

Type 2 diabetes in adults: management of type 2 diabetes in adults

NICE guideline

Draft for consultation, January 2015

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

Introduction	3
Patient-centred care.....	5
Strength of recommendations	6
Update information.....	8
Key priorities for implementation.....	10
1 Recommendations	13
1.1 Individualised care	13
1.2 Patient education	13
1.3 Dietary advice	15
1.4 Blood pressure management.....	16
1.5 Antiplatelet therapy	18
1.6 Blood glucose management	18
1.7 Managing complications	28
2 Research recommendations.....	32
3 Other information.....	35
4 The Guideline Development Group, Internal Clinical Guidelines team and NICE project team, and declarations of interests	39
Appendix A: Recommendations from NICE clinical guideline 87 (2009) that have been deleted or changed	49

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.

Type 2 diabetes usually occurs in people older than 40 years; although it can be commonly diagnosed earlier in people of South Asian, Chinese, African or African-Caribbean family origin. Approximately 90% of adults currently diagnosed with diabetes have type 2 diabetes. In 2013, almost 2.9 million people were diagnosed with diabetes, with prevalence rates of 6% and 6.7% in England and Wales respectively. In the UK, incidence rates are increasing, with more than 1 in 20 people estimated to have diagnosed or undiagnosed diabetes. 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 (18 years and over) 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, type 1 diabetes, diabetes in pregnancy and diabetes in children.

Reasons for the update

Since 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 medicines for an indication for which they do not have a UK marketing authorisation at the date of consultation (metoclopramide, domperidone and erythromycin for gastroparesis). 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 [Good practice in prescribing and managing medicines and devices](#) 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. 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. 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 shaded in grey and 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 clinical guideline 87 (published May 2009) and will replace it. This guidance will also update and replace NICE technology appraisal TA203 (published October 2010) and NICE technology appraisal TA248 (published February 2012).

Recommendations with an evidence review

New recommendations have been added on the following topics:

- antiplatelet therapy
- blood glucose management including:
 - measurement
 - targets
 - self-monitoring of blood glucose
 - drug treatment
- erectile dysfunction.

You are invited to comment on the new and updated recommendations in this guideline. These are marked as:

- **[new 2015]** if the evidence has been reviewed and the recommendation has been added or updated
- **[2015]** if the evidence has been reviewed but no change has been made to the recommended action.

You are also invited to comment on recommendations that NICE proposes to delete from the 2009 guideline, because either the evidence has been reviewed and the recommendations have been updated, or NICE has updated other relevant guidance and has replaced the original recommendations.

Appendix A sets out these recommendations and includes details of replacement recommendations. Where there is no replacement recommendation, an explanation for the proposed deletion is given.

Recommendations without an evidence review

NICE is piloting a new process for identifying and labelling changes to recommendations that have not undergone an evidence review as part of the update. In this guideline:

- minor editorial changes that do not affect the content of the recommendation have not been highlighted in yellow
- the definition of an 'amended' recommendation has been expanded (see below).

Where recommendations are shaded in grey and end **[2009]**, the evidence has not been reviewed since the original guideline. We will not be able to accept comments on these recommendations.

Where recommendations are shaded in grey and end **[2009, amended 2015]**, the evidence has not been reviewed but either:

- changes have been made to the recommendation wording that change the meaning (for example, because of equalities duties or a change in the availability of drugs, or incorporated guidance has been updated) **or**
- NICE has made editorial changes to the original wording to clarify the action to be taken.

These changes are marked with yellow shading, and explanations of the reasons for the changes are given in appendix A for information. We will not routinely accept comments on these recommendations, but will respond if particular concerns are raised around the proposed amendments.

The original NICE guideline and supporting documents are available [here](#).

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 components¹:
 - 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]**

¹ [Structured patient education in diabetes: report from the patient education working group](#)

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 disease). **[2009] [1.4.6]**

Blood glucose management

Targets

- 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]**
- If HbA1c levels rise to 58 mmol/mol (7.5%) or higher, intensify drug treatment, set a target HbA1c level of 53 mmol/mol (7.0%), and reinforce advice about diet, lifestyle and adherence to drug treatment. See section 1.3. For more information about supporting adherence, see the NICE guideline on [medicines adherence](#). **[new 2015] [1.6.8]**

Self-monitoring of blood glucose

- Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless the person:
 - is on insulin **or**
 - experiences symptomatic hypoglycaemia **or**
 - is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery **or**
 - is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on [diabetes in pregnancy](#).

Consider short-term self-monitoring for adults with type 2 diabetes who start treatment with oral or intravenous corticosteroids. **[new 2015] [1.6.13]**

Drug treatment

- Offer standard-release metformin as the initial drug treatment for adults with type 2 diabetes. **[new 2015] [1.6.16]**
- If standard-release metformin is contraindicated or not tolerated, consider repaglinide as the initial drug treatment. Advise the person that if treatment with repaglinide does not control HbA1c, then the person would need to change to pioglitazone, a sulfonylurea or a dipeptidyl peptidase-4 (DPP-4) inhibitor before adding another treatment² (see [First intensification of drug treatment](#)). **[new 2015] [1.6.19]**

² Repaglinide has a marketing authorisation for use only as monotherapy or in combination with metformin. Therefore, for people who cannot take metformin, there is no licensed combination containing repaglinide that can be offered at first intensification. Patients 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](#) [\[hyperlink to be added for final publication\]](#) 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 person's needs and circumstances, taking into account their personal preferences, comorbidities, risks of polypharmacy, and their ability to benefit from long-term interventions due to 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 consider whether to stop any medicines that are not effective. **[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 components³:

- 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

³ [Structured patient education in diabetes: report from the patient education working group](#)

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 individual'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]**

1.4 *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 and the [lifestyle interventions](#) section in 'Hypertension' [NICE clinical guideline 127]) 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 disease). **[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 individual 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, 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 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 Calibrate HbA1c results 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 help adults with type 2 diabetes 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 Set a target HbA1c level of 48 mmol/mol (6.5%) for most 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. **[new 2015]**

1.6.8 If HbA1c levels rise to 58 mmol/mol (7.5%) or higher, intensify drug treatment, set a target HbA1c level of 53 mmol/mol (7.0%), and reinforce advice about diet, lifestyle and adherence to drug treatment. See section 1.3. For more information about supporting adherence, see the NICE guideline on [medicines adherence](#). **[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 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 glycaemic control poses risks
 - with 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 taking multiple drugs and people with significant comorbidities).

