adults with type 1 diabetes should be able to advise about common topics of concern and interest, and should seek advice from specialists when needed. Suggested common topics include:
 - body weight, energy balance and obesity management
 - cultural and religious diets, feasts and fasts
 - foods sold as 'diabetic'
 - sweeteners
 - dietary fibre intake
 - protein intake
 - vitamin and mineral supplements
 - alcohol
 - matching carbohydrate intake, insulin and physical activity
 - salt intake in hypertension

- comorbidities, including nephropathy and renal failure, coeliac disease, cystic fibrosis or eating disorders
- peer support groups. [2004, amended 2015]

1.5 Physical activity

- 1.5.1 Advise adults with type 1 diabetes that physical activity can reduce their enhanced cardiovascular risk in the medium and long term. [2004]
- 1.5.2 For adults with type 1 diabetes who choose to increase their level of physical activity as part of a healthier lifestyle, provide information about:
 - appropriate intensity and frequency of physical activity
 - self-monitoring their changed insulin and or nutritional needs
 - the effect of physical activity on blood glucose levels (which are likely to fall) when insulin levels are adequate
 - the effect of physical activity on blood glucose levels when hyperglycaemic and hypoinsulinaemic (there is a risk of worsening hyperglycaemia and ketonaemia)
 - appropriate adjustments of insulin dosage and or nutritional intake for periods during and immediately after physical activity, and the 24 hours after this
 - interactions of physical activity and alcohol
 - further contacts and sources of information. [2004]

1.6 Blood glucose management

HbA1c measurement and targets

Measurement

- 1.6.1 Measure HbA1c levels every 3 to 6 months in adults with type 1 diabetes.[2015]
- 1.6.2 Consider measuring HbA1c levels more often in adults with type 1 diabetes if their blood glucose control is suspected to be changing rapidly; for example, if their HbA1c level has risen unexpectedly above a previously sustained target.

[2015]

- 1.6.3 Measure HbA1c using methods calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. [2015]
- 1.6.4 Tell adults with type 1 diabetes their HbA1c results after each measurement and have their most recent result available at consultations. Follow the principles on communication in NHS services. [2015]
- 1.6.5 If HbA1c monitoring is invalid because of disturbed erythrocyte turnover or abnormal haemoglobin type, estimate trends in blood glucose control using 1 of the following:
 - fructosamine estimation
 - quality-controlled blood glucose profiles
 - total glycated haemoglobin estimation (if abnormal haemoglobins). [2015]

Targets

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

Continuous glucose monitoring

NICE's diagnostics guidance on integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes is being updated. The guidance is being updated as a

multiple technology appraisal and will assess hybrid closed loop systems.

- 1.6.10 Offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash'), based on their individual preferences, needs, characteristics, and the functionality of the devices available. See box 1 for examples of factors to consider as part of this discussion. [2022]
- 1.6.11 When choosing a continuous glucose monitoring device:
 - use shared decision making to identify the person's needs and preferences, and offer them an appropriate device
 - if multiple devices meet their needs and preferences, offer the device with the lowest cost. [2022]

Box 1 Factors to consider when choosing a continuous glucose monitoring device

- Accuracy of the device
- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else (for example, a carer)
- Whether using the device requires access to particular technologies (such as a smartphone and up-to-date phone software)
- How easy the device is to use and take readings from, including for people with limited dexterity
- Fear, frequency, awareness and severity of hypoglycaemia
- Psychosocial factors
- The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)
- Whether, how often, and how the device needs to be calibrated, and how easy it is for the person to do this themselves
- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment
- Whether the device will affect the person's ability to do their job
- How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life
- Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)
- Clinical factors that may make devices easier or harder to use
- Frequency of sensor replacement
- Sensitivities to the device, for example local skin reactions
- Body image concerns

- 1.6.12 CGM should be provided by a team with expertise in its use, as part of supporting people to self-manage their diabetes. [2015, amended 2022]
- 1.6.13 Advise adults with type 1 diabetes who are using CGM that they will still need to take capillary blood glucose measurements (although they can do this less often). Explain that this is because:
 - they will need to use capillary blood glucose measurements to check the accuracy of their CGM device
 - they will need capillary blood glucose monitoring as a back-up (for example, when their blood glucose levels are changing quickly or if the device stops working).

Provide them with enough test strips to take capillary blood glucose measurements as needed. [2022]

- 1.6.14 If a person cannot use or does not want rtCGM or isCGM, offer capillary blood glucose monitoring. [2022]
- 1.6.15 Include CGM in the structured education programme provided to all adults with type 1 diabetes (see the <u>section on education and information</u>), and ensure that people are empowered to use CGM devices (see the <u>section on empowering people to self-monitor blood glucose</u>). [2022]
- 1.6.16 Monitor and review the person's use of CGM as part of reviewing their diabetes care plan (see recommendations 1.1.7, 1.2.5 and 1.2.6 on what to consider when agreeing a care plan and what a care plan should cover). [2022]
- 1.6.17 If there are concerns about the way a person is using the CGM device:
 - ask if they are having problems using their device
 - look at ways to address any problems or concerns to improve their use of the device, including further education and emotional and psychological support. [2022]

For guidance on CGM for pregnant women, see the <u>NICE guideline on diabetes in pregnancy</u>. [2022]

1.6.18 Commissioners, providers and healthcare professionals should address inequalities in CGM access and uptake by:

- monitoring who is using CGM
- identifying groups who are eligible but who have a lower uptake
- making plans to engage with these groups to encourage them to consider CGM. [2022]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale</u> and <u>impact section on continuous glucose monitoring</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review B:</u> <u>continuous glucose monitoring in adults with type 1 diabetes</u>.

Self-monitoring of capillary blood glucose

Frequency of self-monitoring of blood glucose

- 1.6.19 Advise adults with type 1 diabetes who are using capillary blood glucose monitoring to routinely self-monitor their blood glucose levels, and to measure at least 4 times a day (including before each meal and before bed). [2015, amended 2022]
- 1.6.20 Support adults with type 1 diabetes who are using capillary blood glucose monitoring to measure at least 4 times a day, and up to 10 times a day:
 - if their target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not reached
 - if they are having more frequent hypoglycaemic episodes
 - if there is a legal requirement to do so, such as before driving (see the <u>Driver and Vehicle Licensing Agency (DVLA) guide for medical professionals</u>)
 - during periods of illness
 - before, during and after sport
 - when planning pregnancy, during pregnancy and while breastfeeding (see <u>NICE's</u> guideline on diabetes in pregnancy)

- if they need to know their blood glucose levels more than 4 times a day for other reasons (for example, impaired hypoglycaemia awareness, or they are undertaking high-risk activities). [2015, amended 2022]
- 1.6.21 Enable additional blood glucose measurement (more than 10 times a day) for adults with type 1 diabetes who are using capillary blood glucose monitoring if this is necessary because of:
 - the person's lifestyle (for example, they drive for long periods of time, they undertake high-risk activities or have a high-risk occupation, or they are travelling) or
 - impaired hypoglycaemia awareness. [2015, amended 2022]

