

Type 2 diabetes in adults: management

NICE guideline: short version

June 2015

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Introduction

Type 2 diabetes is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Type 2 diabetes is commonly associated with obesity, physical inactivity, raised blood pressure, disturbed blood lipid levels and a tendency to develop thrombosis, and therefore is recognised to have an increased cardiovascular risk. It is associated with long-term microvascular and macrovascular complications, together with reduced quality of life and life expectancy.

In 2013, over 3.2 million adults were diagnosed with diabetes, with prevalence rates of 6% and 6.7% in England and Wales respectively. It is estimated that about 90% of adults currently diagnosed with diabetes have type 2 diabetes. Type 2 diabetes is more common in people of African, African-Caribbean and South Asian family origin. It can occur in all age groups and is increasingly being diagnosed in children.

Multiple vascular risk factors and wide-ranging complications make diabetes care complex and time-consuming, and many areas of healthcare services must be involved for optimal management. Necessary lifestyle changes, the complexities and possible side effects of therapy make patient education and self-management important aspects of diabetes care. Diabetes care is estimated to account for at least 5% of UK healthcare expenditure, and up to 10% of NHS expenditure.

This guideline contains recommendations for managing type 2 diabetes in adults, and focuses on patient education, dietary advice, managing cardiovascular risk, managing blood glucose levels, and identifying and managing long-term complications. The guideline does not cover diagnosis, secondary diabetes, type 1 diabetes in adults, diabetes in pregnancy and diabetes in children and young people.

Reasons for the update

Since the publication of the 2009 guideline, availability of new evidence and several key developments have prompted an update in the following areas: managing blood glucose levels, antiplatelet therapy and erectile dysfunction. In particular, reasons included safety concerns surrounding some blood glucose lowering medicines, new evidence on new dipeptidyl peptidase-4 (DPP-4) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, new indications and licensed combinations for licensed class members and the potential impact of drugs coming off patent on health-economic issues. In addition, new evidence and safety issues relating to the off-label use of antiplatelet therapy (aspirin and clopidogrel) in the primary prevention of cardiovascular disease motivated an update of this review.

Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some medicines for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information. Where recommendations have been made for the use of medicines outside their licensed indications ('off-label use'), these medicines are marked with a footnote in the recommendations.

Patient-centred care

This guideline offers best practice advice on the care of adults with type 2 diabetes.

When caring for older adults with type 2 diabetes, particular consideration should be given to their broader health and social care needs. Older people are more likely to have co-existing conditions and to be on a greater number of medicines. Their ability to benefit from risk-reduction interventions in the longer term may also be reduced.

Much of the evidence base used to inform this guideline has been generated from studies involving younger adults (study mean ages ranged from 45 to 68 years). While the Guideline Development Group (GDG) thought that the recommendations are applicable to a wider age group, they highlighted that there needs to be flexibility, to ensure that the care of older people with diabetes also addresses their broader health and social care needs.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. If it is clear that the child or young person fully understands the treatment and does not want their family or carers to be involved, they can give their own consent. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#).

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Recommendation wording in guideline updates

NICE began using this approach to denote the strength of recommendations in guidelines that started development after publication of the 2009 version of 'The guidelines manual' (January 2009). This does not apply to any recommendations ending [2009] (see 'Update information' box below for details about how recommendations are labelled). In particular, for recommendations labelled [2009], the word 'consider' may not necessarily be used to denote the strength of the recommendation.

Update information

This guidance is an update of NICE guideline CG87 (published May 2009) and replaces it. This guidance also updates and replaces NICE technology appraisal guidance 203 and NICE technology appraisal guidance 248.

It has not been possible to update all recommendations in this update of the guideline. Areas for review and update were identified and prioritised through the scoping process and stakeholder feedback. Areas that have not been reviewed in this update may be addressed in 2 years' time when NICE next considers updating this guideline. NICE is currently considering setting up a standing update committee for diabetes, which would enable more rapid update of discrete areas of the diabetes guidelines, as and when new and relevant evidence is published.

Recommendations are marked as **[new 2015]**, **[2015]**, **[2009]** or **[2009, amended 2015]**:

- **[new 2015]** indicates that the evidence has been reviewed and the recommendation has been added or updated.
- **[2015]** indicates that the evidence has been reviewed but no change has been made to the recommended action.
- **[2009]** indicates that the evidence has not been reviewed since 2009.
- **[2009, amended 2015]** indicates that the evidence has not been reviewed since 2009, but either changes have been made to the recommendation wording that change the meaning or NICE has made editorial changes to the original wording to clarify the action to be taken.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in [section 1](#).

Patient education

- Offer structured education to adults with type 2 diabetes and/or their family members or carers (as appropriate) at and around the time of diagnosis, with annual reinforcement and review. Explain to people and their carers that structured education is an integral part of diabetes care. **[2009] [1.2.1]**
- Ensure that any structured education programme for adults with type 2 diabetes includes the following components:
 - It is evidence-based, and suits the needs of the person.
 - It 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.
 - It has a structured curriculum that is theory-driven, evidence-based and resource-effective, has supporting materials, and is written down.
 - It is delivered by trained educators who have an understanding of educational theory appropriate to the age and needs of the person, and who are trained and competent to deliver the principles and content of the programme.
 - It is quality assured, and reviewed by trained, competent, independent assessors who measure it against criteria that ensure consistency.
 - The outcomes are audited regularly. **[2015] [1.2.2]**

Dietary advice

- Integrate dietary advice with a personalised diabetes management plan, including other aspects of lifestyle modification, such as increasing physical activity and losing weight. **[2009] [1.3.4]**

Blood pressure management

- Add medications if lifestyle advice does not reduce blood pressure to below 140/80 mmHg (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage). **[2009] [1.4.5]**
- Monitor blood pressure every 1–2 months, and intensify therapy if the person is already on antihypertensive drug treatment, until the blood pressure is consistently below 140/80 mmHg (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage). **[2009] [1.4.6]**

Blood glucose management

- Involve adults with type 2 diabetes in decisions about their individual HbA1c target. Encourage them to achieve the target and maintain it unless any resulting adverse effects (including hypoglycaemia), or their efforts to achieve their target, impair their quality of life. **[new 2015] [1.6.5]**
- In adults with type 2 diabetes, if HbA1c levels are not adequately controlled by a single drug and rise to 58 mmol/mol (7.5%) or higher:
 - reinforce advice about diet, lifestyle and adherence to drug treatment **and**
 - intensify drug treatment **and**
 - agree a target and aim for an HbA1c level of 53 mmol/mol (7.0%). **[new 2015] [1.6.8]**
- Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:
 - the person is on insulin **or**
 - there is evidence of hypoglycaemic episodes **or**
 - the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery **or**
 - the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on [diabetes in pregnancy](#). **[new 2015] [1.6.13]**

Drug treatment

- Offer standard-release metformin as the initial drug treatment for adults with type 2 diabetes. **[new 2015] [1.6.19]**
- In adults with type 2 diabetes, if metformin is contraindicated or not tolerated, consider initial drug treatment with:
 - a dipeptidyl peptidase-4 (DPP-4) inhibitor **or**
 - pioglitazone¹ **or**
 - repaglinide² **or**
 - a sulfonylurea. **[new 2015] [1.6.23]**

¹ When prescribing pioglitazone, exercise particular caution if the person is at high risk of the adverse effects of the drug. The MHRA has issued safety alerts on pioglitazone for [bladder cancer](#) and [cardiac failure](#).

² Repaglinide has a marketing authorisation for use only as monotherapy or in combination with metformin. Therefore, for adults with type 2 diabetes who cannot take metformin, there is no licensed combination containing repaglinide that can be offered at first intensification. People should be made aware of this when initial therapy is being discussed.