These factors will need particular consideration for people who are older and frail. **[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. **[new 2015]**
- 1.6.11 For guidance on HbA1c targets for women 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. **[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**

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

Consider short-term self-monitoring for adults with type 2 diabetes who start treatment with oral or intravenous corticosteroids. **[new 2015]**

1.6.14 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
- how the results are used
- the impact on the person's quality of life
- the continued benefit to the person
- the equipment used. **[2015]**

Drug treatment

The [full guideline](#) has an algorithm for blood glucose lowering therapy.

[hyperlink to be added for final publication]

Rescue therapy at any phase of treatment

1.6.15 If an adult with type 2 diabetes is symptomatically hyperglycaemic, consider insulin (see recommendations 1.6.32–1.6.34) or a sulfonylurea, and review treatment when blood glucose control has been achieved. **[new 2015]**

Initial drug treatment

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

- 1.6.17 Gradually increase the dose of standard-release metformin over several weeks to minimise the risk of gastrointestinal side effects. **[new 2015]**
- 1.6.18 Review the dose of standard-release metformin if the estimated glomerular filtration rate (eGFR) is below 45 ml/minute/1.73m²:
- Stop standard-release metformin if the eGFR is below 30 ml/minute/1.73m².
 - Prescribe standard-release metformin with caution for those at risk of a sudden deterioration in kidney function and those at risk of eGFR falling below 45 ml/minute/1.73m². **[2015]**
- 1.6.19 If standard-release metformin is contraindicated or not tolerated, consider repaglinide as the initial drug treatment. Advise the person that if treatment with repaglinide does not control HbA1c, then the person would need to change to pioglitazone, a sulfonylurea or a dipeptidyl peptidase-4 (DPP-4) inhibitor before adding another treatment⁴ (see [First intensification of drug treatment](#)). **[new 2015]**
- 1.6.20 If both standard-release metformin and repaglinide are contraindicated or not tolerated, or if repaglinide is not the preferred option, consider pioglitazone as the initial drug treatment. **[new 2015]**
- 1.6.21 If both standard-release metformin and pioglitazone are contraindicated or not tolerated, and repaglinide is contraindicated, not tolerated or not preferred, consider initial drug treatment with either:
- a DPP-4 inhibitor **or**
 - a sulfonylurea.

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

Base the choice on the person's preference after discussing the risks and benefits of each option. If a DPP-4 inhibitor is preferred, choose the option with the lowest acquisition cost. **[new 2015]**

First intensification of drug treatment

1.6.22 If initial drug treatment with standard-release metformin has not controlled HbA1c to below the person's individually agreed threshold for intensification:

- Offer combination therapy with standard-release metformin and pioglitazone.
- If pioglitazone is contraindicated or not tolerated, offer combination therapy with standard-release metformin and a sulfonylurea.
- If both pioglitazone and sulfonylureas are contraindicated or not tolerated, offer combination therapy with standard-release metformin and a DPP-4 inhibitor (choose the option with the lowest acquisition cost). **[new 2015]**

1.6.23 If initial drug treatment with repaglinide has not controlled HbA1c to below the person's individually agreed threshold for intensification:

- Consider switching to combination therapy with either:
 - pioglitazone and a sulfonylurea **or**
 - pioglitazone and a DPP-4 inhibitor **or**
 - a sulfonylurea and a DPP-4 inhibitor.

Base the choice on the person's preference after discussing the risks and benefits of each combination. If a DPP-4 inhibitor is preferred, choose the option with the lowest acquisition cost.

- When switching from repaglinide to any of these combinations, introduce the 2 new medicines in a stepwise manner, checking for tolerability of each. **[new 2015]**

1.6.24 If initial drug treatment with pioglitazone has not controlled HbA1c to below the person's individually agreed threshold for intensification:

- Consider combination therapy with either:
 - pioglitazone and a sulfonylurea **or**
 - pioglitazone and a DPP-4 inhibitor.

Base the choice on the person's preference after discussing the risks and benefits of each option. If a DPP-4 inhibitor is preferred, choose the option with the lowest acquisition cost. **[new 2015]**

1.6.25 If initial drug treatment with a DPP-4 inhibitor has not controlled HbA1c to below the person's individually agreed threshold for intensification, consider combination therapy with the DPP-4 inhibitor and a sulfonylurea. **[new 2015]**

1.6.26 If initial drug treatment with a sulfonylurea has not controlled HbA1c to below the person's individually agreed threshold for intensification, consider combination therapy with the sulfonylurea and a DPP-4 inhibitor (choose the option with the lowest acquisition cost). **[new 2015]**

Treatment with combinations of medicines including sodium–glucose cotransporter 2 (SGLT-2) inhibitors may be appropriate for some people; see the NICE guidance on [dapagliflozin in combination therapy for treating type 2 diabetes](#) and [canagliflozin in combination therapy for treating type 2 diabetes](#)⁵.

Second intensification of drug treatment

1.6.27 If combination therapy with either standard-release metformin and pioglitazone or standard-release metformin and a sulfonylurea has not controlled HbA1c to below the person's individually agreed threshold for intensification:

⁵ NICE guidance on [empagliflozin for treating type 2 diabetes](#) is in development and is due to be published in March 2015.

- Consider combination therapy with standard-release metformin, pioglitazone and a sulfonylurea.
- If pioglitazone is contraindicated or not tolerated, consider either:
 - combination therapy with standard-release metformin, a sulfonylurea and a DPP-4 inhibitor **or**
 - starting insulin-based treatment (see recommendations 1.6.32–1.6.34).

Base the choice on the person's preference after discussing the risks and benefits of each approach. If a DPP-4 inhibitor is preferred, choose the option with the lowest acquisition cost.

- If sulfonylureas are contraindicated or not tolerated, consider starting insulin-based treatment (see recommendations 1.6.32–1.6.34). **[new 2015]**

1.6.28 If standard-release metformin is contraindicated or not tolerated, and if combination therapy with 2 oral drug treatments has not controlled HbA1c to below the person's individually agreed threshold for intensification, consider starting insulin-based treatment (see recommendations 1.6.32–1.6.34). **[new 2015]**

1.6.29 If combination therapy with 2 oral drug treatments has not controlled HbA1c to below the person's individually agreed threshold for intensification, consider combination therapy with standard-release metformin, a sulfonylurea and a glucagon-like peptide-1 (GLP-1) mimetic (instead of 3 oral drug treatments or introducing insulin).