Blood glucose targets

- 1.6.22 Advise adults with type 1 diabetes to aim for:
 - a fasting plasma glucose level of 5 to 7 mmol/litre on waking and
 - a plasma glucose level of 4 to 7 mmol/litre before meals at other times of the day. [2015]
- 1.6.23 Advise adults with type 1 diabetes who choose to measure after meals to aim for a plasma glucose level of 5 to 9 mmol/litre at least 90 minutes after eating. (This timing may be different in pregnancy for guidance on plasma glucose targets in pregnancy, see NICE's guideline on diabetes in pregnancy.) [2015]
- 1.6.24 Agree bedtime target plasma glucose levels with each adult with type 1 diabetes. Take into account the timing of their last meal of the day and the related insulin dose, and ensure the target is consistent with the recommended fasting level on waking (see recommendation 1.6.22). [2015]

Empowering people to self-monitor blood glucose

- 1.6.25 Teach self-monitoring skills at the time of diagnosis and the start of insulin therapy. [2004, amended 2015]
- 1.6.26 When choosing blood glucose meters:
 - take the needs of the adult with type 1 diabetes into account

- ensure that meters meet current ISO standards. [2015]
- 1.6.27 Teach adults with type 1 diabetes how to measure their blood glucose level, interpret the results and take appropriate action. Review these skills at least annually. [2015]
- 1.6.28 Support adults with type 1 diabetes through structured education (see the section on education and information) to make the best use of data from self-monitoring of blood glucose. [2015]

Sites for self-monitoring of blood glucose

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

1.7 Insulin therapy

Insulin regimens

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

Long-acting insulin

- 1.7.3 Offer twice-daily insulin detemir as basal insulin therapy for adults with type 1 diabetes. [2021]
- 1.7.4 Consider 1 of the following as an alternative basal insulin therapy to twice-daily insulin detemir for adults with type 1 diabetes:
 - an insulin regimen that is already being used by the person if it is meeting their agreed treatment goals (such as meeting their HbA1c targets or time in target glucose range and minimising hypoglycaemia)

- once-daily insulin glargine (100 units/ml) if insulin detemir is not tolerated or the person has a strong preference for once-daily basal injections
- once-daily insulin degludec (100 units/ml) if there is a particular concern about nocturnal hypoglycaemia
- once-daily <u>ultra-long-acting insulin</u> such as degludec (100 units/ml) for people who need help from a carer or healthcare professional to administer injections.

There is a risk of severe harm and death due to inappropriately withdrawing insulin from pen devices. See <u>NHS England's patient safety alert</u> for further information. [2021]

- 1.7.5 When starting an insulin for which a biosimilar is available, use the product with the lowest acquisition cost. [2021]
- 1.7.6 Ensure the risk of medication errors with insulins is minimised by following Medicines and Healthcare products Regulatory Agency (MHRA) guidance on minimising the risk of medication error with high strength, fixed combination and biosimilar insulin products, which includes advice for healthcare professionals when starting treatment with a biosimilar. [2021]
- 1.7.7 When people are already using an insulin for which a lower cost biosimilar is available, discuss the possibility of switching to the biosimilar. Make a shared decision with the person after discussing their preferences. [2021]
- 1.7.8 Consider other basal insulin regimens for adults with type 1 diabetes only if the regimens in recommendations 1.7.3 and 1.7.4 do not meet their agreed treatment goals. When choosing an alternative insulin regimen, take account of:
 - the person's preferences
 - comorbidities
 - risk of hypoglycaemia and diabetic ketoacidosis
 - any concerns around adherence
 - acquisition cost. [2021]
- 1.7.9 When prescribing, ensure that insulins are prescribed by brand name. [2021]

For a short explanation of why the committee made these recommendations and how they might affect practice, see the <u>rationale and impact section on long-acting insulin</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review A: longacting insulins in type 1 diabetes</u>.

Insulin pumps

1.7.10 For guidance on the use of insulin pumps for adults with type 1 diabetes, see NICE's technology appraisal guidance on continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. [2015]

Rapid-acting insulin

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

Mixed insulin

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

Optimising insulin therapy

1.7.16 For adults with erratic and unpredictable blood glucose control (hyperglycaemia and hypoglycaemia at no consistent times), consider the following rather than

changing a previously optimised insulin regimen:

- injection technique
- injection sites
- self-monitoring skills
- knowledge and self-management skills
- lifestyle
- mental health and psychosocial problems
- possible organic causes, such as gastroparesis. [2004, amended 2015]
- 1.7.17 Give clear guidelines and protocols ('sick-day rules') to all adults with type 1 diabetes, to help them adjust insulin doses appropriately when they are ill.[2004]

Adjuncts

- 1.7.18 Consider adding metformin to insulin therapy for adults with type 1 diabetes if:
 - they have a BMI of 25 kg/m² or above (23 kg/m² or above for people from South Asian and related family backgrounds) and
 - they want to improve their blood glucose control while minimising their effective insulin dose.

In August 2015, this was an off-label use of metformin. See <u>NICE's information on prescribing medicines</u>. [2015]

1.8 Insulin delivery

- 1.8.1 For adults with type 1 diabetes who inject insulin, provide their preferred insulin injection delivery device (this often means using one or more types of insulin injection pen). [2004]
- 1.8.2 For adults with type 1 diabetes and special visual or psychological needs, provide injection devices or needle-free systems that they can use

independently for accurate dosing. [2004]

- 1.8.3 Offer needles of different lengths to adults with type 1 diabetes who are having problems such as pain, local skin reactions and injection site leakages. [2015]
- 1.8.4 After taking clinical factors into account, choose needles with the lowest acquisition cost to use with pre-filled and reusable insulin pen injectors. [2015]
- 1.8.5 Advise adults with type 1 diabetes to rotate insulin injection sites and avoid repeated injections at the same point within sites. [2015]
- 1.8.6 Provide adults with type 1 diabetes with:
 - suitable containers for collecting used needles and other sharps
 - a way to safely get rid of these containers.