1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

Terms used in this guideline

Initial drug treatment	Treatment with a single non-insulin blood glucose lowering therapy (monotherapy)
First intensification of drug treatment	Treatment with 2 non-insulin blood glucose lowering therapies in combination (dual therapy)
Second intensification of drug treatment	Treatment with either 3 non-insulin blood glucose lowering therapies in combination (triple therapy) or any treatment combination containing insulin

1.1 *Individualised care*

1.1.1 Adopt an individualised approach to diabetes care that is tailored to the needs and circumstances of adults with type 2 diabetes, taking into account their personal preferences, comorbidities, risks from polypharmacy, and their ability to benefit from long-term interventions because of reduced life expectancy. Such an approach is especially important in the context of multimorbidity. Reassess the person's needs and circumstances at each review and think about whether to stop any medicines that are not effective. **[new 2015]**

1.1.2 Take into account any disabilities, including visual impairment, when planning and delivering care for adults with type 2 diabetes. **[new 2015]**

1.2 *Patient education*

1.2.1 Offer structured education to adults with type 2 diabetes and/or their family members or carers (as appropriate) at and around the time of diagnosis, with annual reinforcement and review. Explain to

people and their carers that structured education is an integral part of diabetes care. **[2009]**

1.2.2 Ensure that any structured education programme for adults with type 2 diabetes includes the following components:

- It is evidence-based, and suits the needs of the person.
- It 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.
- It has a structured curriculum that is theory-driven, evidence-based and resource-effective, has supporting materials, and is written down.
- It is delivered by trained educators who have an understanding of educational theory appropriate to the age and needs of the person, and who are trained and competent to deliver the principles and content of the programme.
- It is quality assured, and reviewed by trained, competent, independent assessors who measure it against criteria that ensure consistency.
- The outcomes are audited regularly. **[2015]**

- 1.2.3 Ensure the patient-education programme provides the necessary resources to support the educators, and that educators are properly trained and given time to develop and maintain their skills. **[2009]**
- 1.2.4 Offer group education programmes as the preferred option. Provide an alternative of equal standard for a person unable or unwilling to participate in group education. **[2009]**
- 1.2.5 Ensure that the patient-education programmes available meet the cultural, linguistic, cognitive and literacy needs within the local area. **[2009]**
- 1.2.6 Ensure that all members of the diabetes healthcare team are familiar with the patient-education programmes available locally, that these programmes are integrated with the rest of the care pathway, and that adults with type 2 diabetes and their family members or carers (as appropriate) have the opportunity to contribute to the design and provision of local programmes. **[2009]**

1.3 *Dietary advice*

- 1.3.1 Provide individualised and ongoing nutritional advice from a healthcare professional with specific expertise and competencies in nutrition. **[2009]**
- 1.3.2 Provide dietary advice in a form sensitive to the person's needs, culture and beliefs, being sensitive to their willingness to change and the effects on their quality of life. **[2009]**
- 1.3.3 Emphasise advice on healthy balanced eating that is applicable to the general population when providing advice to adults with type 2 diabetes. Encourage high-fibre, low-glycaemic-index sources of carbohydrate in the diet, such as fruit, vegetables, wholegrains and pulses; include low-fat dairy products and oily fish; and control the intake of foods containing saturated and trans fatty acids. **[2009]**

- 1.3.4 Integrate dietary advice with a personalised diabetes management plan, including other aspects of lifestyle modification, such as increasing physical activity and losing weight. **[2009]**
- 1.3.5 For adults with type 2 diabetes who are overweight, set an initial body weight loss target of 5–10%. Remember that lesser degrees of weight loss may still be of benefit, and that larger degrees of weight loss in the longer term will have advantageous metabolic impact. **[2009]**
- 1.3.6 Individualise recommendations for carbohydrate and alcohol intake, and meal patterns. Reducing the risk of hypoglycaemia should be a particular aim for a person using insulin or an insulin secretagogue. **[2009]**
- 1.3.7 Advise adults with type 2 diabetes that limited substitution of sucrose-containing foods for other carbohydrate in the meal plan is allowable, but that they should take care to avoid excess energy intake. **[2009]**
- 1.3.8 Discourage the use of foods marketed specifically for people with diabetes. **[2009]**
- 1.3.9 When adults with type 2 diabetes are admitted to hospital as inpatients or to any other care setting, implement a meal planning system that provides consistency in the carbohydrate content of meals and snacks. **[2009]**
- 1.3.10 For recommendations on lifestyle advice, see the NICE guidelines on: [maintaining a healthy weight and preventing excess weight gain among adults and children](#), [managing overweight and obesity in adults – lifestyle weight management services](#), [obesity](#), [physical activity: brief advice for adults in primary care](#), [brief interventions and referral for smoking cessation](#), [smoking cessation services](#),

[tobacco: harm reduction approaches to smoking](#), and [smoking cessation in secondary care](#). [new 2015]

1.4 Blood pressure management

- 1.4.1 Measure blood pressure at least annually in an adult with type 2 diabetes without previously diagnosed hypertension or renal disease. Offer and reinforce preventive lifestyle advice. [2009]
- 1.4.2 For an adult with type 2 diabetes on antihypertensive drug treatment when diabetes is diagnosed, review blood pressure control and medications used. Make changes only if there is poor control or if current drug treatment is not appropriate because of microvascular complications or metabolic problems. [2009]
- 1.4.3 Repeat blood pressure measurements within:
- 1 month if blood pressure is higher than 150/90 mmHg
 - 2 months if blood pressure is higher than 140/80 mmHg
 - 2 months if blood pressure is higher than 130/80 mmHg and there is kidney, eye or cerebrovascular damage.
- Provide lifestyle advice (diet and exercise) at the same time. [2009]
- 1.4.4 Provide lifestyle advice (see section 1.3 in this guideline and the [lifestyle interventions](#) section in 'Hypertension' [NICE guideline CG127]) if blood pressure is confirmed as being consistently above 140/80 mmHg (or above 130/80 mmHg if there is kidney, eye or cerebrovascular damage). [2009]
- 1.4.5 Add medications if lifestyle advice does not reduce blood pressure to below 140/80 mmHg (below 130/80 mmHg if there is kidney, eye or cerebrovascular damage). [2009]
- 1.4.6 Monitor blood pressure every 1–2 months, and intensify therapy if the person is already on antihypertensive drug treatment, until the blood pressure is consistently below 140/80 mmHg (below

130/80 mmHg if there is kidney, eye or cerebrovascular damage).

[2009]

- 1.4.7 First-line antihypertensive drug treatment should be a once-daily, generic angiotensin-converting enzyme (ACE) inhibitor. Exceptions to this are people of African or Caribbean family origin, or women for whom there is a possibility of becoming pregnant. **[2009]**
- 1.4.8 The first-line antihypertensive drug treatment for a person of African or Caribbean family origin should be an ACE inhibitor plus either a diuretic or a generic calcium-channel blocker. **[2009]**
- 1.4.9 A calcium-channel blocker should be the first-line antihypertensive drug treatment for a woman for whom, after an informed discussion, it is agreed there is a possibility of her becoming pregnant. **[2009]**
- 1.4.10 For a person with continuing intolerance to an ACE inhibitor (other than renal deterioration or hyperkalaemia), substitute an angiotensin II-receptor antagonist for the ACE inhibitor. **[2009]**
- 1.4.11 If the person's blood pressure is not reduced to the individually agreed target with first-line therapy, add a calcium-channel blocker or a diuretic (usually a thiazide or thiazide-related diuretic). Add the other drug (that is, the calcium-channel blocker or diuretic) if the target is not reached with dual therapy. **[2009, amended 2015]**
- 1.4.12 If the person's blood pressure is not reduced to the individually agreed target with triple therapy, add an alpha-blocker, a beta-blocker or a potassium-sparing diuretic (the last with caution if the person is already taking an ACE inhibitor or an angiotensin II-receptor antagonist). **[2009]**
- 1.4.13 Monitor the blood pressure of a person who has attained and consistently remained at his or her blood pressure target every 4–6 months. Check for possible adverse effects of antihypertensive

drug treatment – including the risks from unnecessarily low blood pressure. **[2009]**

1.5 *Antiplatelet therapy*

1.5.1 Do not offer antiplatelet therapy (aspirin or clopidogrel) for adults with type 2 diabetes without cardiovascular disease. **[new 2015]**

1.5.2 For guidance on the primary and secondary prevention of cardiovascular disease in adults with type 2 diabetes, see the NICE guidelines on [lipid modification](#) and [myocardial infarction – secondary prevention](#). **[new 2015]**