Consider this for adults with type 2 diabetes who:

- have a BMI of 35 kg/m² or higher **and** specific psychological or other medical problems associated with obesity, **or**
- have a BMI lower than 35 kg/m² **and**
 - for whom insulin therapy would have significant occupational implications, **or**

- weight loss would benefit other significant obesity-related comorbidities.

Base the choice of GLP-1 mimetic on the person's preference after discussing the risks and benefits of each licensed option. If more than 1 option is considered appropriate for the person, choose the GLP-1 mimetic with the lowest acquisition cost. **[new 2015]**

- 1.6.30 Only continue GLP-1 mimetic therapy if the person has had a beneficial metabolic response (a reduction of at least 11 mmol/mol [1.0%] in HbA1c and a weight loss of at least 3% of initial body weight in 6 months). **[2015]**
- 1.6.31 Only offer a GLP-1 mimetic in combination with insulin in a specialist care setting. **[new 2015]**

Treatment with combinations of medicines including SGLT2 inhibitors may be appropriate for some people; see the NICE guidance on [dapagliflozin in combination therapy for treating type 2 diabetes](#) and [canagliflozin in combination therapy for treating type 2 diabetes](#)⁶.

Insulin-based treatments

- 1.6.32 When starting insulin therapy, use a structured programme employing active insulin dose titration that encompasses:
- structured education
 - continuing telephone support
 - frequent self-monitoring
 - dose titration to target
 - dietary understanding
 - management of hypoglycaemia
 - management of acute changes in plasma glucose control
 - support from an appropriately trained and experienced healthcare professional. **[2015]**

⁶ NICE guidance on [empagliflozin for treating type 2 diabetes](#) is in development and is due to be published in March 2015.

- 1.6.33 When starting insulin therapy, continue to offer standard-release metformin for people without contraindications or intolerance. **[new 2015]**
- 1.6.34 Initiate insulin therapy from a choice of a number of insulin types and regimens:
- Offer human neutral protamine Hagedorn (NPH) insulin injected at bed-time or twice daily according to need.
 - Consider, as an alternative, using a long-acting insulin analogue (insulin detemir, insulin glargine) if:
 - the person needs assistance from a carer or healthcare professional to inject insulin, and use of a long-acting insulin analogue (insulin detemir, insulin glargine) would reduce the frequency of injections from twice to once daily, **or**
 - the person's lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes, **or**
 - the person would otherwise need twice-daily NPH insulin injections in combination with oral glucose-lowering drugs, **or**
 - the person cannot use the device to inject NPH insulin.
 - Consider twice-daily pre-mixed (biphasic) human insulin (particularly if HbA1c is 75 mmol/mol [9.0%] or higher). A once-daily regimen may be an option.
 - Consider pre-mixed preparations that include short-acting insulin analogues, rather than pre-mixed preparations that include short-acting human insulin preparations, if:
 - a person prefers injecting insulin immediately before a meal, **or**
 - hypoglycaemia is a problem, **or**
 - blood glucose levels rise markedly after meals. **[2015]**
- 1.6.35 Consider switching to a long-acting insulin analogue (insulin detemir, insulin glargine) from NPH insulin in people:

- who do not reach their target HbA1c because of significant hypoglycaemia, **or**
- who experience significant hypoglycaemia on NPH insulin irrespective of the level of HbA1c reached, **or**
- who cannot use the device needed to inject NPH insulin but who could administer their own insulin safely and accurately if a switch to a long-acting insulin analogue were made, **or**
- who need help from a carer or healthcare professional to administer insulin injections and for whom switching to a long-acting insulin analogue would reduce the number of daily injections. **[2015]**

1.6.36 Monitor a person on a basal insulin regimen (NPH insulin or a long-acting insulin analogue [insulin detemir, insulin glargine]) for the need for short-acting insulin before meals (or a pre-mixed insulin preparation). **[2015]**

1.6.37 Monitor a person on pre-mixed insulin for the need for a further injection of short-acting insulin before meals or for a change to a basal bolus regimen with NPH insulin or long-acting insulin analogues (insulin detemir, insulin glargine), if blood glucose control remains inadequate. **[2015]**

Insulin delivery

1.6.38 For guidance on insulin delivery, see the NICE guideline on [type 1 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 Consider a trial of metoclopramide, domperidone or erythromycin⁷ for an adult with type 2 diabetes with gastroparesis⁸. [2009, amended 2015]
- 1.7.3 If gastroparesis is suspected, consider referral to specialist services if:

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

Painful neuropathy

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

Autonomic neuropathy

- 1.7.5 **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]
- 1.7.6 **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]
- 1.7.7 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]

⁷ At the time of consultation (January 2015), metoclopramide, domperidone and 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 [Good practice in prescribing and managing medicines and devices](#) for further information.

⁸ Diagnosis of gastroparesis needing specific therapy can only be made in the absence of hyperglycaemia at the time of testing, because hyperglycaemia induces a physiological delay in gastric emptying.

- 1.7.8 Investigate the possibility of autonomic neuropathy affecting the bladder in adults with type 2 diabetes who have unexplained bladder-emptying problems. **[2009]**
- 1.7.9 In managing autonomic neuropathy symptoms, include specific interventions indicated by the manifestations (for example, for abnormal sweating or nocturnal diarrhoea). **[2009]**

Diabetic foot problems

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

Diabetic kidney disease

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

Erectile dysfunction

- 1.7.12 Offer men with type 2 diabetes the opportunity to discuss erectile dysfunction as part of their annual review. **[2015]**
- 1.7.13 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]**
- 1.7.14 Consider a phosphodiesterase-5 inhibitor to treat problematic erectile dysfunction, initially choosing the drug with the lowest acquisition cost and taking into account any contraindications. **[new 2015]**
- 1.7.15 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, if appropriate) has been unsuccessful. **[2015]**

Eye damage

- 1.7.16 Arrange or perform eye screening at or around the time of diagnosis. Arrange repeat of structured eye screening annually. **[2009]**
- 1.7.17 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]**
- 1.7.18 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]**
- 1.7.19 Use a quality-assured digital retinal photography programme using appropriately trained staff. **[2009]**
- 1.7.20 Perform visual acuity testing as a routine part of eye screening programmes. **[2009]**
- 1.7.21 Depending on the findings, follow structured eye screening by:
- routine review in 1 year **or**
 - earlier review **or**
 - referral to an ophthalmologist. **[2009]**
- 1.7.22 Arrange emergency review by an ophthalmologist for:
- sudden loss of vision
 - rubeosis iridis
 - pre-retinal or vitreous haemorrhage
 - retinal detachment. **[2009]**
- 1.7.23 Arrange rapid review by an ophthalmologist for new vessel formation. **[2009]**

1.7.24 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. Double-blind 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) 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. Double-blind randomised controlled trials are therefore needed to better understand the treatment choices that are available which improve glycaemic 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 glycaemic 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. Double-blind 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 co-transporter 2 (SGLT2) inhibitors and meglitinides?