See also the <u>section on safe use and disposal of sharps in NICE's guideline on healthcare-associated infections: prevention and control in primary and community care</u>. [2004, amended 2015]

1.8.7 Check injection site condition at least annually, and whenever new problems with blood glucose control occur. [2004, amended 2015]

1.9 Referral for islet or pancreas transplantation

- 1.9.1 For adults with type 1 diabetes who have recurrent severe hypoglycaemia that has not responded to other treatments (see the <u>section on hypoglycaemia awareness and management</u>), consider referral to a centre that assesses people for islet and/or pancreas transplantation. [2015]
- 1.9.2 Consider islet or pancreas transplantation for adults with type 1 diabetes with suboptimal diabetes control, if they have had a renal transplant and are currently on immunosuppressive therapy. [2015]

1.10 Hypoglycaemia awareness and management Identifying and quantifying impaired hypoglycaemia awareness

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

Managing impaired hypoglycaemia awareness

- 1.10.4 Ensure that adults with type 1 diabetes and impaired hypoglycaemia awareness have had structured education in flexible insulin therapy using basal-bolus regimens, and are following its principles correctly. [2015]
- 1.10.5 Offer additional education focusing on avoiding and treating hypoglycaemia to adults with type 1 diabetes who still have impaired hypoglycaemia awareness after structured education in flexible insulin therapy. [2015]
- 1.10.6 Avoid relaxing individualised blood glucose targets to address impaired hypoglycaemia awareness for adults with type 1 diabetes. [2015]
- 1.10.7 For adults with type 1 diabetes and impaired hypoglycaemia awareness who are using lower target blood glucose levels than recommended in this guideline, encourage them to use the recommended targets (see the <u>recommendations on blood glucose targets</u>). [2015]
- 1.10.8 Review insulin regimens and doses, and prioritise ways to avoid hypoglycaemia in adults with type 1 diabetes with impaired hypoglycaemia awareness, including:
 - reinforcing the principles of structured education

- offering an insulin pump
- offering real-time continuous glucose monitoring. [2015]
- 1.10.9 If, despite these interventions, an adult with type 1 diabetes has impaired hypoglycaemia awareness that is associated with recurrent severe hypoglycaemia, consider referring them to a specialist centre. [2015]

Preventing and managing hypoglycaemia

- 1.10.10 Explain to adults with type 1 diabetes that a fast-acting form of glucose is needed for managing hypoglycaemic symptoms or signs in people who can swallow. [2004, amended 2015]
- 1.10.11 Adults with type 1 diabetes who have a decreased level of consciousness because of hypoglycaemia and so cannot safely take oral treatment should be:
 - given intramuscular glucagon by a family member or friend who has been shown how to use it (intravenous glucose may be used by healthcare professionals skilled in getting intravenous access)
 - checked for response at 10 minutes, and then given intravenous glucose if their level of consciousness is not improving significantly
 - then given oral carbohydrate when it is safe to administer it, and put under continued observation by someone who has been warned about the risk of relapse. [2004, amended 2015]
- 1.10.12 Explain to adults with type 1 diabetes that:
 - it is very common to experience some hypoglycaemic episodes with any insulin regimen
 - they should use a regimen that avoids or reduces the frequency of hypoglycaemic episodes, while maintaining the most optimal blood glucose control possible. [2004]
- 1.10.13 Make hypoglycaemia advice available to all adults with type 1 diabetes, to help them find the best possible balance with any insulin regimen. (See the <u>sections on insulin therapy</u> and <u>insulin delivery</u>.) [2004]
- 1.10.14 If hypoglycaemia becomes unusually problematic or increases in frequency,

review the following possible causes:

- inappropriate insulin regimens (incorrect dose distributions and insulin types)
- meal and activity patterns, including alcohol
- injection technique and skills, including insulin resuspension if necessary
- injection site problems
- possible organic causes, including gastroparesis
- changes in insulin sensitivity (including drugs affecting the renin-angiotensin system and renal failure)
- mental health problems
- previous physical activity
- lack of appropriate knowledge and skills for self-management. [2004]
- 1.10.15 Manage nocturnal hypoglycaemia (symptomatic or detected on monitoring) by:
 - reviewing knowledge and self-management skills
 - reviewing current insulin regimen, evening eating habits and previous physical activity
 - choosing an insulin type and regimen that is less likely to cause low glucose levels at night. [2004, amended 2015]
- 1.10.16 If early cognitive decline occurs in adults on long-term insulin therapy, then in addition to normal investigations consider possible brain damage from overt or covert hypoglycaemia, and the need to manage this. [2004]

1.11 Ketone monitoring and managing diabetic ketoacidosis

Ketone self-monitoring to prevent diabetic ketoacidosis

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

Ketone monitoring in hospital

- 1.11.2 In adults with type 1 diabetes presenting to emergency services, consider capillary blood ketone testing if:
 - diabetic ketoacidosis (DKA) is suspected or
 - the person has uncontrolled diabetes during an illness, and urine ketone testing is positive. [2015]
- 1.11.3 Consider capillary blood ketone testing (incorporated into a formal protocol) for inpatient management of DKA in adults with type 1 diabetes. [2015]

Management of DKA

- 1.11.4 Professionals managing DKA in adults should have adequate and up-to-date training, and be familiar with all aspects of DKA management that are associated with mortality and morbidity. These topics should include:
 - fluid balance
 - acidosis
 - cerebral oedema
 - electrolyte imbalance
 - that DKA can affect the results of standard diagnostic tests (white cell count, body temperature, electrocardiogram [ECG])
 - respiratory distress syndrome
 - cardiac abnormalities
 - precipitating causes
 - infection management, including opportunistic infections
 - gastroparesis
 - use of high dependency and intensive care units

• recommendations 1.11.5 to 1.11.12 in this guideline.

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

- 1.11.5 Use isotonic saline for primary fluid replacement in adults with DKA, not given too rapidly except in cases of circulatory collapse. [2004]
- 1.11.6 Do not generally use bicarbonate for managing DKA in adults. [2004, amended 2015]
- 1.11.7 Give intravenous insulin by infusion to adults with DKA. [2004]
- 1.11.8 When the plasma glucose concentration has fallen to 10 to 15 mmol/litre in adults with DKA, give glucose-containing fluids (not more than 2 litres in 24 hours) so that the insulin infusion can be continued at a sufficient rate to clear ketones (for example, 6 units/hour, monitored for effect). [2004, amended 2015]
- 1.11.9 Begin potassium replacement early in DKA in adults, with frequent monitoring for hypokalaemia. [2004]
- 1.11.10 Do not generally use phosphate replacement when managing DKA in adults. [2004, amended 2015]
- 1.11.11 In adults with DKA who have reduced consciousness, think about:
 - inserting a nasogastric tube and
 - monitoring urine output using a urinary catheter and
 - giving venous thromboembolism (VTE) prophylaxis. [2004, amended 2021]
- 1.11.12 To reduce the risk of catastrophic outcomes in adults with DKA, use continuous monitoring and frequent reviews that cover all aspects of clinical management. [2004, amended 2015]

1.12 Associated illness

1.12.1 In adults with type 1 diabetes who have unexplained weight loss, assess for coeliac disease. For guidance on testing for coeliac disease, see <u>NICE's guideline</u>

on coeliac disease. [2004, amended 2015]

1.12.2 Be alert to the possibility of other autoimmune diseases in adults with type 1 diabetes (including Addison's disease and pernicious anaemia). For advice on monitoring for thyroid disease, see the <u>recommendation on thyroid disease</u> monitoring. [2004, amended 2015]

1.13 Control of cardiovascular risk

Aspirin

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

Identifying cardiovascular risk

- 1.13.2 Assess cardiovascular risk factors annually, including:
 - estimated glomerular filtration rate (eGFR) and urine albumin:creatinine ratio (ACR)
 - smoking
 - blood glucose control
 - blood pressure
 - full lipid profile (including high-density lipoprotein [HDL] and low-density lipoprotein [LDL] cholesterol, and triglycerides)
 - age
 - family history of cardiovascular disease
 - abdominal adiposity. [2004, amended 2015 and 2021]
- 1.13.3 For guidance on tools for assessing risk of cardiovascular disease in adults with type 1 diabetes, see the <u>recommendations on full formal risk assessment in NICE's guideline on lipid modification</u>. [2015]