1.6 *Blood glucose management*

HbA1c measurement and targets

Measurement

1.6.1 In adults with type 2 diabetes, measure HbA1c levels at:

- 3–6-monthly intervals (tailored to individual needs), until the HbA1c is stable on unchanging therapy
- 6-monthly intervals once the HbA1c level and blood glucose lowering therapy are stable. **[2015]**

1.6.2 Use methods to measure HbA1c that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. **[new 2015]**

1.6.3 If HbA1c monitoring is invalid because of disturbed erythrocyte turnover or abnormal haemoglobin type, estimate trends in blood glucose control using one of the following:

- fructosamine estimation
- quality-controlled plasma glucose profiles
- total glycated haemoglobin estimation (if abnormal haemoglobins). **[2015]**

- 1.6.4 Investigate unexplained discrepancies between HbA1c and other glucose measurements. Seek advice from a team with specialist expertise in diabetes or clinical biochemistry. **[2015]**

Targets

- 1.6.5 Involve adults with type 2 diabetes in decisions about their individual HbA1c target. Encourage them to achieve the target and maintain it unless any resulting adverse effects (including hypoglycaemia), or their efforts to achieve their target, impair their quality of life. **[new 2015]**
- 1.6.6 Offer lifestyle advice and drug treatment to support adults with type 2 diabetes to achieve and maintain their HbA1c target (see section 1.3). For more information about supporting adherence, see the NICE guideline on [medicines adherence](#). **[new 2015]**
- 1.6.7 For adults with type 2 diabetes that is managed either by lifestyle and diet, or by lifestyle and diet in combination with a single drug that is not associated with hypoglycaemia, agree a target and aim for an HbA1c level of 48 mmol/mol (6.5%). **[new 2015]**
- 1.6.8 In adults with type 2 diabetes, if HbA1c levels are not adequately controlled by a single drug and rise to 58 mmol/mol (7.5%) or higher:
- reinforce advice about diet, lifestyle and adherence to drug treatment **and**
 - intensify drug treatment **and**
 - agree a target and aim for an HbA1c level of 53 mmol/mol (7.0%). **[new 2015]**

1.6.9 Consider relaxing the target HbA1c level (see recommendations 1.6.7 and 1.6.8) on a case-by-case basis, with particular consideration for people who are older or frail, for adults with type 2 diabetes:

- who are unlikely to achieve longer-term risk-reduction benefits, for example, people with a reduced life expectancy
- for whom tight blood glucose control poses a high risk of the consequences of hypoglycaemia, for example, people who are at risk of falling, people who have impaired awareness of hypoglycaemia, and people who drive or operate machinery as part of their job
- for whom intensive management would not be appropriate, for example, people with significant comorbidities. **[new 2015]**

1.6.10 If adults with type 2 diabetes achieve an HbA1c level that is lower than their target and they are not experiencing hypoglycaemia, encourage them to maintain it. Be aware that there are other possible reasons for a low HbA1c level, for example, deteriorating renal function or sudden weight loss. **[new 2015]**

1.6.11 For guidance on HbA1c targets for women with type 2 diabetes who are pregnant or planning to become pregnant, see the NICE guideline on [diabetes in pregnancy](#). **[new 2015]**

Self-monitoring of blood glucose

1.6.12 Take the Driver and Vehicle Licensing Agency (DVLA) [At a glance guide to the current medical standards of fitness to drive](#) into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes. **[new 2015]**

1.6.13 Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:

- the person is on insulin **or**

- there is evidence of hypoglycaemic episodes **or**
- the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery **or**
- the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on [diabetes in pregnancy](#). **[new 2015]**

1.6.14 Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):

- when starting treatment with oral or intravenous corticosteroids, **or**
- to confirm suspected hypoglycaemia. **[new 2015]**

1.6.15 Be aware that there is a risk of hyperglycaemia in adults with type 2 diabetes who have acute intercurrent illness. Review treatment as necessary. **[new 2015]**

1.6.16 If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include:

- the person's self-monitoring skills
- the quality and frequency of testing
- checking that the person knows how to interpret the blood glucose results and what action to take
- the impact on the person's quality of life
- the continued benefit to the person
- the equipment used. **[2015]**

1 **Drug treatment**

2 1.6.17 For adults with type 2 diabetes, discuss the benefits and risks of
3 drug treatment, and the options available. Base the choice of drug
4 treatment(s) on:

- 5 • the effectiveness of the drug treatment(s) in terms of metabolic
6 response
- 7 • safety (see [Medicines and Healthcare products Regulatory](#)
8 [Agency \[MHRA\]](#) guidance) and tolerability of the drug
9 treatment(s)
- 10 • the person's individual clinical circumstances, for example,
11 comorbidities, risks from polypharmacy
- 12 • the person's individual preferences and needs
- 13 • the licensed indications or combinations available
- 14 • cost (if 2 drugs in the same class are appropriate, choose the
15 option with the lowest acquisition cost). **[new 2015]**

16 ***Rescue therapy at any phase of treatment***

17 1.6.18 If an adult with type 2 diabetes is symptomatically hyperglycaemic,
18 consider insulin (see recommendations 1.6.31–1.6.33) or a
19 sulfonylurea, and review treatment when blood glucose control has
20 been achieved. **[new 2015]**

21 ***Initial drug treatment***

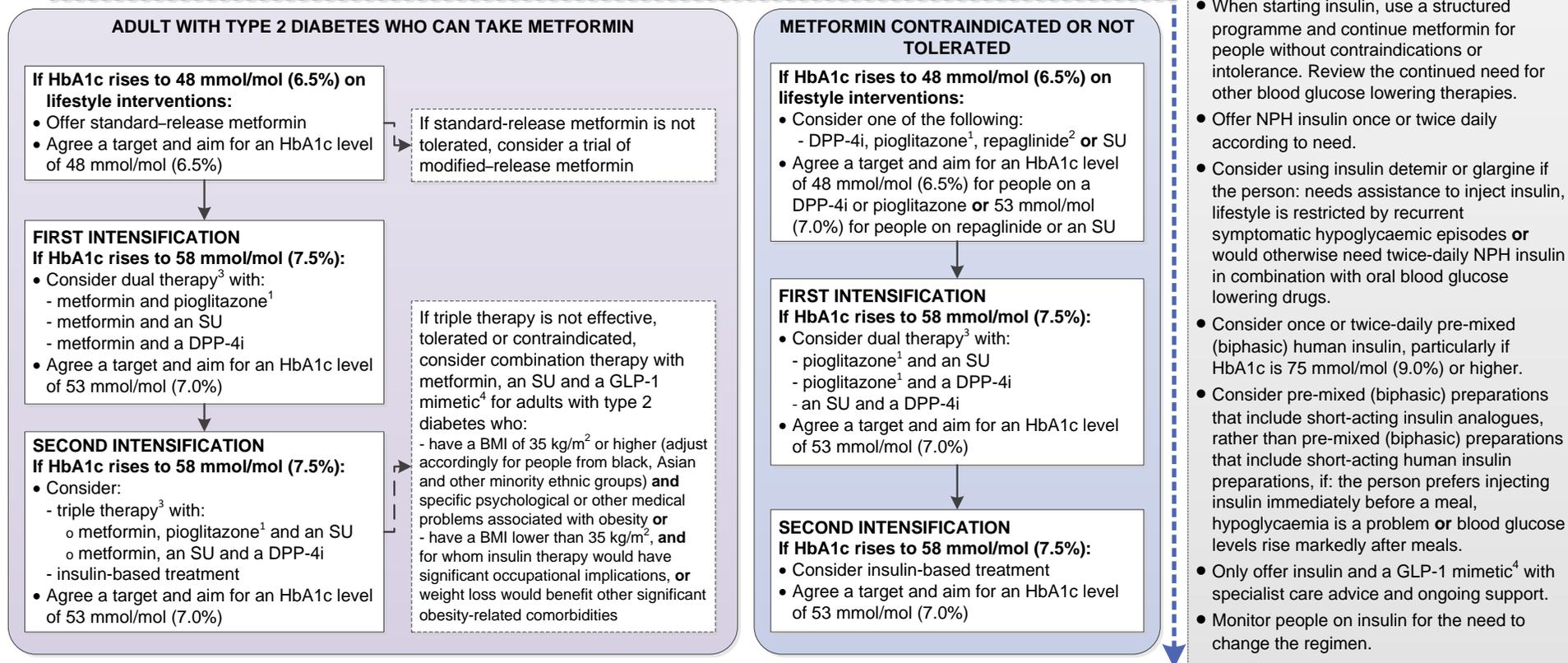
22 1.6.19 Offer standard-release metformin as the initial drug treatment for
23 adults with type 2 diabetes. **[new 2015]**