Why this is important

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

studies are needed to better understand the long-term 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 glycaemic targets. Given the inconvenience and expense of self-monitoring, robust evidence from double-blind 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 consultation on the guideline (January 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

- [Obesity](#) (2014) NICE guideline CG189
- [Exercise referral schemes to promote physical activity](#) (2014) NICE guideline PH54
- [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
- [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
- [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
- [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:

- [Diabetes in pregnancy](#). NICE guideline (publication expected February 2015)
- [Empagliflozin for treating type 2 diabetes](#). NICE technology appraisal guidance (publication expected March 2015)
- [Diabetic foot problems](#). NICE guideline (publication expected July 2015)

DRAFT FOR CONSULTATION

- [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)

Consultant Liaison Psychiatrist, Manchester Mental Health and Social Care Trust

Amanda Adler

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

Anne Bentley

Medicines Optimisation Lead Pharmacist, NHS East Lancashire Primary Care Trust

Christine Bundy (co-opted expert member)

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

Bernard Clarke (co-opted expert member)

Honorary Clinical Professor of Cardiology, Manchester Academic Health Science Centre, University of Manchester

Maria Cowell

Community Diabetes Specialist Nurse, Cambridge

Indranil Dasgupta (co-opted expert member)

Consultant Nephrologist, Heart of England NHS Foundation Trust, Birmingham

David Ronald Edwards

Principal in General Practice, Whitehouse Surgery, Oxfordshire

Andrew Farmer

Professor in General Practice, Department of Primary Care Health Sciences,
University of Oxford

Natasha Jacques

Principal Pharmacist in Diabetes, Heart of England NHS Foundation Trust,
Birmingham

Yvonne Johns

Patient/carer member

Ian Lewin

Consultant Diabetologist, North Devon District Hospital, Northern Devon
Healthcare NHS Trust

Natasha Marsland

Patient/carer member, Diabetes UK

Prunella Neale

Practice Nurse, Herschel Medical Centre, Berkshire

Jonathan Roddick

Principal General Practitioner, Woodseats Medical Centre, Sheffield

Mohammed Roshan (August 2012 - October 2013)

Principal in General Practice, Leicester City and County

Sailesh Sankaranarayanan

Consultant Diabetologist, University Hospitals Coventry and Warwickshire
NHS Trust

4.2 *Internal Clinical Guidelines team*

Susan Ellerby

Clinical Adviser

DRAFT FOR CONSULTATION

Nicole Elliott (until June 2014)

Associate Director

Victoria Gillis (until November 2012)

Assistant Technical Analyst

Michael Heath (until October 2014)

Programme Manager

Hugh McGuire (from March 2014)

Technical Adviser

Stephanie Mills

Project Manager

Robby Richey (June 2013 to June 2014)

Technical Analyst

Gabriel Rogers

Technical Adviser, Health Economics

Abitha Senthinathan (until June 2014)

Technical Analyst

Susan Spiers (from June 2014)

Associate Director

Toni Tan (until March 2014)

Technical Adviser

Sharlene Ting (from June 2014)

Technical Analyst

Steven Ward

Technical Analyst, Health Economics

Sheryl Warttig (February 2014 to June 2014)

Technical Analyst

4.3 ***NICE project team***

Christine Carson

Guideline Lead

Phil Alderson

Clinical Adviser

Clifford Middleton (from August 2013)

Guideline Commissioning Manager

Claire Ruiz (until August 2013)

Guideline Commissioning Manager

Besma Nash (from November 2013)

Guideline Coordinator

Anthony Gildea (March 2013 to November 2014)

Guideline Coordinator

Laura Donegani (until March 2013)

Guideline Coordinator

Nichole Taske

Technical Lead

Bhash Naidoo

Technical Adviser, Health Economics

Jasdeep Hayre (until June 2014)

Technical Analyst, Health Economics

Sarah Palombella

Senior Medical Editor

Asma Khalik

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	Non-specific personal pecuniary	Declare and participate

DRAFT FOR CONSULTATION

	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.		
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 stake holders. Travel/occasional accommodation but not time is paid for by Bayer.	Non-specific personal pecuniary	Declare and participate
David Edwards	Clinical advisor 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	Specific personal pecuniary interest	Declare and participate as in line with NICE policy, it is more than 1 year since

DRAFT FOR CONSULTATION

	by Boehringer Ingelheim) 17.01.12		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 GLP1's	Personal non-pecuniary	Declare and participate
Natasha Marsland	Employed by Diabetes UK	Non-personal pecuniary	Declare and participate
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	Personal non-pecuniary	Declare and participate

DRAFT FOR CONSULTATION

	therapies between 2011 and 2013. No money was received.		
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	Specific personal	Able to

DRAFT FOR CONSULTATION

	meeting on the 12th of June 2012 for GP educational session supported by Novo Nordisk.	pecuniary	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 - Diabetologist	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	Specific non-personal pecuniary	Declare and participate

DRAFT FOR CONSULTATION

	<p>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 ABOTT diabetes care This was done over September to October 2012 period. Approximately 10 patients' data were collected for this study.</p>		
<p>Sailesh Sankar - Diabetologist</p>	<p>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 Nordisk produce insulin licensed for use in people with type 1 and type 2 diabetes.</p>	<p>Specific non-personal pecuniary</p>	<p>Declare and participate</p>

Appendix A: Recommendations from NICE clinical guideline 87 (2009) that have been deleted or changed

Recommendations to be deleted

The table shows recommendations from 2009 that NICE proposes deleting in the 2015 update. The right-hand column gives the replacement recommendation, or explains the reason for the deletion if there is no replacement recommendation.