Interventions to reduce risk and manage cardiovascular disease

- 1.13.4 For guidance on the primary prevention of cardiovascular disease in adults with type 1 diabetes, see the <u>section on primary prevention for people with type 1</u> diabetes in NICE's guideline on lipid modification. [2015]
- 1.13.5 Give adults with type 1 diabetes who smoke advice on stopping smoking and stop smoking services, including NICE guidance-recommended therapies (see the NICE webpage on smoking and tobacco). Reinforce these messages annually for people who currently do not plan to stop smoking, and at all clinical contacts if there is a prospect of the person stopping. [2004]
- 1.13.6 Advise adults who do not smoke never to start smoking. [2004, amended 2021]
- 1.13.7 Provide intensive management for adults who have had myocardial infarction or stroke, according to relevant non-diabetes guidelines. For angina or other ischaemic heart disease, beta-blockers should be considered (for insulin use in these circumstances, see the section on caring for adults with type 1 diabetes in hospital). For guidance on secondary prevention of myocardial infarction, see NICE's guideline on acute coronary syndromes. [2004, amended 2015]

Blood pressure management

- 1.13.8 Recommend blood pressure management at 135/85 mmHg for adults with type 1 diabetes. If they have albuminuria or 2 or more features of metabolic syndrome, recommend blood pressure management at 130/80 mmHg. See also the recommendations on diabetic kidney disease and NICE's guideline on hypertension in adults. [2004, amended 2021]
- 1.13.9 Discuss the following with adults with type 1 diabetes who have hypertension to help them make an informed choice:
 - reasons for the choice of intervention level
 - the substantial potential gains from small improvements in blood pressure control
 - any possible negative consequences of therapy. [2004, amended 2015]
- 1.13.10 Start a trial of a renin–angiotensin system blocking drug as first-line therapy for hypertension in adults with type 1 diabetes. [2004, amended 2015]

- 1.13.11 Provide information to adults with type 1 diabetes on how lifestyle changes can improve their blood pressure control and associated outcomes, and offer help to achieve their aims in this area. [2004]
- 1.13.12 Do not allow concerns over potential side effects to inhibit advising and offering the necessary use of any class of drugs, unless side effects become symptomatic or otherwise clinically significant. In particular:
 - do not avoid selective beta-blockers for adults on insulin if these are indicated
 - low-dose thiazides may be combined with beta-blockers
 - when prescribing calcium channel antagonists, only use long-acting preparations
 - ask adults directly about potential side effects of erectile dysfunction, lethargy and orthostatic hypotension with different drug classes. [2004, amended 2015]
- 1.13.13 For guidance on blood pressure management in adults with type 1 diabetes and evidence of renal involvement, see the <u>section on blood pressure control in NICE's guideline on chronic kidney disease</u>. [2015]

1.14 Caring for adults with type 1 diabetes in hospital Blood glucose control

- 1.14.1 Aim for a target plasma glucose level of 5 to 8 mmol/litre for adults with type 1 diabetes during surgery or acute illness. [2015]
- 1.14.2 Establish a local protocol for controlling blood glucose levels in adults with type 1 diabetes during surgery or acute illness to reach the target level. [2015]
- 1.14.3 Use intravenous rather than subcutaneous insulin regimens for adults with type 1 diabetes if:
 - they are unable to eat or are predicted to miss more than 1 meal or
 - an acute situation is expected to result in unpredictable blood glucose levels for example, major surgery, high-dose steroid treatment, inotrope treatment or sepsis or

- insulin absorption is expected to be unpredictable, for example, because of circulatory compromise. [2015]
- 1.14.4 Consider continuing the person's existing basal insulin regimen (including basal rate if they are using insulin pump therapy) together with protocol-driven insulin delivery for controlling blood glucose levels in adults with type 1 diabetes during surgery or acute illness. [2015]
- 1.14.5 Use subcutaneous insulin regimens (including rapid-acting insulin before meals) if an adult with type 1 diabetes and acute illness is eating. [2015]
- 1.14.6 Enable adults with type 1 diabetes who are hospital inpatients to self-administer subcutaneous insulin if they are willing and able and it is safe for them to do so. [2015]

Delivering care in hospital and other institutions

These recommendations are for care teams caring for adults with type 1 diabetes in hospital and in institutions such as nursing homes, residential homes and prisons.

- 1.14.7 From admission, provide ongoing advice to adults with type 1 diabetes and the team caring for them from a trained multidisciplinary team with expertise in diabetes. [2004]
- 1.14.8 Throughout inpatient admission, respect the personal expertise of adults with type 1 diabetes in managing their own diabetes and incorporate this into routine ward-based blood glucose monitoring and insulin delivery. [2004, amended 2015]
- 1.14.9 Throughout inpatient admission, support adults with type 1 diabetes to make their own food choices based on their personal knowledge of their dietary needs, except when illness or medical or surgical intervention significantly disturbs those requirements. [2004]
- 1.14.10 Provide optimal insulin therapy, which can be achieved using intravenous insulin and glucose, to all adults with type 1 diabetes with threatened or actual stroke. Critical care and emergency departments should have a protocol for such management. [2004, amended 2011]

1.15 Managing complications

Eye disease

- 1.15.1 When adults are diagnosed with type 1 diabetes, refer them immediately to the local eye screening service. [2004, amended 2020]
- 1.15.2 Encourage adults to attend eye screening, and explain that it will help them to keep their eyes healthy and help to prevent problems with their vision. Explain that the screening service is effective at identifying problems so that they can be treated early. [2004]
- 1.15.3 Arrange emergency review by an ophthalmologist for:
 - sudden loss of vision
 - rubeosis iridis
 - pre-retinal or vitreous haemorrhage
 - retinal detachment. [2004, amended 2015]
- 1.15.4 Refer to an ophthalmologist in accordance with the UK National Screening Committee criteria and timelines for any large sudden unexplained drop in visual acuity. [2004, amended 2020]

Diabetic kidney disease

- 1.15.5 For guidance on managing kidney disease in adults with type 1 diabetes, see NICE's guideline on chronic kidney disease. [2015]
- 1.15.6 Ask all adults with type 1 diabetes, with or without detected nephropathy, to bring in the first urine sample of the day ('early morning urine') once a year. Send this for estimation of albumin:creatinine ratio (estimating urine albumin concentration alone is a poor alternative) and measure eGFR at the same time. See NICE's guideline on chronic kidney disease. [2004, amended 2021]
- 1.15.7 Suspect other renal disease if:
 - progressive retinopathy is absent