24 1.6.20 Gradually increase the dose of standard-release metformin over
25 several weeks to minimise the risk of gastrointestinal side effects in
26 adults with type 2 diabetes. **[new 2015]**

Algorithm for blood glucose lowering therapy in adults with type 2 diabetes

- Reinforce advice on diet, lifestyle and adherence to drug treatment.
- Agree an individualised HbA1c target based on: the person's needs and circumstances including preferences, comorbidities, risks from polypharmacy and tight blood glucose control and ability to achieve longer-term risk-reduction benefits. Where appropriate, aim for the recommended HbA1c targets in the algorithm. Measure HbA1c levels at 3/6 monthly intervals, as appropriate. If the person achieves an HbA1c target lower than target with no hypoglycaemia, encourage them to maintain it. Be aware that there are other possible reasons for a low HbA1c level.
- Base choice of drug treatment on: effectiveness, safety (see MHRA guidance), tolerability, the person's individual clinical circumstances, preferences and needs, available licensed indications or combinations, and cost (if 2 drugs in the same class are appropriate, choose the option with the lowest acquisition cost).
- Do not routinely offer self-monitoring of blood glucose levels unless the person is on insulin, on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery, is pregnant or planning to become pregnant or if there is evidence of hypoglycaemic episodes.

If the person is symptomatically hyperglycaemic, consider insulin or an SU. Review treatment when blood glucose control has been achieved.



Abbreviations: DPP-4i Dipeptidyl peptidase-4 inhibitor, GLP-1 Glucagon-like peptide-1, SU Sulfonylurea

1. When prescribing pioglitazone, exercise particular caution if the person is at high risk of the adverse effects of the drug. The Medicines and Healthcare products Regulatory Agency (MHRA) has issued safety alerts on pioglitazone for bladder cancer and cardiac failure.

2. Repaglinide has a marketing authorisation for use only as monotherapy or in combination with metformin. For adults with type 2 diabetes who cannot take metformin, there is no licensed combination containing repaglinide that can be offered at first intensification. People should be made aware of this when initial therapy is discussed. At first intensification, any dual therapy combination (DPP-4 inhibitor, pioglitazone, sulfonylurea) may be offered. The 2 new drugs should be introduced in a stepwise manner, checking for tolerability and effectiveness.

3. Treatment with combinations of drugs including sodium-glucose cotransporter 2 (SGLT-2) inhibitors may be appropriate for some people; see NICE technology appraisal guidance 288, 315 and 336.

4. Only continue GLP-1 mimetic therapy if the person has a beneficial metabolic response (a reduction of HbA1c by at least 11 mmol/mol [1.0%] **and** a weight loss of at least 3% of initial body weight in 6 months).

- 1 1.6.21 If an adult with type 2 diabetes experiences gastrointestinal side
 2 effects with standard-release metformin, consider a trial of
 3 modified-release metformin. **[new 2015]**
- 4 1.6.22 In adults with type 2 diabetes, review the dose of metformin if the
 5 estimated glomerular filtration rate (eGFR) is below
 6 45 ml/minute/1.73m²:
- 7 • Stop metformin if the eGFR is below 30 ml/minute/1.73m².
 - 8 • Prescribe metformin with caution for those at risk of a sudden
 9 deterioration in kidney function and those at risk of eGFR falling
 10 below 45 ml/minute/1.73m². **[2015]**
- 11 1.6.23 In adults with type 2 diabetes, if metformin is contraindicated or not
 12 tolerated, consider initial drug treatment with:
- 13 • a dipeptidyl peptidase-4 (DPP-4) inhibitor, **or**
 - 14 • pioglitazone³, **or**
 - 15 • repaglinide⁴, **or**
 - 16 • a sulfonylurea. **[new 2015]**

17 ***First intensification of drug treatment***

- 18 1.6.24 In adults with type 2 diabetes, if initial drug treatment with
 19 metformin has not continued to control HbA1c to below the
 20 person’s individually agreed threshold for intensification, consider
 21 dual therapy with:
- 22 • metformin and pioglitazone³, **or**
 - 23 • metformin and a sulfonylurea, **or**
 - 24 • metformin and a DPP-4 inhibitor. **[new 2015]**

³ When prescribing pioglitazone, exercise particular caution if the person is at high risk of the adverse effects of the drug. The MHRA has issued safety alerts on pioglitazone for [bladder cancer](#) and [cardiac failure](#).

⁴ Repaglinide has a marketing authorisation for use only as monotherapy or in combination with metformin. Therefore, for adults with type 2 diabetes who cannot take metformin, there is no licensed combination containing repaglinide that can be offered at first intensification. People should be made aware of this when initial therapy is being discussed.

1 1.6.25 In adults with type 2 diabetes, if metformin is contraindicated or not
2 tolerated and initial drug treatment has not continued to control
3 HbA1c to below the person's individually agreed threshold for
4 intensification, consider dual therapy⁵ with:

- 5 • pioglitazone³ and a sulfonylurea, **or**
- 6 • pioglitazone³ and a DPP-4 inhibitor, **or**
- 7 • a sulfonylurea and a DPP-4 inhibitor. **[new 2015]**

8 Treatment with combinations of medicines including sodium–glucose
9 cotransporter 2 (SGLT-2) inhibitors may be appropriate for some people with
10 type 2 diabetes; see the NICE guidance on [dapagliflozin in combination](#)
11 [therapy for treating type 2 diabetes](#), [canagliflozin in combination therapy for](#)
12 [treating type 2 diabetes](#) and [empagliflozin in combination therapy for treating](#)
13 [type 2 diabetes](#).

14 ***Second intensification of drug treatment***

15 1.6.26 In adults with type 2 diabetes, if dual therapy with metformin and
16 another oral drug (see recommendation 1.6.24) has not continued
17 to control HbA1c to below the person's individually agreed
18 threshold for intensification, consider either:

- 19 • triple therapy with:
 - 20 – metformin, pioglitazone³ and a sulfonylurea, **or**
 - 21 – metformin, a sulfonylurea and a DPP-4 inhibitor, **or**
- 22 • starting insulin-based treatment (see recommendations 1.6.31–
23 1.6.33). **[new 2015]**

24 1.6.27 If triple therapy with metformin and 2 other oral drugs (see
25 recommendation 1.6.26) is not effective, tolerated or
26 contraindicated, consider combination therapy with metformin, a

⁵ Be aware that initial drug treatment with repaglinide should be stopped and the drugs in the dual therapy should be introduced in a stepwise manner, checking for tolerability and effectiveness of each drug.

1 sulfonylurea and a glucagon-like peptide-1 (GLP-1) mimetic for
2 adults with type 2 diabetes who:

- 3 • have a BMI of 35 kg/m² or higher (adjust accordingly for people
4 from black, Asian and other minority ethnic groups) **and** specific
5 psychological or other medical problems associated with obesity,
6 **or**
- 7 • have a BMI lower than 35 kg/m² **and**:
 - 8 – for whom insulin therapy would have significant occupational
9 implications, **or**
 - 10 – weight loss would benefit other significant obesity-related
11 comorbidities. **[new 2015]**

12 1.6.28 Only continue GLP-1 mimetic therapy if the person with type 2
13 diabetes has had a beneficial metabolic response (a reduction of at
14 least 11 mmol/mol [1.0%] in HbA1c and a weight loss of at least 3%
15 of initial body weight in 6 months). **[2015]**

16 1.6.29 In adults with type 2 diabetes, if metformin is contraindicated or not
17 tolerated, and if dual therapy with 2 oral drugs (see
18 recommendation 1.6.25) has not continued to control HbA1c to
19 below the person's individually agreed threshold for intensification,
20 consider insulin-based treatment (see recommendations 1.6.31–
21 1.6.33). **[new 2015]**

22 1.6.30 In adults with type 2 diabetes, only offer a GLP-1 mimetic in
23 combination with insulin with specialist care advice and ongoing
24 support (for example, from a diabetologist or GP with a special
25 interest in diabetes). **[new 2015]**

26 Treatment with combinations of medicines including SGLT-2 inhibitors may be
27 appropriate for some people with type 2 diabetes; see the NICE guidance on
28 [dapagliflozin in combination therapy for treating type 2 diabetes](#), [canagliflozin](#)
29 [in combination therapy for treating type 2 diabetes](#) and [empagliflozin in](#)
30 [combination therapy for treating type 2 diabetes](#).