Recommendation in 2009 guideline	Comment
<p>1.1.2 Select a patient-education programme that meets the criteria laid down by the Department of Health and Diabetes UK Patient Education Working Group.</p> <ul style="list-style-type: none"> • Any programme should be evidence-based, and suit the needs of the individual. The programme should have specific aims and learning objectives, and should support development of self management attitudes, beliefs, knowledge and skills for the learner, their family and carers. • The programme should have a structured curriculum that is theory-driven and evidence-based, resource-effective, has supporting materials, and is written down. • The programme should be delivered by trained educators who have an understanding of education theory appropriate to the age and needs of the programme learners, and are trained and competent in delivery of the principles and content of the programme they are offering. • The programme itself should be quality assured, and be reviewed by trained, competent, independent assessors who assess it against key criteria to ensure sustained consistency. • The outcomes from the programme should be regularly audited. [1.1.2] 	<p>The GDG agreed to adopt the wording of this recommendation on this topic from the NICE guideline on type 1 diabetes.</p>
<p>Follow the recommendations in</p>	<p>This recommendation has been deleted</p>

DRAFT FOR CONSULTATION

<p>Depression: management of depression in primary and secondary care clinical guideline (NICE clinical guideline 23). [1.2.2.1]</p>	<p>because this is now mentioned in the 'Related guidance' section. Depression: management of depression in primary and secondary care clinical guideline (NICE clinical guideline 23) has also been updated and is now NICE clinical guideline 90.</p>
<p>When setting a target glycated haemoglobin (HbA1c):</p> <ul style="list-style-type: none"> • involve the person in decisions about their individual HbA1c target level, which may be above that of 6.5% set for people with type 2 diabetes in general • encourage the person to maintain their individual target unless the resulting side • effects (including hypoglycaemia) or their efforts to achieve this impair their quality • of life offer therapy (lifestyle and medication) to help achieve and maintain the HbA1c target level • inform a person with a higher HbA1c that any reduction in HbA1c towards the agreed target is advantageous to future health • avoid pursuing highly intensive management to levels of less than 6.5%. [1.3.1] 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Measure HbA1c using high-precision methods and report results in units aligned with those used in the DCCT trial[3] (or as recommended by national agreement after publication of this guideline). [1.3.4]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Offer self-monitoring of plasma glucose to a person newly diagnosed with type 2 diabetes only as an integral part of his or her self-management education. Discuss its purpose and agree how it should be interpreted and acted upon. [1.4.1]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Self-monitoring of plasma glucose should be available:</p> <ul style="list-style-type: none"> • to those on insulin treatment • to those on oral glucose-lowering medications to provide information on hypoglycaemia • to assess changes in glucose control resulting from medications and lifestyle changes 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>

DRAFT FOR CONSULTATION

<ul style="list-style-type: none"> to monitor changes during intercurrent illness to ensure safety during activities, including driving. [1.4.2] 	
If self-monitoring is appropriate but blood glucose monitoring is unacceptable to the person, discuss using urine glucose monitoring. [1.4.4]	This recommendation has been deleted because this entire section has been updated in 2015.
Start metformin treatment in a person who is overweight or obese (tailoring the assessment of body-weight-associated risk according to ethnic group[4]) and whose blood glucose is inadequately controlled (see 1.3.1) by lifestyle interventions (nutrition and exercise) alone. [1.5.1.1]	This recommendation has been deleted because this entire section has been updated in 2015.
Consider metformin as an option for first-line glucose-lowering therapy for a person who is not overweight. [1.5.1.2]	This recommendation has been deleted because this entire section has been updated in 2015.
Continue with metformin if blood glucose control remains or becomes inadequate (see 1.3.1) and another oral glucose-lowering medication (usually a sulfonylurea) is added. [1.5.1.3]	This recommendation has been deleted because this entire section has been updated in 2015.
Step up metformin therapy gradually over weeks to minimise risk of gastrointestinal (GI) side effects. Consider a trial of extended-absorption metformin tablets where GI tolerability prevents continuation of metformin therapy. [1.5.1.4]	This recommendation has been deleted because this entire section has been updated in 2015.
<p>The benefits of metformin therapy should be discussed with a person with mild to moderate liver dysfunction or cardiac impairment so that:</p> <ul style="list-style-type: none"> due consideration can be given to the cardiovascular-protective effects of the drug an informed decision can be made on whether to continue or stop the metformin. [1.5.1.6] 	This recommendation has been deleted because this entire section has been updated in 2015.
<p>Consider a sulfonylurea as an option for first-line glucose-lowering therapy if:</p> <ul style="list-style-type: none"> the person is not overweight the person does not tolerate metformin (or it is contraindicated) or a rapid response to therapy is required because of hyperglycaemic symptoms. [1.5.2.1] 	This recommendation has been deleted because this entire section has been updated in 2015.
Add a sulfonylurea as second-line	This recommendation has been deleted

DRAFT FOR CONSULTATION

therapy when blood glucose control remains or becomes inadequate (see 1.3.1) with metformin. [1.5.2.2]	because this entire section has been updated in 2015.
Continue with a sulfonylurea if blood glucose control remains or becomes inadequate (see 1.3.1) and another oral glucose-lowering medication is added. [1.5.2.3]	This recommendation has been deleted because this entire section has been updated in 2015.
Prescribe a sulfonylurea with a low acquisition cost (but not glibenclamide) when an insulin secretagogue is indicated (see 1.5.2.1 and 1.5.2.2). [1.5.2.4]	This recommendation has been deleted because this entire section has been updated in 2015.
When drug concordance is a problem, offer a once-daily, long-acting sulfonylurea. [1.5.2.5]	This recommendation has been deleted because this entire section has been updated in 2015.
Educate a person being treated with an insulin secretagogue, particularly if renally impaired, about the risk of hypoglycaemia. [1.5.2.6]	This recommendation has been deleted because this entire section has been updated in 2015.
Consider offering a rapid-acting insulin secretagogue to a person with an erratic lifestyle. [1.5.3.1]	This recommendation has been deleted because this entire section has been updated in 2015.
Consider acarbose for a person unable to use other oral glucose-lowering medications. [1.5.4.1]	This recommendation has been deleted because this entire section has been updated in 2015.
Consider adding a DPP-4 inhibitor (sitagliptin, vildagliptin) instead of a sulfonylurea as second-line therapy to first-line metformin when control of blood glucose remains or becomes inadequate (HbA1c \geq 6.5%, or other higher level agreed with the individual) if: <ul style="list-style-type: none"> the person is at significant risk of hypoglycaemia or its consequences (for example, older people and people in certain jobs [for example, those working at heights or with heavy machinery] or people in certain social circumstances [for example, those living alone]), or the person does not tolerate a sulfonylurea or a sulfonylurea is contraindicated. [1.6.1.1] 	This recommendation has been deleted because this entire section has been updated in 2015.
Consider adding a DPP-4 inhibitor (sitagliptin, vildagliptin) as second-line therapy to first-line sulfonylurea monotherapy when control of blood glucose remains or becomes inadequate (HbA1c \geq 6.5%, or other higher level agreed with the individual) if:	This recommendation has been deleted because this entire section has been updated in 2015.