- blood pressure is particularly high
- proteinuria develops suddenly
- significant haematuria is present (see NICE's guideline on chronic kidney disease)
- the person is systemically unwell. [2004]
- 1.15.8 If albuminuria is found, discuss with the person what this means. [2004, amended 2015]
- 1.15.9 For guidance on medicines for managing chronic kidney disease, see the <u>section</u> on pharmacotherapy for CKD in adults, children, and young people with related persistent proteinuria in the NICE guideline on chronic kidney disease. [2022]
- 1.15.10 Maintain the person's blood pressure below 130/80 mmHg by adding other anti-hypertensive drugs if necessary. [2004]
- 1.15.11 Advise adults with type 1 diabetes and nephropathy about the advantages of avoiding a high-protein diet. [2004]
- 1.15.12 Referral criteria for tertiary care should be agreed between local diabetes specialists and nephrologists. See <u>NICE's guideline on chronic kidney disease</u>.
 [2004]

Chronic painful diabetic neuropathy

1.15.13 For guidance on managing chronic painful diabetic neuropathy in adults with type 1 diabetes, see <u>NICE's guideline on neuropathic pain in adults</u>. [2015]

Autonomic neuropathy

- 1.15.14 Think about the possibility of autonomic neuropathy affecting the gut if adults with type 1 diabetes have unexplained diarrhoea, particularly at night. [2004]
- 1.15.15 When prescribing antihypertensive medicines, take care not to increase the risk of orthostatic hypotension from the combined effects of sympathetic autonomic neuropathy and blood pressure lowering medicines. [2004]
- 1.15.16 For adults with type 1 diabetes who have bladder emptying problems,

- investigate the possibility of autonomic neuropathy affecting the bladder, unless another explanation is found. [2004]
- 1.15.17 When managing the symptoms of autonomic neuropathy, include specific interventions for the manifestations encountered (for example, for abnormal sweating and postural hypotension). [2004, amended 2015]
- 1.15.18 Anaesthetists should be aware of the possibility of parasympathetic autonomic neuropathy affecting the heart in adults with type 1 diabetes who:
 - are listed for procedures under general anaesthetic and
 - have evidence of somatic neuropathy or other manifestations of autonomic neuropathy. [2004]

Gastroparesis

- 1.15.19 Advise adults with type 1 diabetes who have vomiting caused by gastroparesis to follow a small-particle-size diet (mashed or pureed food) to relieve their symptoms. [2015]
- 1.15.20 Be aware that gastroparesis needing specific therapy can only be diagnosed in the absence of hyperglycaemia at the time of testing, because hyperglycaemia delays gastric emptying. [2015]
- 1.15.21 Consider insulin pump therapy for adults with type 1 diabetes who have gastroparesis. [2015]
- 1.15.22 For adults with type 1 diabetes who have vomiting caused by gastroparesis, explain that:
 - there is no strong evidence that any available antiemetic therapy is effective
 - some people have had benefit with domperidone (see the <u>Medicines and Healthcare</u> products Regulatory Agency (MHRA) guidance on domperidone: risks of cardiac side <u>effects</u>), erythromycin or metoclopramide (see the <u>MHRA guidance on metoclopramide: risks of neurological adverse effects</u>)

• the strongest evidence for effectiveness is for domperidone, but prescribers must take into account its safety profile, in particular its cardiac risk and potential interactions with other medicines.

In August 2015, this was an off-label use of erythromycin and many higher doses or treatment durations of domperidone. See <u>NICE's information on prescribing</u> medicines. [2015]

- 1.15.23 To treat vomiting caused by gastroparesis in adults with type 1 diabetes:
 - consider alternating erythromycin and metoclopramide (see the MHRA guidance on metoclopramide: risks of neurological adverse effects)
 - consider domperidone only in exceptional circumstances (that is, when it is the only effective treatment) and in accordance with the MHRA guidance on domperidone: risks of cardiac side effects.

In August 2015, this was an off-label use of erythromycin and many higher doses or treatment durations of domperidone. See <u>NICE's information on prescribing</u> medicines. [2015]

1.15.24 Refer adults with type 1 diabetes who have gastroparesis for specialist advice if the interventions in this section have not helped or are not appropriate. [2015]

Acute painful neuropathy from rapid improvement of blood glucose control

- 1.15.25 Reassure adults with type 1 diabetes that acute painful neuropathy resulting from rapid improvement of blood glucose control is a self-limiting condition and symptoms improve over time. [2015]
- 1.15.26 Explain to adults with type 1 diabetes that the specific treatments for acute painful neuropathy resulting from rapid improvement of blood glucose control:
 - aim to make symptoms tolerable until the condition resolves
 - may not relieve pain immediately and may need to be taken regularly for several weeks to be effective. [2015]
- 1.15.27 Use simple analgesics (paracetamol, aspirin) and local measures (bed cradles) as

- a first step to treat acute painful neuropathy, and if these do not help, try other measures. [2004, amended 2021]
- 1.15.28 Do not relax diabetes control to address acute painful neuropathy resulting from rapid improvement of blood glucose control in adults with type 1 diabetes. [2015]
- 1.15.29 If simple analgesia does not provide sufficient pain relief for adults with type 1 diabetes who have acute painful neuropathy resulting from rapid improvement of blood glucose control, offer treatment as described in NICE's guideline on neuropathic pain in adults. Simple analgesia may be continued until the effects of additional treatments have been established. [2015]
- 1.15.30 When offering medicines for managing acute painful neuropathy resulting from rapid improvement of blood glucose control to adults with type 1 diabetes, be aware of the risk of dependency associated with opioids. [2015]

Diabetic foot problems

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

Erectile dysfunction

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

Thyroid disease monitoring

1.15.35 Measure blood thyroid-stimulating hormone (TSH) levels in adults with type 1

diabetes at their annual review. [2015]

Mental health problems

1.15.36 Members of diabetes professional teams providing care or advice to adults with type 1 diabetes should be alert to possible clinical or subclinical depression and/or anxiety, particularly if someone reports or appears to be having difficulties with self-management. [2004]

1.15.37 Diabetes professionals should:

- ensure they have appropriate skills to identify and provide basic management of non-severe mental health problems in people from different cultural backgrounds
- be familiar with appropriate counselling techniques and drug therapy, while arranging prompt referral to specialists for people whose mental health problems continue to interfere significantly with their wellbeing or diabetes self-management.

See also the:

- NICE guideline on common mental health problems
- NICE guideline on generalised anxiety disorder and panic disorder in adults
- NICE guideline on depression in adults with a chronic physical health problem. [2004, amended 2015]

Eating disorders and disordered eating

- 1.15.38 Members of diabetes professional teams should be alert to the possibility of bulimia nervosa, anorexia nervosa and <u>disordered eating</u> in adults with type 1 diabetes with:
 - over-concern with body shape and weight
 - low BMI
 - hypoglycaemia

suboptimal overall blood glucose control.

See also NICE's guideline on eating disorders. [2004, amended 2021]

- 1.15.39 Think about making an early (or if needed, urgent) referral to local eating disorder services for adults with type 1 diabetes with an eating disorder. [2004, amended 2021]
- 1.15.40 From diagnosis, the diabetes professional team should provide regular high-quality support and counselling about lifestyle and diet for all adults with type 1 diabetes (see the <u>sections on education and information</u> and <u>dietary</u> management). [2004]

Terms used in this guideline

This section defines terms that have been used in a particular way for this guideline.