1 **Insulin-based treatments**

2 1.6.31 When starting insulin therapy in adults with type 2 diabetes, use a
3 structured programme employing active insulin dose titration that
4 encompasses:

- 5 • structured education
- 6 • continuing telephone support
- 7 • self-monitoring
- 8 • dose titration to target levels
- 9 • dietary understanding
- 10 • DVLA guidance ([At a glance guide to the current medical](#)
11 [standards of fitness to drive](#))
- 12 • management of hypoglycaemia
- 13 • management of acute changes in plasma glucose control
- 14 • support from an appropriately trained and experienced
15 healthcare professional. **[2015]**

16 1.6.32 When starting insulin therapy in adults with type 2 diabetes,
17 continue to offer metformin for people without contraindications or
18 intolerance. Review the continued need for other blood glucose
19 lowering therapies. **[new 2015]**

20 1.6.33 Start insulin therapy for adults with type 2 diabetes from a choice of
21 a number of insulin types and regimens:

- 22 • Offer NPH insulin injected once or twice daily according to need.
- 23 • Consider, as an alternative, using insulin detemir or insulin
24 glargine if:
 - 25 – the person needs assistance from a carer or healthcare
26 professional to inject insulin, and use of insulin detemir or
27 insulin glargine would reduce the frequency of injections from
28 twice to once daily, **or**
 - 29 – the person's lifestyle is restricted by recurrent symptomatic
30 hypoglycaemic episodes, **or**

- 1 – the person would otherwise need twice-daily NPH insulin
- 2 injections in combination with oral glucose-lowering drugs.
- 3 • Consider twice-daily pre-mixed (biphasic) human insulin
- 4 (particularly if HbA1c is 75 mmol/mol [9.0%] or higher). A once-
- 5 daily regimen may be an option.
- 6 • Consider pre-mixed (biphasic) preparations that include short-
- 7 acting insulin analogues, rather than pre-mixed (biphasic)
- 8 preparations that include short-acting human insulin
- 9 preparations, if:
- 10 – a person prefers injecting insulin immediately before a meal,
- 11 **or**
- 12 – hypoglycaemia is a problem, **or**
- 13 – blood glucose levels rise markedly after meals. **[2015]**

14 1.6.34 Consider switching to insulin detemir or insulin glargine from NPH
15 insulin in adults with type 2 diabetes:

- 16 • who do not reach their target HbA1c because of significant
- 17 hypoglycaemia, **or**
- 18 • who experience significant hypoglycaemia on NPH insulin
- 19 irrespective of the level of HbA1c reached, **or**
- 20 • who cannot use the device needed to inject NPH insulin but who
- 21 could administer their own insulin safely and accurately if a
- 22 switch to one of the long-acting insulin analogues was made, **or**
- 23 • who need help from a carer or healthcare professional to
- 24 administer insulin injections and for whom switching to one of
- 25 the long-acting insulin analogues would reduce the number of
- 26 daily injections. **[2015]**

1 1.6.35 Monitor adults with type 2 diabetes who are on a basal insulin
2 regimen (NPH insulin, insulin detemir or insulin glargine) for the
3 need for short-acting insulin before meals (or a pre-mixed [biphasic]
4 insulin preparation). **[2015]**

5 1.6.36 Monitor adults with type 2 diabetes who are on pre-mixed
6 (biphasic) insulin for the need for a further injection of short-acting
7 insulin before meals or for a change to a basal bolus regimen with
8 NPH insulin or insulin detemir or insulin glargine, if blood glucose
9 control remains inadequate. **[2015]**

10 Treatment with combinations of medicines including SGLT-2 inhibitors may be
11 appropriate for some people with type 2 diabetes; see the NICE guidance on
12 [dapagliflozin in combination therapy for treating type 2 diabetes](#), [canagliflozin](#)
13 [in combination therapy for treating type 2 diabetes](#) and [empagliflozin in](#)
14 [combination therapy for treating type 2 diabetes](#).

15 **Insulin delivery**

16 1.6.37 For guidance on insulin delivery for adults with type 2 diabetes, see
17 the [insulin delivery](#) section in the NICE guideline on type 1
18 diabetes. **[new 2015]**

1.7 ***Managing complications***

Gastroparesis

1.7.1 Think about a diagnosis of gastroparesis in adults with type 2
diabetes with erratic blood glucose control or unexplained gastric
bloating or vomiting, taking into account possible alternative
diagnoses. **[2009, amended 2015]**

1.7.2 For adults with type 2 diabetes who have vomiting caused by
gastroparesis, explain that:

- there is not strong evidence that any available antiemetic
therapy is effective

- some people have had benefit with domperidone⁶, erythromycin⁷ or metoclopramide.
 - 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.
- [new 2015]**

1.7.3 For treating vomiting caused by gastroparesis in adults with type 2 diabetes:

- consider alternating use of erythromycin⁷ and metoclopramide
- consider domperidone⁶ only in exceptional circumstances (if domperidone is the only effective treatment) and in accordance with MHRA guidance. **[new 2015]**

1.7.4 If gastroparesis is suspected, consider referral to specialist services if:

- the differential diagnosis is in doubt, **or**
- persistent or severe vomiting occurs. **[2009]**

Painful diabetic neuropathy

1.7.5 For guidance on managing painful diabetic peripheral neuropathy in adults with type 2 diabetes, see the NICE guideline on [neuropathic pain – pharmacological management](#). **[new 2015]**

⁶ [Medicines and Healthcare Products Regulatory Agency \(MHRA\) guidance](#) (2014) notes that domperidone is associated with a small increased risk of serious cardiac side effects. Domperidone is now contraindicated in certain groups in whom the risk of cardiac effects is higher; its marketing authorisations have also been restricted to its use in the relief of nausea and vomiting only, at the lowest effective dose and for the shortest possible time (usually not more than 1 week): see the MHRA guidance and summaries of product characteristics. The MHRA advises that prescribers should take into account the overall safety profile of domperidone, and in particular its cardiac risk and potential interactions with other medicines (such as erythromycin), if there is a clinical need to use it at doses or durations greater than those authorised. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

⁷ At the time of publication (August 2015), erythromycin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Prescribing guidance: prescribing unlicensed medicines](#) for further information.