DRAFT FOR CONSULTATION

<ul style="list-style-type: none"> the person does not tolerate metformin, or metformin is contraindicated. [1.6.1.2] 	
<p>Consider adding sitagliptin[5] as third-line therapy to first-line metformin and a second-line sulfonylurea when control of blood glucose remains or becomes inadequate (HbA1c \geq 7.5% or other higher level agreed with the individual) and insulin is unacceptable or inappropriate[6]. [1.6.1.3]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Only continue DPP-4 inhibitor therapy (sitagliptin, vildagliptin) if the person has had a beneficial metabolic response (a reduction of at least 0.5 percentage points in HbA1c in 6 months). [1.6.1.4]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Discuss the potential benefits and risks of treatment with a DPP-4 inhibitor (sitagliptin, vildagliptin) with the person to enable them to make an informed decision.</p> <p>A DPP-4 inhibitor (sitagliptin, vildagliptin) may be preferable to a thiazolidinedione (pioglitazone) if:</p> <ul style="list-style-type: none"> further weight gain would cause or exacerbate significant problems associated with a high body weight, or a thiazolidinedione (pioglitazone) is contraindicated, or the person has previously had a poor response to, or did not tolerate, a thiazolidinedione (pioglitazone). <p>There may be some people for whom either a DPP-4 inhibitor (sitagliptin, vildagliptin) or a thiazolidinedione (pioglitazone) may be suitable and, in this case, the choice of treatment should be based on patient preference. [1.6.1.5]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Consider adding a thiazolidinedione (pioglitazone) instead of a sulfonylurea as second-line therapy to first-line metformin when control of blood glucose remains or becomes inadequate (HbA1c \geq 6.5%, or other higher level agreed with the individual) if:</p> <ul style="list-style-type: none"> the person is at significant risk of hypoglycaemia or its consequences (for example, older people and people in certain jobs [for example, those working at heights or with heavy machinery] or people in certain 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>

DRAFT FOR CONSULTATION

<p>social circumstances [for example, those living alone]), or</p> <ul style="list-style-type: none"> • a person does not tolerate a sulfonylurea or a sulfonylurea is contraindicated. [1.6.2.1] 	
<p>Consider adding a thiazolidinedione (pioglitazone) as second-line therapy to first-line sulfonylurea monotherapy when control of blood glucose remains or becomes inadequate (HbA1c \geq 6.5%, or other higher level agreed with the individual) if:</p> <ul style="list-style-type: none"> • the person does not tolerate metformin or metformin is contraindicated. [1.6.2.2] 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Consider adding a thiazolidinedione (pioglitazone) as third-line therapy to firstline metformin and a second-line sulfonylurea when control of blood glucose remains or becomes inadequate (HbA1c \geq 7.5%, or other higher level agreed with the individual) and insulin is unacceptable or inappropriate[7]. [1.6.2.3]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Do not commence or continue a thiazolidinedione (pioglitazone) in people who have heart failure, or who are at higher risk of fracture. [1.6.2.4]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>When selecting a thiazolidinedione (pioglitazone), take into account up-to-date advice from the relevant regulatory bodies (the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency), cost, safety and prescribing issues (see 1.6.2.8). [1.6.2.5]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Only continue thiazolidinedione therapy (pioglitazone) if the person has had a beneficial metabolic response (a reduction of at least 0.5 percentage points in HbA1c in 6 months). [1.6.2.6]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Consider combining pioglitazone with insulin therapy[6] for a person:</p> <ul style="list-style-type: none"> • who has previously had a marked glucose-lowering response to thiazolidinedione therapy (pioglitazone), or • who is on high-dose insulin therapy and whose blood glucose is inadequately controlled. [1.6.2.7] 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Discuss the potential benefits and risks of</p>	<p>This recommendation has been deleted</p>

DRAFT FOR CONSULTATION

<p>treatment with a thiazolidinedione (pioglitazone) with the person to enable them to make an informed decision. A thiazolidinedione (pioglitazone) may be preferable to a DPP-4 inhibitor (sitagliptin, vildagliptin) if:</p> <ul style="list-style-type: none"> • the person has marked insulin insensitivity, or • a DPP-4 inhibitor (sitagliptin, vildagliptin) is contraindicated, or • the person has previously had a poor response to, or did not tolerate, a DPP-4 inhibitor (sitagliptin, vildagliptin). <p>There may be some people for whom either a thiazolidinedione (pioglitazone) or a DPP-4 inhibitor (sitagliptin, vildagliptin) may be suitable and, in this case, the choice of treatment should be based on patient preference. [1.6.2.8]</p>	<p>because this entire section has been updated in 2015.</p>
<p>Consider adding a GLP-1 mimetic (exenatide) as third-line therapy to first-line metformin and a second-line sulfonylurea when control of blood glucose remains or becomes inadequate (HbA1c \geq 7.5%, or other higher level agreed with the individual), and the person has:</p> <ul style="list-style-type: none"> • a body mass index (BMI) \geq 35.0 kg/m² in those of European descent (with appropriate adjustment for other ethnic groups) and specific psychological or • medical problems associated with high body weight, or • a BMI $<$ 35.0 kg/m², and therapy with insulin would have significant occupational implications or weight loss would benefit other significant obesity-related comorbidities. [1.6.3.1] 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>Discuss the potential benefits and risks of treatment with a GLP-1 mimetic (exenatide) with the person to enable them to make an informed decision. [1.6.3.3]</p>	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>
<p>When starting basal insulin therapy:</p> <ul style="list-style-type: none"> • continue with metformin and the sulfonylurea (and acarbose, if used) • review the use of the sulfonylurea if 	<p>This recommendation has been deleted because this entire section has been updated in 2015.</p>

DRAFT FOR CONSULTATION

hypoglycaemia occurs. [1.7.1.1]	
When starting pre-mixed insulin therapy (or mealtime plus basal insulin regimens): <ul style="list-style-type: none"> • continue with metformin • continue the sulfonylurea initially, but review and discontinue if hypoglycaemia occurs. [1.7.1.2] 	This recommendation has been deleted because this entire section has been updated in 2015.
Discuss the benefits and risks of insulin therapy when control of blood glucose remains or becomes inadequate (HbA1c \geq 7.5% or other higher level agreed with the individual) with other measures. Start insulin therapy if the person agrees. [1.7.2.1]	This recommendation has been deleted because this entire section has been updated in 2015.
For a person on dual therapy who is markedly hyperglycaemic, consider starting insulin therapy in preference to adding other drugs to control blood glucose unless there is strong justification[7] not to. [1.7.2.2]	This recommendation has been deleted because this entire section has been updated in 2015.
Offer education to a person who requires insulin about using an injection device (usually a pen injector and cartridge or a disposable pen) that they and/or their carer find easy to use. [1.7.3.1]	NICE took the decision to stand down this recommendation because the Type1 diabetes guideline undertook an updated evidence review in this area. The Guideline Development Group (GDG) for type 2 diabetes agreed that the management of insulin delivery within the type 2 diabetes population would be similar and therefore it would be appropriate to cross refer to the Type 1 diabetes guideline for insulin delivery.