Continuous glucose monitoring

This covers both real-time (rtCGM) and intermittently scanned (isCGM, commonly referred to as 'flash') continuous glucose monitoring.

A continuous glucose monitor is a device that measures blood glucose levels and sends the readings to a display device or smartphone.

Disordered eating

Disordered eating describes a range of irregular eating behaviours. These can include symptoms that reflect many but not all of the symptoms of eating disorders, such as anorexia nervosa, bulimia nervosa and binge eating disorder. Examples of disordered eating include fasting or chronic restrained eating, skipping meals, binge eating, self-induced vomiting, restrictive dieting, and laxative or diuretic misuse.

Ultra-long-acting insulin

Insulin analogues that have a longer duration of action (beyond 24 hours) compared with standard long-acting insulins.

Recommendations for research

The guideline committee has made the following recommendations for research.

1 Clinical features for distinguishing between type 1 diabetes and other types of diabetes

What are the best clinical features or combination of features for distinguishing between type 1 diabetes and other types of diabetes? [2022]

For a short explanation of why the committee made the recommendation for research, see the rationale section on diagnosis.

Full details of the evidence and the committee's discussion are in <u>evidence review C: diagnosis</u> of diabetes.

2 The use of C-peptide in diagnosing diabetes

What is the effectiveness of C-peptide at correcting misclassification of diabetes diagnosis and what is the optimal timing for the test in distinguishing subtypes of diabetes? [2022]

For a short explanation of why the committee made the recommendation for research, see the <u>rationale section on diagnosis</u>.

Full details of the evidence and the committee's discussion are in <u>evidence review C</u>: <u>diagnosis</u> of diabetes.

3 Use of routinely collected real-world data to examine the effectiveness and cost effectiveness of continuous glucose monitoring

Based on routinely collected real-world data, what is the effectiveness and cost effectiveness of CGM devices to improve glycaemic control? [2022]

For a short explanation of why the committee made the recommendation for research, see the rationale section on continuous glucose monitoring.

Full details of the evidence and the committee's discussion are in <u>evidence review A:</u> <u>continuous glucose monitoring in adults with type 1 diabetes.</u>

Rationale and impact

These sections briefly explain why the committee made the 2021 and 2022 recommendations and how they might affect practice.

Diagnosis

Recommendations 1.1.1 to 1.1.9

Why the committee made the recommendations

The committee wanted to highlight the importance of distinguishing between type 1 diabetes and other diabetes types because these conditions are treated differently (particularly in terms of insulin use).

The most common misdiagnosis is type 1 diabetes being misdiagnosed as type 2, which could lead to the person not receiving insulin treatment and a subsequent risk of diabetic ketoacidosis.

It is less harmful to be diagnosed with type 1 diabetes when the person actually has type 2 diabetes. However, there are still harms, including:

- the long-term effects and costs of unnecessary insulin therapy
- the missed opportunity for oral diabetes therapies
- the psychological impact of misdiagnosis.

There was no new definitive evidence on clinical features for identifying diabetes type, so recommendation 1.1.1 remains unchanged from the 2015 guideline. Because of this lack of new evidence, the committee made a <u>recommendation for research on identifying diabetes type</u>.

The evidence showed that no single clinical feature had a sufficient predictive value to make a diagnosis by itself. The committee were particularly concerned that age and BMI might be used in isolation. They noted that the average BMI in people with type 1 diabetes is increasing, and the age at which people are diagnosed with type 2 diabetes is decreasing. This means these clinical features are becoming less useful on their own to differentiate between the subtypes. Despite this, the committee agreed that these characteristics are still useful for making an initial working diagnosis of diabetes subtype in many people. However, further testing is increasingly needed, as previously

'atypical' features of type 1 and 'uncertain' classifications become more common.

In a change from the 2015 guideline, the committee agreed it was important to encourage the use of diabetes-specific autoantibody testing at diagnosis, to avoid misclassifying diabetes subtype. They also clarified that autoantibody testing is appropriate for people with suspected type 1 diabetes.

There was no high-quality evidence on tests to distinguish type 1 from type 2 or other types of diabetes, so the committee based the recommendations on the timings when the tests might be most useful (autoantibody testing is best used at the time of presentation, and C-peptide is best used with increasing time from initial presentation) rather than which tests were most accurate.

Based on clinical experience, the committee were confident that measuring autoantibodies in people with suspected type 1 diabetes would be cost effective. This is because:

- autoantibody tests are cheap when compared with the much higher costs associated with inaccurate diagnosis
- misclassification using clinical criteria alone results in additional costs, both from the use of ineffective treatments and from clinical harm.

Further, because autoantibody tests are more accurate when done at the time of presentation rather than later at a clinical review, they would also be more cost effective at that time rather than later, since the cost will be the same but more useful information will be obtained from the test at the time of diagnosis.

The committee noted that using autoantibody testing also means that healthcare professionals do not have to rely on characteristics alone when people first present. This can help avoid assumptions about links between ethnicity and diabetes type (for example, assuming that people in Black, Asian and other minority ethnic groups are more likely to have type 2 diabetes).

The committee could not recommend routine non-fasting serum C-peptide testing because of a lack of high-quality and clinical evidence, and this would be a significant and costly change in clinical practice. However, they thought it would be an appropriate test if clinical presentation and autoantibody testing did not provide a clear classification of diabetes (for example, if clinical features were consistent with type 1 diabetes but autoantibody results were negative).

The committee noted that serum C-peptide is more appropriate in individual clinical diagnosis settings as it can be paired with blood glucose, while urine C-peptide is mainly used in

epidemiological studies.

Because of the lack of high-quality evidence, the committee made a <u>recommendation for research</u> to examine the effectiveness of C-peptide at correcting misclassification of diabetes at initial <u>diagnosis</u> and the optimal timing for this test in distinguishing between subtypes of diabetes.

How the recommendations might affect practice

It is likely that these recommendations will lead to increased autoantibody testing in people presenting with suspected type 1 diabetes. This will increase testing costs, but this increase is not expected to be substantial, because of the low costs of the tests themselves. An increased use of serum C-peptide testing in the classification of diabetes is less likely, because the guideline only recommends this be done if there is still diagnostic uncertainty after the use of autoantibody testing.

Although there is a cost associated with some of the new recommendations and concerns about the availability of the tests in all settings, the committee felt this would be balanced out by benefits from reducing the misclassification of diabetes at presentation and ensuring early appropriate treatment of type 1 (and in some cases type 2) diabetes. This will avoid unnecessary tests, treatment and side-effects from prolonged insulin use.

Return to recommendations

Continuous glucose monitoring

Recommendations 1.6.10 to 1.6.18

Why the committee made the recommendations

The committee agreed that there was enough evidence in key outcomes, such as HbA1c, time in range and severe or nocturnal hypoglycaemia, to demonstrate that both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) provide clinical benefits over standard self-monitoring of blood glucose. However, they considered that the evidence for rtCGM compared with isCGM was not good enough in terms of quality or sample size to clearly show clinical benefits of 1 technology over the other.