Autonomic neuropathy

- 1.7.6 Think about the possibility of contributory sympathetic nervous system damage for adults with type 2 diabetes who lose the warning signs of hypoglycaemia. **[2009, amended 2015]**
- 1.7.7 Think about the possibility of autonomic neuropathy affecting the gut in adults with type 2 diabetes who have unexplained diarrhoea that happens particularly at night. **[2009, amended 2015]**
- 1.7.8 When using tricyclic drugs and antihypertensive drug treatments in adults with type 2 diabetes who have autonomic neuropathy, be aware of the increased likelihood of side effects such as orthostatic hypotension. **[2009]**
- 1.7.9 Investigate the possibility of autonomic neuropathy affecting the bladder in adults with type 2 diabetes who have unexplained bladder-emptying problems. **[2009]**
- 1.7.10 In managing autonomic neuropathy symptoms, include specific interventions indicated by the manifestations (for example, for abnormal sweating or nocturnal diarrhoea). **[2009]**

Diabetic foot problems

- 1.7.11 For guidance on preventing and managing foot problems in adults with type 2 diabetes, see the NICE guideline on [diabetic foot problems](#). **[new 2015]**

Diabetic kidney disease

- 1.7.12 For guidance on managing kidney disease in adults with type 2 diabetes, see the NICE guideline on [chronic kidney disease](#). **[new 2015]**

Erectile dysfunction

- 1.7.13 Offer men with type 2 diabetes the opportunity to discuss erectile dysfunction as part of their annual review. **[2015]**

- 1.7.14 Carry out an assessment, and provide education and support for men with type 2 diabetes who have problematic erectile dysfunction, addressing contributory factors such as cardiovascular disease as well as possible treatment options. **[2015]**
- 1.7.15 Consider a phosphodiesterase-5 inhibitor to treat problematic erectile dysfunction in men with type 2 diabetes, initially choosing the drug with the lowest acquisition cost and taking into account any contraindications. **[new 2015]**
- 1.7.16 Following discussion, refer men with type 2 diabetes to a service offering other medical, surgical or psychological management of erectile dysfunction if treatment (including a phosphodiesterase-5 inhibitor, as appropriate) has been unsuccessful. **[2015]**

Eye disease

- 1.7.17 Arrange or perform eye screening at or around the time of diagnosis. Arrange repeat of structured eye screening annually. **[2009]**
- 1.7.18 Explain the reasons for, and success of, eye screening systems to adults with type 2 diabetes, so that attendance is not reduced by lack of knowledge or fear of outcome. **[2009]**
- 1.7.19 Use mydriasis with tropicamide when photographing the retina, after prior informed agreement following discussion of the advantages and disadvantages. Discussions should include precautions for driving. **[2009]**
- 1.7.20 Use a quality-assured digital retinal photography programme using appropriately trained staff. **[2009]**
- 1.7.21 Perform visual acuity testing as a routine part of eye screening programmes. **[2009]**

- 1.7.22 Depending on the findings, follow structured eye screening by:
- routine review in 1 year **or**
 - earlier review **or**
 - referral to an ophthalmologist. **[2009]**
- 1.7.23 Arrange emergency review by an ophthalmologist for:
- sudden loss of vision
 - rubeosis iridis
 - pre-retinal or vitreous haemorrhage
 - retinal detachment. **[2009]**
- 1.7.24 Arrange rapid review by an ophthalmologist for new vessel formation. **[2009]**
- 1.7.25 Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines if any of these features are present:
- referable maculopathy:
 - exudate or retinal thickening within 1 disc diameter of the centre of the fovea
 - circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, with a diameter the distance between the temporal border of the optic disc and the fovea)
 - any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea, only if associated with deterioration of best visual acuity to 6/12 or worse.
 - referable pre-proliferative retinopathy (if cotton wool spots are present, look carefully for the following features, but cotton wool spots themselves do not define pre-proliferative retinopathy):
 - any venous beading
 - any venous reduplication

- any intraretinal microvascular abnormalities
- multiple deep, round or blot haemorrhages.
- any large, sudden unexplained drop in visual acuity. **[2009, amended 2015]**

2 Research recommendations

The Guideline Development Group (GDG) has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The GDG's full set of research recommendations is detailed in the full guideline.

2.1 *The effects of stopping and/or switching drug treatments to control blood glucose levels*

In adults with type 2 diabetes, what are the effects of stopping and/or switching drug treatments to control blood glucose levels, and what criteria should inform the decision?

Why this is important

There is a lack of evidence on the effects of stopping and/or switching drug treatments to control blood glucose levels. The current practice of 'stopping rules' is typically motivated by either inadequate blood glucose control (rising HbA1c levels) or intolerable side effects. There is limited understanding of the short- and long-term effects of stopping a therapy and switching to another in terms of diabetes control (HbA1c levels), hypoglycaemic risk, weight gain, and cardiovascular morbidity and mortality. In addition, there is limited understanding of how quickly consideration should be given to stopping and switching to another drug treatment and, if stopping and switching may be needed, what the optimal sequencing is of drug treatments. Randomised controlled trials examining these different issues would help to improve diabetes care.

2.2 *Non-metformin-based drug treatment combinations to control blood glucose levels*

In adults with type 2 diabetes, what treatment combinations (for example, glucagon-like peptide-1 [GLP-1] mimetics and insulin combination therapy with meglitinides) are most effective when initial drug treatment with non-metformin monotherapy fails to adequately control blood glucose levels?

Why this is important

Although it is recognised that metformin therapy is suitable for most adults with type 2 diabetes, its use is contraindicated or not tolerated in approximately 15% of individuals. To date, research evidence has largely focused on metformin-based treatment combinations. Given the progressive nature of the condition, in which intensification of blood glucose lowering drug therapies are indicated over time, there is little evidence, for some adults, to guide management strategies on treatment combinations that do not include metformin. Randomised controlled trials are therefore needed to better understand the treatment choices that are available which improve blood glucose control and long-term risks of complications associated with diabetes.

2.3 *Drug treatment (third intensification) for when blood glucose levels are inadequately controlled by 3 oral antidiabetic drugs and/or insulin combinations*

When third intensification of treatment is indicated, which blood glucose lowering therapies should be used to control blood glucose levels?

Why this is important

As the incidence of type 2 diabetes increases in the younger population and as blood glucose control declines naturally over time, it is likely that further intensification of therapies would be needed. Currently, there is evidence up to second intensification of drug therapies, that is, when 2 or more non-insulin based treatment combinations fail to adequately control blood glucose levels. Randomised controlled trials are needed to improve understanding of alternative treatment options for adults at second intensification who are

inadequately controlled with insulin and/or triple non-insulin based drug therapies.

2.4 *Long-term outcomes associated with blood glucose lowering agents*

In adults with type 2 diabetes, what are the long-term effects of blood glucose lowering therapies such as dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium–glucose cotransporter-2 (SGLT-2) inhibitors and meglitinides?

Why this is important

There is limited evidence in relation to the long-term effects (at least 5 years) of blood glucose lowering therapies, particularly newer agents in terms of efficacy and adverse events (for example, cardiovascular outcomes).

Randomised controlled trials and prospective longitudinal studies are needed to better understand the long-term efficacy and safety issues surrounding these medicines.

2.5 *Self-monitoring of blood glucose levels*

What is the optimal frequency for self-monitoring of blood glucose in adults with type 2 diabetes?

Why this is important

It is widely recognised that self-monitoring of blood glucose is a multicomponent intervention. As well as being educated about how to use a self-monitoring device to assess blood glucose levels, adults with type 2 diabetes need to be able to understand their results and act on the observed readings.

In adults for whom self-monitoring is appropriate, there is limited evidence to guide clinical practice in prescribing self-monitoring regimens, in terms of frequency of testing and optimal blood glucose targets. Given the inconvenience and expense of self-monitoring, robust evidence from randomised controlled trials is needed to guide the optimal use of this intervention.

3 Other information

3.1 *Scope and how this guideline was developed*

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the Internal Clinical Guidelines team to develop this guideline. The team established a Guideline Development Group (see section 4), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

3.2 *Related NICE guidance*

Details are correct at the time of publication of the guideline (August 2015). Further information is available on [the NICE website](#).