<p>Appropriate local arrangements should be in place for the disposal of sharps. [1.7.3.2]</p>	<p>NICE took the decision to stand down this recommendation because the Type 1 diabetes guideline undertook an updated evidence review in this area. The GDG for type 2 diabetes agreed that the management of insulin delivery within the type 2 diabetes population would be similar and therefore it would be appropriate to cross refer to the Type 1 diabetes guideline for insulin delivery.</p>
<p>If a person has a manual or visual disability and requires insulin, offer a device or adaptation that:</p> <ul style="list-style-type: none"> • takes into account his or her individual needs • he or she can use successfully [1.7.3.3] 	<p>NICE took the decision to stand down this recommendation because the Type 1 diabetes guideline undertook an updated evidence review in this area. The GDG for type 2 diabetes agreed that the management of insulin delivery within the type 2 diabetes population would be similar and therefore it would be appropriate to cross refer to the Type 1 diabetes guideline for insulin delivery.</p>
<p>Review cardiovascular risk status annually by assessment of cardiovascular risk factors, including features of the metabolic syndrome and waist circumference, and change in personal or family cardiovascular history. [1.10.1.1]</p>	<p>The type 2 diabetes GDG wanted to stand down the outstanding lipids recs 1.10.1.1, 1.10.1.4, 1.10.2.1 and 1.10.2.2 but these are not directly updated by the lipids guideline. This is because the GDG felt these recommendations were covered by NICE's lipids guideline (CG181) and it is advisable to have all recommendations on lipid management in 1 place. The type 2 diabetes GDG felt it would be very important to cross refer to management of lipid levels within CG181 because management of cardiovascular risk is an essential part of managing type 2 diabetes.</p>
<p>Once a person has been started on cholesterol-lowering therapy, assess his or her lipid profile (together with other modifiable risk factors and any new diagnosis of cardiovascular disease) 1–3 months after starting treatment, and annually thereafter. In those not on cholesterol-lowering therapy, reassess cardiovascular risk annually and consider initiating a statin (see 1.10.1.2 and 1.10.1.3). [1.10.1.4]</p>	<p>The type 2 diabetes GDG wanted to stand down the outstanding lipids recs 1.10.1.1, 1.10.1.4, 1.10.2.1 and 1.10.2.2 but these are not directly updated by the lipids guideline. This is because the GDG felt these recommendations were covered by NICE's lipids guideline (CG181) and it is advisable to have all recommendations on lipid management in 1 place. The type 2 diabetes GDG felt it would be very important to cross refer to management of lipid levels within CG181 because management of cardiovascular risk is an essential part of managing type 2 diabetes.</p>
<p>If there is a history of elevated serum triglycerides, perform a full fasting lipid profile (including HDL cholesterol and</p>	<p>The type 2 diabetes GDG wanted to stand down the outstanding lipids recs 1.10.1.1, 1.10.1.4, 1.10.2.1 and 1.10.2.2</p>

triglyceride estimations) when assessing cardiovascular risk annually. [1.10.2.1]	but these are not directly updated by the lipids guideline. This is because the GDG felt these recommendations were covered by NICE's lipids guideline (CG181) and it is advisable to have all recommendations on lipid management in 1 place. The type 2 diabetes GDG felt it would be very important to cross refer to management of lipid levels within CG181 because management of cardiovascular risk is an essential part of managing type 2 diabetes.
Assess possible secondary causes of high serum triglyceride levels, including poor blood glucose control (others include hypothyroidism, renal impairment and liver inflammation, particularly from alcohol). If a secondary cause is identified, manage according to need. [1.10.2.2]	The type 2 diabetes GDG wanted to stand down the outstanding lipids recs 1.10.1.1, 1.10.1.4, 1.10.2.1 and 1.10.2.2 but these are not directly updated by the lipids guideline. This is because the GDG felt these recommendations were covered by NICE's lipids guideline (CG181) and it is advisable to have all recommendations on lipid management in 1 place. The type 2 diabetes GDG felt it would be very important to cross refer to management of lipid levels within CG181 because management of cardiovascular risk is an essential part of managing type 2 diabetes.
Offer low-dose aspirin, 75 mg daily, to a person who is 50 years old or over, if blood pressure is below 145/90 mmHg[8]. [1.11.1]	This recommendation has been deleted because this entire section has been updated in 2015.
Offer low-dose aspirin, 75 mg daily, to a person who is under 50 years old and has significant other cardiovascular risk factors (features of the metabolic syndrome, strong early family history of cardiovascular disease, smoking, hypertension, extant cardiovascular disease, microalbuminuria)[8]. [1.11.2]	This recommendation has been deleted because this entire section has been updated in 2015.
Clopidogrel should be used instead of aspirin only in those with clear aspirin intolerance (except in the context of acute cardiovascular events and procedures). Follow the recommendations in 'Clopidogrel and modified-release dipyridamole in the prevention of occlusive vascular events' (NICE technology appraisal guidance 90). [1.11.3]	This recommendation has been deleted because this entire section has been updated in 2015.
Ask all people with or without detected nephropathy to bring in a first-pass morning urine specimen once a year. In the absence of proteinuria/urinary tract	Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182 .