The committee also acknowledged that CGM technologies were changing very quickly, with increasing overlap between rtCGM and isCGM as features such as predictive alerts are added to newer isCGM devices.

The health economic modelling found that, when the benefit of reduced fear of hypoglycaemia with CGM was included, both technologies were cost effective for the full population of adults with type 1 diabetes compared with standard self-monitoring of blood glucose.

Based on the above factors and the evidence, the committee agreed that there was no advantage to recommending 1 specific device over another compared with standard self-monitoring of blood glucose. They concluded that the specific functionality of isCGM versus rtCGM devices should be discussed between the person and their healthcare professional. In particular, finding the right device for each person is likely to improve adherence, which means the device will provide more benefits and so will be more cost effective.

The committee did not make a recommendation on using specific devices because CGM technologies are changing very quickly, and this recommendation would soon be out of date. Local healthcare services are better placed to assess which devices are evidence-based and suitable for use at any given time.

There are benefits of providing a choice of different CGM devices because the most suitable device would vary for each person. The committee produced a list of factors to consider when choosing a CGM device with people. The committee agreed that this freedom of choice is beneficial, particularly because adherence to the technology is likely to be higher if the device is matched to the person's needs and preferences.

The committee retained the 2015 recommendation on providing people with support from a healthcare specialist team with expertise in diabetes and the use of CGM. Community-based specialist teams are now available and are no longer always based in secondary care, so 'centre' was changed to 'team' to make this clearer.

Despite the positive recommendations on CGM, the committee were concerned that existing health inequalities may still lead to lower uptake of CGM in some groups of people. To address this, the committee made a recommendation outlining actions for commissioners, providers and healthcare professionals.

Given the rapid advances in technology, the committee made a <u>recommendation for research on using routinely collected real-world data to examine the effectiveness and cost effectiveness of CGM</u>. If routine healthcare data is collected, it can show the direct effect of implemented technology on the population, rather than it being interpreted through the results of clinical trials. Increased monitoring of routine healthcare data including registries and audits would ensure that the findings from a broader population is captured.

How the recommendations might affect practice

These recommendations are likely to result in broader access to isCGM and rtCGM devices, as opposed to a binary decision on access based on stringent criteria. This should reduce inequalities and enable more people to use CGM. Currently, people with more time and knowledge to self-advocate are often more likely to gain access to these devices.

Some people have insulin insufficiency because of other conditions. The committee noted that these people would get the same care as people with type 1 diabetes, so they should have access to CGM in the same way.

There is likely to be an increase in costs from more use of CGM devices. A number of different devices are available, so if more than 1 device would be appropriate for a person and would meet their needs and preferences, using the lowest cost device among those options would help to reduce the cost impact.

Return to recommendations

Long-acting insulin

Recommendations 1.7.3 to 1.7.9

Why the committee made the recommendations

Evidence showed that there were fewer severe and nocturnal hypoglycaemic events with insulin detemir twice daily compared with neutral protamine Hagedorn (NPH). Insulin detemir twice daily was also found to be the most cost-effective treatment strategy in the economic analysis. Based on this evidence and their clinical experience, the committee recommended twice-daily insulin detemir as a basal insulin therapy for adults with type 1 diabetes.

The committee agreed there were situations in which an insulin other than twice-daily insulin determined might be preferred, and set out specific clinical scenarios where alternative long-acting insulins could be used. This includes if the person is already using an insulin regimen that is working well for them and helping them meet their treatment goals.

Some people may not be able to tolerate insulin detemir, or for some, a once-daily regimen may be necessary (either because the person has a strong preference for once-daily injections or there are circumstances that make twice daily not practical). Glargine (100 units/ml) was found to be the most cost-effective once-daily insulin (particularly when the costs of glargine biosimilars were

considered) so it was recommended as the appropriate alternative in these cases.

People on insulin therapies can still have hypoglycaemic episodes. This can be a cause of concern, particularly if they have nocturnal hypoglycaemic events. Evidence showed a lower proportion of nocturnal hypoglycaemic events with degludec (100 units/ml), when compared with other oncedaily insulins. Degludec (100 units/ml) is an ultra-long-acting insulin, which means it has a longer duration of action compared with long-acting insulins. The committee agreed that once-daily degludec could therefore be considered as an alternative basal insulin therapy if there is a particular concern about nocturnal hypoglycaemia.

The committee agreed that once-daily ultra-long-acting insulin regimens, such as insulin degludec (100 units/ml), may also be needed by people who need support from a carer or healthcare professional to administer injections, for example, because they are frail or have a physical or mental health condition, or learning disability. Insulins that offer flexibility in dosing time, such as insulin degludec (100 units/ml), have a long duration of action and may be particularly useful because they give more flexibility in when the dose can be given. Insulin glargine (300 units/ml) is another example of an ultra-long-acting insulin. Healthcare professionals should also refer to NHS England's patient safety alert on the risk of severe harm and death from inappropriately withdrawing insulin from pen devices.

Biosimilars have the potential to offer the NHS considerable cost savings. To gain approval for use, biosimilar medicines have to be shown to be safe and as effective as the original reference medicine, and have the same quality. Based on this understanding, the committee noted it was appropriate when starting a new prescription of an insulin where a biosimilar is available, to use the one with the lowest cost.

Additionally, people may be using an insulin for which a lower cost biosimilar is available. In such cases, the committee recommended discussing with people the possibility of switching to the biosimilar. This could happen at the person's routine review. They also agreed that switching to the biosimilar should be carefully planned, taking into consideration the dose-switching protocols, monitoring and the person's concerns about switching from their existing regimen, and a shared decision reached. Healthcare professionals should also refer to the summary of product characteristics for further information when considering switching to biosimilars.

The committee retained the recommendation from the 2015 version of the guideline on considering the use of other basal insulin regimens not covered by other recommendations. Based on their clinical understanding, they added comorbidities (such as renal function), risks of hypoglycaemia and diabetic ketoacidosis and concerns about adherence to the factors to take into

account when considering alternative regimens. To support pharmacovigilance and patient safety, the committee also recommended that insulins should be prescribed by brand name.

How the recommendations might affect practice

Use of long-acting insulins varies across the country, with some centres offering twice-daily insulin detemir to people who are newly diagnosed, whereas other centres start with once-daily regimens. A major shift in practice is unlikely but the recommendations do set out scenarios where other insulins such as ultra-long-acting insulins and biosimilars may be useful and cost effective.

Return to recommendations

Context

Type 1 diabetes affects over 370,000 adults in the UK. It results from destruction of the cells that normally make insulin. Loss of insulin secretion results in high blood glucose and other metabolic and haematological abnormalities, which have both short-term and long-term adverse effects on health.

Over years, type 1 diabetes causes tissue damage which, if not detected and managed early, can result in disability: blindness, kidney failure and foot ulceration leading to amputation, as well as premature heart disease, stroke and death. The risk of all of these complications is greatly reduced by treatment that keeps circulating glucose levels to as near normal as possible, reducing tissue damage. Disability from complications that are not avoided can often be prevented by early detection and active management.