Published

General

- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Medicines adherence](#) (2009) NICE guideline CG76

Condition-specific

- [Empagliflozin for treating type 2 diabetes \(2015\)](#) NICE technology appraisal guidance 336
- [Implantation of a duodenal–jejunal bypass liner for managing type 2 diabetes](#) (2015) NICE interventional procedures guidance 518
- [Maintaining a healthy weight and preventing excess weight gain among adults and children](#) (2015) NICE guideline NG7

- [Diabetes in pregnancy](#) (2015) NICE guideline NG3
- [Obesity: identification, assessment and management of overweight and obesity in children, young people and adults](#) (2014) NICE guideline CG189
- [Exercise referral schemes to promote physical activity](#) (2014) NICE guideline PH54
- [Managing overweight and obesity in adults – lifestyle weight management services](#) (2014) NICE guideline PH53
- [Chronic kidney disease](#) (2014) NICE guideline CG182
- [Gastroelectrical stimulation for gastroparesis](#) (2014) NICE guideline IPG489
- [Lipid modification](#) (2014) NICE guideline CG181
- [Canagliflozin in combination therapy for treating type 2 diabetes](#) (2014) NICE technology appraisal guidance 315
- [Neuropathic pain – pharmacological management](#) (2013) NICE guideline CG173
- [Smoking cessation in secondary care: acute, maternity and mental health services](#) (2013) NICE guideline PH48
- [Assessing body mass index and waist circumference thresholds for intervening to prevent ill health and premature death among adults from black, Asian and other minority ethnic groups in the UK](#) (2013) NICE guideline PH46
- [Tobacco: harm reduction approaches to smoking](#) (2013) NICE guideline PH45
- [Physical activity: brief advice for adults in primary care](#) (2013) NICE guideline PH44
- [Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema after an inadequate response to prior therapy](#) (2013) NICE technology appraisal guidance 301
- [Dapagliflozin in combination therapy for treating type 2 diabetes](#) (2013) NICE technology appraisal guidance 288

- [Ranibizumab for treating visual impairment caused by macular oedema secondary to retinal vein occlusion](#) (2013) NICE technology appraisal guidance 283
- [Ranibizumab for treating diabetic macular oedema](#) (2013) NICE technology appraisal guidance 274
- [Obesity: working with local communities](#) (2012) NICE guideline PH42
- [Walking and cycling](#) (2012) NICE guideline PH41
- [Lower limb peripheral arterial disease](#) (2012) NICE guideline CG147
- [Preventing type 2 diabetes: risk identification and interventions for individuals at high risk](#) (2012) NICE guideline PH38
- [Hypertension](#) (2011) NICE guideline CG127
- [Hyperglycaemia in acute coronary syndromes](#) (2011) NICE guideline CG130
- [Preventing type 2 diabetes: population and community-level interventions](#) (2011) NICE guideline PH35
- [Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events](#) (2010) NICE technology appraisal guidance 210
- [Smoking cessation services](#) (2008) NICE guideline PH10
- [Depression in adults with a chronic physical health problem](#) (2009) NICE guideline CG91
- [Depression in adults](#) (2009) NICE guideline CG90
- [Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus](#) (2008) NICE technology appraisal guidance 151
- [Obesity: guidance on the prevention of overweight and obesity in adults and children](#) (2006) NICE guideline CG43
- [Nutrition support in adults](#) (2006) NICE guideline CG32
- [Brief interventions and referral for smoking cessation](#) (2006) NICE guideline PH1

Under development

NICE is [developing](#) the following guidance:

- [Aflibercept for treating diabetic macular oedema](#) NICE technology appraisal guidance (publication expected June 2015)
- [Dexamethasone intravitreal implant for treating diabetic macular oedema](#) NICE technology appraisal guidance (publication expected June 2015)
- [Diabetic foot problems](#). NICE guideline (publication expected August 2015)
- [Type 1 diabetes](#). NICE guideline (publication expected August 2015)
- [Diabetes in children and young people](#). NICE guideline (publication expected August 2015)
- [Canagliflozin, dapagliflozin and empagliflozin for the monotherapy treatment of type 2 diabetes](#). NICE technology appraisal guidance (publication expected May 2016)
- [Buccal insulin for the management of type 1 diabetes](#). NICE technology appraisal guidance (publication date to be confirmed)
- [Pegaptanib sodium for the treatment of diabetic macular oedema](#). NICE technology appraisal guidance (publication date to be confirmed)

4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team, and declarations of interests

4.1 *Guideline Development Group*

The Guideline Development Group members listed are those for the 2015 update. For the composition of the previous Guideline Development Group, see the [full guideline](#).

Damien Longson (Guideline Chair)

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Amanda Adler

Consultant Diabetologist, Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust

Anne Bentley

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Christine Bundy (co-opted expert member)

Senior Lecturer in Behavioural Medicine, Institute for Inflammation and Repair, University of Manchester

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Yvonne Johns

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Ian Lewin

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Natasha Marsland

Patient/carer member, Diabetes UK

Prunella Neale

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Jonathan Roddick

Principal General Practitioner, Woodseats Medical Centre, Sheffield

Mohammed Roshan (August 2012 – October 2013)

Principal in General Practice, Leicester City and County

Sailesh Sankar

Consultant Diabetologist, University Hospitals Coventry and Warwickshire NHS Trust

4.2 Internal Clinical Guidelines team

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Programme Manager

Hugh McGuire (from March 2014)

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Robby Richey (June 2013 to June 2014)

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Susan Spiers (from June 2014)

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4.3 NICE project team

Christine Carson

Guideline Lead

Phil Alderson

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Clifford Middleton (from August 2013)

Guideline Commissioning Manager

Claire Ruiz (until August 2013)

Guideline Commissioning Manager

Trudie Willingham (from June 2015)

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James Povah (from April 2015 to June 2015)

Guideline Coordinator

Besma Nash (from November 2013 to May 2015)

Guideline Coordinator

Anthony Gildea (March 2013 to November 2014)

Guideline Coordinator

Laura Donegani (until March 2013)

Guideline Coordinator

Nichole Taske

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Bhash Naidoo

Technical Adviser, Health Economics

Jasdeep Hayre (until June 2014)

Technical Analyst, Health Economics

Sarah Palombella

Senior Medical Editor

4.4 Declarations of interests

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare.

Member	Interest declared	Type of interest	Decision taken
Christine Bundy	Holds a Scientific Advisory Board position with Simple Healthcare Products for which an honorarium is received for attending approximately 3 meetings per year	Non-specific personal pecuniary	Declare and participate
Indranil Dasgupta	Has been a member of an advisory board on a new phosphate binder for chronic kidney disease for Mitsubishi Pharma	Non-specific personal pecuniary	Declare and participate
Indranil Dasgupta	Working department has received a research grant from Medtronic for a study of renal denervation for resistant hypertension	Non-specific, non-personal pecuniary	Declare and participate
David Edwards	Acts as a Chair and member on a number of advisory boards. Has organised, chaired and presented at local, national and international meetings on male and/or female sexual problems and stress. Has written guidelines, been filmed, reviewed/ written articles for both lay and medical press. These activities have been reimbursed by organisations including pharmaceutical companies in the form of transport, accommodation and sometimes honoraria. Companies that travel, accommodation and honoraria have been received from are Bayer, Eli Lilly, Schwabe and Takeda & Menarini, Pfizer, ProStrakan and Owen Mumford	Non-specific personal pecuniary	Declare and participate
David Edwards	President of the British Society for Sexual Medicine, Member of Men's Health Expert Policy Group which aims to educate those in power especially government and key	Non-specific personal pecuniary	Declare and participate

	stakeholders. Travel/occasional accommodation but not time is paid for by Bayer		
David Edwards	Clinical adviser to the Klinefelter's National Association. Member of an advisory board for prostate cancer management known as atypical small acinar proliferation (ASAP)	Non-specific personal pecuniary	Declare and participate
David Edwards	Participated as a medical researcher for studies undertaken by the Universities of Oxford and Southampton	Non-specific personal pecuniary	Declare and participate
David Edwards	Chief investigator in the UK for a study on low dose aspirin. The study is sponsored by Bayer	Non-specific personal pecuniary	Declare and participate
Natasha Jacques	Participation in advisory board on Management of Diabetes in Renal Disease (sponsored by Boehringer Ingelheim) 17.01.12	Specific personal pecuniary interest	Declare and participate as in line with NICE policy, it is more than 1 year since the conflict occurred and the topics this may relate to are discussed
Natasha Jacques	Speaker on 'Adherence Issues in Diabetes'- event sponsored by MSD 25.04.12	Specific personal pecuniary interest	Declare and participate as in line with NICE policy, it is more than 1 year since the conflict occurred and the topics this may relate to are discussed
Yvonne Johns	Has been asked by Diabetes UK Wales on behalf of the Welsh Medical Council to discuss and bring forward patient views on lixisenatide for the diabetes group in which she is involved. None of the patients have been asked to use the drug but were asked whether they would consider using it based in an information leaflet they received and their experiences of other GLP-1's	Personal non-pecuniary	Declare and participate
Natasha Marsland	Employed by Diabetes UK	Non-personal	Declare and participate