DRAFT FOR CONSULTATION

<p>infection (UTI), send this for laboratory estimation of albumin:creatinine ratio. Request a specimen on a subsequent visit if UTI prevents analysis. [1.12.1]</p>	
<p>Make the measurement on a spot sample if a first-pass sample is not provided (and repeat on a first-pass specimen if abnormal) or make a formal arrangement for a first-pass specimen to be provided. [1.12.2]</p>	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>
<p>Measure serum creatinine and estimate the glomerular filtration rate (using the method-abbreviated modification of diet in renal disease [MDRD] four-variable equation) annually at the time of albumin:creatinine ratio estimation. [1.12.3]</p>	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>
<p>Repeat the test if an abnormal albumin:creatinine ratio is obtained (in the absence of proteinuria/UTI) at each of the next two clinic visits but within a maximum of 3–4 months. Take the result to be confirming microalbuminuria if a further specimen (out of two more) is also abnormal (> 2.5 mg/mmol for men, > 3.5 mg/mmol for women). [1.12.4]</p>	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>
<p>Suspect renal disease other than diabetic nephropathy and consider further investigation or referral when the albumin:creatinine ratio (ACR) is raised and any of the following apply:</p> <ul style="list-style-type: none"> • there is no significant or progressive retinopathy • blood pressure is particularly high or resistant to treatment • the person previously had a documented normal ACR and develops heavy proteinuria (ACR > 100 mg/mmol) • significant haematuria is present • the glomerular filtration rate has worsened rapidly • the person is systemically ill. [1.12.5] 	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>
<p>Discuss the significance of a finding of abnormal albumin excretion rate, and its trend over time, with the individual concerned. [1.12.6]</p>	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>
<p>Start ACE inhibitors with the usual precautions and titrate to full dose in all individuals with confirmed raised albumin excretion rate (> 2.5 mg/mmol for men, ></p>	<p>Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182.</p>

DRAFT FOR CONSULTATION

3.5 mg/mmol for women). [1.12.7]	
Have an informed discussion before starting an ACE inhibitor in a woman for whom there is a possibility of pregnancy, assessing the relative risks and benefits of the use of the ACE inhibitor. [1.12.8]	Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182 .
Substitute an angiotensin II-receptor antagonist for an ACE inhibitor for a person with an abnormal albumin:creatinine ratio if an ACE inhibitor is poorly tolerated. [1.12.9]	Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182 .
For a person with an abnormal albumin:creatinine ratio, maintain blood pressure below 130/80 mmHg. [1.12.10]	Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182 .
Agree referral criteria for specialist renal care between local diabetes specialists and nephrologists.[1.12.11]	Recommendations on chronic kidney disease in NICE clinical guideline 87 have been updated by NICE clinical guideline 182 .
For the management of foot problems relating to type 2 diabetes, follow recommendations in Type 2 diabetes: prevention and management of foot problems (NICE clinical guideline 10). [1.14.1]	NICE clinical guideline 10 is currently being updated and replaced. We will cross refer to the updated guideline on diabetic foot problems.
<p>Make a formal enquiry annually about the development of neuropathic symptoms causing distress.</p> <ul style="list-style-type: none"> • Discuss the cause and prognosis (including possible medium-term remission) of troublesome neuropathic symptoms, if present (bearing in mind alternative diagnoses). • Agree appropriate therapeutic options and review understanding at each clinical contact. [1.14.2.1] 	Will be deleted and will cross refer to neuropathic pain (NICE clinical guideline 173).
Be alert to the psychological consequences of chronic, painful diabetic neuropathy and offer psychological support according to the needs of the individual. [1.14.2.2]	Will be deleted and will cross refer to neuropathic pain (NICE clinical guideline 173).
<p>If neuropathic symptoms cannot be controlled adequately, it may be helpful to further discuss:</p> <ul style="list-style-type: none"> • the reasons for the problem • the likelihood of remission in the medium term • the role of improved blood glucose control. [1.14.2.7] 	Will be deleted and will cross refer to neuropathic pain (NICE clinical guideline 173).

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.

These changes are marked with yellow shading.

Recommendation in 2009 guideline	Recommendation in current guideline	Reason for change
<p>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]</p>	<p>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)</p>	<p>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.</p>
<p>Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines if any of these features is present:</p> <ul style="list-style-type: none"> • referable maculopathy: <ul style="list-style-type: none"> ○ exudate or retinal thickening within one 	<p>Refer to an ophthalmologist in accordance with the National Screening Committee criteria and timelines if any of these features is present:</p> <ul style="list-style-type: none"> • referable maculopathy: <ul style="list-style-type: none"> ○ exudate or retinal thickening within 1 	<p>The recommendations on eye damage were reviewed by the National Screening Programme and were amended to make them consistent with the current practice of</p>

<p>disc diameter of the centre of the fovea</p> <ul style="list-style-type: none"> ○ 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] 	<p>disc diameter of the centre of the fovea</p> <ul style="list-style-type: none"> ○ 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] (1.7.24) 	<p>the diabetes eye screening programme.</p>
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Consider a trial of metoclopramide, domperidone or erythromycin for an adult with gastroparesis. [1.14.3.2]	<p>1.6.2 Consider a trial of metoclopramide, domperidone or erythromycin¹ for an adult with type 2 diabetes with gastroparesis². [2009, amended 2015] (1.7.2)</p> <p>1. At the time of consultation (January 2015), metoclopramide, domperidone and 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 Good practice in prescribing and managing medicines and devices for further information.</p> <p>2: Diagnosis of gastroparesis needing specific therapy can only be made in the absence of hyperglycaemia at the time of testing, because hyperglycaemia induces a physiological delay in gastric emptying.</p>	Two footnotes have been added to clarify the off label use of these medicines for gastroparesis and diagnosing gastroparesis.
1.14.3.1, 1.14.5.1, 1.14.5.2	1.7.1, 1.7.5, 1.7.6	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, or the verb used has been changed.

Changes to recommendation wording for clarification only (no change to meaning)

Recommendation numbers in current guideline	Comment
All recommendations except those labelled [new 2015].	Recommendations have been edited into the direct style (in line with current NICE style for recommendations in clinical guidelines) where possible. Yellow highlighting has not been applied to these changes. Where applicable, terminology has been made consistent within the guideline and with terminology that will be used in other updates of NICE guidelines on diabetes (diabetes in pregnancy [publication expected February 2015], type 1 diabetes and

DRAFT FOR CONSULTATION

	diabetes in children and young people [publication expected August 2015]).
1.2.1, 1.2.6, 1.3.3, 1.3.5, 1.3.7, 1.3.9, 1.4.1, 1.4.2, 1.7.6, 1.7.7, 1.7.8, 1.7.17, 1.7.1, 1.7.3.	Type 2 diabetes is specified for clarity (original wording had 'diabetes' or did not specify diabetes at all).
1.7.16, 1.7.17, 1.7.20, 1.7.21	'Eye surveillance' has been changed to 'eye screening', in line with current terminology.