Type 1 diabetes is treated by insulin replacement and supported by active management of other cardiovascular risk factors, such as hypertension and high circulating lipids. Modern insulin replacement therapy aims to recreate normal fluctuations in circulating insulin concentrations. This supports a flexible lifestyle with minimal restrictions and, properly done, can improve blood glucose levels, reducing the risk of both structural complications and episodes of hypoglycaemia.

Flexible insulin therapy usually involves self-injecting multiple daily doses of insulin, with doses adjusted based on taken or planned exercise, intended food intake and other factors, including current blood glucose, which the insulin user needs to test on a regular basis. This self-management needs the insulin user to have the skills and confidence to manage the regimen.

One of the most important roles of healthcare professionals providing diabetes care to adults with type 1 diabetes is to ensure that systems are in place to provide informed expert support, education and training for insulin users, as well as a range of other more conventional biomedical services and interventions.

Although type 1 diabetes in adults is not rare, it is not common enough that all healthcare professionals who deal with it are able to acquire and maintain all the necessary skills for its management. The aim of this guideline is to provide evidence-based, practical advice on supporting adults with type 1 diabetes to live full, largely unrestricted, lives and to avoid the short-term and long-term complications of both the disease and of its treatment.

Finding more information and committee details

To find NICE guidance on related topics, including guidance in development, see the <u>NICE webpage</u> on diabetes.

For full details of the evidence and the guideline committee's discussions, see the <u>full guideline and</u> the evidence review. You can also find information about <u>how the guideline was developed</u>, including <u>details of the committee</u>.

NICE has produced <u>tools</u> and <u>resources</u> to help you put this <u>guideline</u> into <u>practice</u>. For general help and advice on putting our <u>guidelines</u> into <u>practice</u>, see <u>resources</u> to help you put NICE <u>guidance</u> into <u>practice</u>.

Update information

March 2022: We have reviewed evidence on the diagnosis of type 1 diabetes and continuous glucose monitoring (CGM). These recommendations are marked [2022].

We have also made some changes without an evidence review: In the first diagnosis recommendation, the term 'diagnosis' has been changed to 'initial diagnosis' to differentiate between this and later recommendations on revisiting the initial diagnosis.

- The word 'centre' has been replaced with 'team' in a reference to a centre with expertise in the use of CGM, because community-based specialist teams are now available. In the same recommendation, the wording 'as part of a strategy to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes' has also been simplified to 'supporting people to self-manage their diabetes'.
- Recommendations in the section on self-monitoring of capillary blood glucose have been clarified to clearly differentiate adults who are using capillary blood glucose monitoring from those using CGM.

These recommendations are marked [2015, amended 2022].

Recommendations marked [2004] or [2015] last had an evidence review in that year. In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

July 2021: We have reviewed the evidence and updated the recommendations on long-acting insulin therapy for adults with type 1 diabetes. These recommendations are marked [2021].

We have also made some changes without an evidence review:

• In recommendation 1.1.11, 'urine albumin excretion, urine protein and serum creatinine' was changed to 'urine albumin:creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR)' to bring the recommendation in line with NICE's guideline on chronic kidney disease.

- In recommendation 1.2.2, the statement 'A common environment (diabetes centre) is an
 important resource in allowing a diabetes multidisciplinary team to work and communicate
 efficiently while providing consistent advice' was removed to reflect changes in practice and
 the fact that working in a coordinated approach does not rely on having a single location of
 care.
- In recommendation 1.4.13, 'eating disorder' was changed to 'disordered eating' because it is a broader term that encompasses issues that are prevalent in type 1 diabetes.
- In recommendation 1.11.11, heparin was replaced by venous thromboembolism (VTE) prophylaxis because there is more than 1 type of prophylaxis that could be used.
- In recommendation 1.13.2, 'albuminuria' was changed to 'estimated glomerular filtration rate (eGFR) and urine albumin:creatinine ratio (ACR)' for consistency.
- In recommendation 1.13.6, 'young' was removed from 'Advise young adults who do not smoke never to start smoking' so that it applies to all adults.
- In recommendation 1.13.8, a cross-reference was added to the NICE guideline on hypertension in adults.
- In recommendation 1.15.6, 'serum creatinine' was changed to 'eGFR' to bring the recommendation in line with NICE's guideline on chronic kidney disease, and a cross-reference was added to this guideline.
- In recommendation 1.15.27 about initial measures for painful neuropathy, 'discontinue them' was removed because it contradicted recommendation 1.15.29, which stated to keep using them while trying further measures.
- In recommendation 1.15.38, the term 'insulin dose manipulation' was changed to 'disordered eating' because the term encompasses issues that are prevalent in type 1 diabetes.
- In recommendation 1.15.39, 'who are at risk of morbidity from the complications of poor metabolic control' was replaced by 'with an eating disorder' for clarity.

These recommendations are marked [2004, amended 2021] or [2004, amended 2015 and 2021].

In recommendation 1.15.24, specific recommendation numbers were replaced by 'interventions in this section'.

December 2020: Recommendations on diabetic retinopathy have been amended to bring them in line with the diabetic eye screening programme.

August 2015: This guidance updates NICE guideline CG15 (published July 2004). It also updates and replaces NICE technology appraisal guidance 53 and NICE technology appraisal guidance 60.

Some changes were made without an evidence review:

- Recommendations 1.4.11, 1.4.12 and 1.4.14 were updated to remove mention of a low glycaemic index diet, because there is no evidence of benefit for this.
- Recommendation 1.6.25 was amended to make it clear that self-monitoring skills should be taught as soon as type 1 diabetes is diagnosed.
- Recommendation 1.6.29 has been amended to remove references to small volumes of blood (which is now normal for all meters) and devices for alternative site monitoring (which are not recommended anyway).
- Recommendation 1.7.12 (now 1.7.16) was amended to remove a reference to resuspension of insulin, because this is out of date.
- Recommendation 1.10.10 has been updated to reflect changes in practice for managing hypoglycaemia.
- Recommendation 1.10.11 has been amended for clarity, and to highlight that glucagon can be given by untrained users in an emergency.
- Recommendation 1.10.15 has been amended to remove out of date and inconsistent information about different types of insulin.
- Recommendation 1.12.1 has been updated to remove low body mass index (BMI). This change brings the recommendation in line with NICE's guideline on coeliac disease.
- Recommendation 1.12.2 has been updated to remove mention of thyroid disorders, which are now covered in a separate recommendation.
- Recommendation 1.13.10 has been updated to reflect changes in hypertension management (covered in NICE's guideline on hypertension in adults).
- Recommendation 1.14.8 has been updated to reflect changes in hospital practice around monitoring systems.
- Recommendation 1.15.22 (now 1.15.17) has been updated to mention postural hypotension, because this is an important sign of autonomic neuropathy.

Minor changes since publication

December 2021: We removed the reference to dapagliflozin in recommendation 1.7.18 because it is no longer licensed for treating type 1 diabetes.

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Accreditation