		pecuniary	
Jonathan Roddick	Member of MSD advisory board for sitagliptin until appointment	Specific personal pecuniary	Able to participate as recommendations on drug treatment in type 2 diabetes were not made until 2014
Mohamed Roshan	Attended a diabetes advisory meeting. Reimbursement paid to the GP practice	Specific non-personal pecuniary	Declare and participate
Mohamed Roshan	Developer of Diabetes Education modules in Leicester which include modules on diabetes therapies between 2011 and 2013. No money was received	Personal non-pecuniary	Declare and participate
Mohamed Roshan	Developed and chaired meetings for GLP-1 educational program in Leicester for Primary Care as part of Department of Diabetes	Personal non-pecuniary	Declare and participate
Mohamed Roshan	Attends advisory committee on Lixisenatide for Sanofi and will be trained in future as speaker (last attended March 2013). Received reimbursement to cover locum fees and staff time	Specific personal pecuniary	Declare and withdraw
Mohamed Roshan	Will attend conference for discussion on saxagliptin and cardiovascular outcomes evidence recently published. Reimbursement from Astra Zeneca	Specific personal pecuniary	Declare and withdraw
Mohamed Roshan	Will be training as speaker for Bristol Myer Squibb	Specific personal pecuniary	Declare and withdraw
Mohamed Roshan	Have chaired meeting for Insulin Degludec (Tresiba) in Sept 2013. Locum expenses reimbursed by Novo Nordisk	Specific personal pecuniary	Declare and withdraw
Sailesh Sankar	Attended the International Diabetes Federation in 4th December 2011, the travel and subsistence was supported by Boehringer Ingleheim with in the ABPI regulation guidelines	Specific personal pecuniary	Able to participate as recommendations on drug treatment in type 2 diabetes were not made until 2014
Sailesh Sankar	Chaired an evening meeting on the 12th of June 2012 for GP educational session supported by Novo Nordisk	Specific personal pecuniary	Able to participate as recommendations on drug treatment in type 2 diabetes

			were not made until 2014
Sailesh Sankar	October 2011 – did an evening educational session for GPs supported by Boehringer Ingelheim	Specific personal pecuniary	Able to participate as recommendations on drug treatment in type 2 diabetes were not made until 2014
Sailesh Sankar	Principal Investigator for Roche EXPERT study. The study recruited patient to use an EXPERT bolus advisor blood glucose monitor versus a Nano monitor. This study was in relation to feasibility of use of bolus advisor in patients with type 1 diabetes. In this study 9 patients were recruited from Feb 2012 onwards and study was completed in October 2012. This study was funded by ROCHE to meet the expenses of the overheads and running of the study at UHCW site. The UHCW Trust has invoiced the company and the funding yet to be received. The exact amount can be confirmed on receipt	Non-personal specific pecuniary	Declare and participate
Sailesh Sankar	Research nurse team was also involved in a retrospective data collection for study/audit conducted at UHCW trust in relation to use of INSULINX blood glucose monitoring in patients with type 1 diabetes. Funding was (£150.00 per patient data collected) was agreed by the trust R and D in relation to this project. This study was funded by ABBOTT diabetes care This was done over September to October 2012 period. Approximately 10 patients' data were collected for this study	Specific non-personal pecuniary	Declare and participate
Sailesh Sankar	Receiving a grant from Novo Nordisk to lead development of an education application for computer and phone devices for clinicians and medical students. The application will covering managing blood glucose levels for people with diabetes on insulin and preventing ketoacidosis. Novo	Specific non-personal pecuniary	Declare and participate

	Nordisk produce insulin licensed for use in people with type 1 and type 2 diabetes		
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Appendix A: Recommendations from NICE clinical guideline 87 (2009) that have been amended

Amended recommendation wording (change to meaning)

Recommendations are labelled **[2009, amended 2015]** if the evidence has not been reviewed but either:

- changes have been made to the recommendation wording that change the meaning, **or**
NICE has made editorial changes to the original wording to clarify the action to be taken.

Recommendation in 2009 guideline	Recommendation in current guideline	Reason for change
If the person's blood pressure is not reduced to the individually agreed target with first-line therapy, add a calcium-channel blocker or a diuretic (usually bendroflumethiazide, 2.5 mg daily). Add the other drug (that is, the calcium-channel blocker or diuretic) if the target is not reached with dual therapy. [1.8.11]	If the person's blood pressure is not reduced to the individually agreed target with first-line therapy, add a calcium-channel blocker or a diuretic (usually a thiazide or thiazide-related diuretic). Add the other drug (that is, the calcium-channel blocker or diuretic) if the target is not reached with dual therapy. [2009, amended 2015] (1.4.11)	The GDG noted that there are other thiazides and related diuretics which are used in standard clinical practice, and agreed that reference should be made to the drug group rather than restricting the recommendation to a specific drug, in line with NICE hypertension guideline CG127. Therefore, the GDG wanted to change this recommendation to allow healthcare professionals greater flexibility in prescribing.
Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines if any of these features is present: <ul style="list-style-type: none"> • referable maculopathy: 	Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines if any of these features is present: <ul style="list-style-type: none"> • referable maculopathy: 	The recommendations on eye damage were reviewed by the National Screening Programme and were amended to make them

<ul style="list-style-type: none"> ○ exudate or retinal thickening within one disc diameter of the centre of the fovea ○ circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, with a diameter the distance between the temporal border of the optic disc and the fovea) ○ any microaneurysm or haemorrhage within one disc diameter of the centre of the fovea, only if associated with deterioration of best visual acuity to 6/12 or worse • referable pre-proliferative retinopathy (if cotton wool spots are present, look carefully for the following features, but cotton wool spots themselves do not define pre-proliferative retinopathy): <ul style="list-style-type: none"> ○ any venous beading ○ any venous loop or reduplication ○ any intraretinal microvascular abnormalities ○ multiple deep, round or blot haemorrhages • any unexplained drop in visual acuity. [1.13.9] 	<ul style="list-style-type: none"> ○ exudate or retinal thickening within 1 disc diameter of the centre of the fovea ○ circinate or group of exudates within the macula (the macula is defined here as a circle centred on the fovea, with a diameter the distance between the temporal border of the optic disc and the fovea) ○ any microaneurysm or haemorrhage within 1 disc diameter of the centre of the fovea, only if associated with deterioration of best visual acuity to 6/12 or worse • referable pre-proliferative retinopathy (if cotton wool spots are present, look carefully for the following features, but cotton wool spots themselves do not define pre-proliferative retinopathy): <ul style="list-style-type: none"> ○ any venous beading ○ any venous reduplication ○ any intraretinal microvascular abnormalities ○ multiple deep, round or blot haemorrhages • any large, sudden, unexplained drop in visual acuity. [2009, amended 2015] (1.7.25) 	<p>consistent with the current practice of the diabetes eye screening programme.</p>
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<p>Consider a trial of metoclopramide, domperidone or erythromycin for an adult with gastroparesis. [1.14.3.2]</p>	<p>For adults with type 2 diabetes who have vomiting caused by gastroparesis explain that:</p> <ul style="list-style-type: none"> • there is not strong evidence that any available antiemetic therapy is effective • some people have had benefit with domperidone, erythromycin or metoclopramide. • 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. [new 2015] (1.7.2) <p>For treating vomiting caused by gastroparesis in adults with type 2 diabetes:</p> <ul style="list-style-type: none"> • consider alternating use of erythromycin and metoclopramide • consider domperidone only in exceptional circumstances (if domperidone is the only effective treatment) and in accordance with MHRA guidance. [new 2015] (1.7.3) 	<p>The recommendation on the treatment of gastroparesis from clinical guideline 87 has been replaced by recommendations from the guideline update of type 1 diabetes which undertook a new evidence review on the management of gastroparesis in type 1 diabetes. It was agreed by the guideline committees for type 1 and type 2 diabetes that the management of gastroparesis would be similar for people with diabetes. It was considered important to highlight the MHRA warning around the use of domperidone.</p>
	<p>1.7.1, 1.7.5, 1.7.6</p>	<p>NICE has made editorial changes to the original wording to clarify the action to be taken (no change to meaning): a verb has been added, the verb used has been changed or other wording has changed for clarification.</p>