# National Institute for Health and Care Excellence

Surveillance proposal consultation document

Diabetes prevention – 2018 surveillance review

# Background information

This 2018 surveillance review covers 2 NICE guidelines:

- <u>Type 2 diabetes prevention: population and community-level interventions</u>. NICE guideline PH35 (May 2011)
- <u>Type 2 diabetes: prevention in people at high risk</u>. NICE guideline PH38 (May 2018)

Previous surveillance of these guidelines in 2014–15 resulted in a partial update to the guideline on diabetes prevention in people at high risk (NICE guideline PH38), which was published in September 2017.

# Surveillance proposal for consultation

We propose to not update the two guidelines on diabetes prevention at this time.

During surveillance, editorial or factual corrections were identified. Details are included in <u>appendix A</u>: summary of evidence from surveillance.

# Reason for the proposal

Early in this surveillance review, we contacted topic experts and stakeholders for their views on the need to update the two guidelines on diabetes prevention. The <u>NHS Diabetes Prevention Programme</u> is rolling out in a joint commitment between the stakeholders Public Health England, NHS England and Diabetes UK. The NHS Diabetes Prevention Programme is based on a service specification that adheres closely to NICE guidelines. Public Health England and NHS England noted that it would be prudent to postpone updating the guideline on population and community-level interventions (NICE guideline PH35) until evaluation data from the NHS Diabetes Prevention Programme is available (expected from 2020). We agreed with this view, therefore, no further assessment of the need to update the guideline on population and community-level interventions (NICE guideline PH35) was undertaken for this surveillance review.

The surveillance review for the guideline on prevention in people at high risk (NICE guideline PH38) proceeded as normal.

Assessing the evidence for prevention in people at high risk (NICE guideline PH38) We found 132 relevant studies in a search for systematic reviews, randomised controlled trials, and observational studies published between 01 July 2014 and 30 October 2017. We also included 5 relevant studies from a total of 26 identified by members of the guideline committee who originally worked on this guideline. A further study was identified through external communications received after the guideline was published.

From all sources, we considered 138 studies to be relevant to the guideline.

This included studies that support current recommendations on the following:

- diabetes risk assessment
- diabetes risk identification
- matching interventions to risk
- reassessing risk
- commissioning of risk identification and intensive lifestyle-change programmes
- design and delivery of quality-assured, intensive lifestyle-change programmes
- evaluation of quality-assured, intensive lifestyle-change programmes
- providing tailored advice on physical activity
- dietary advice
- supporting lifestyle change in vulnerable groups
- drug treatments for non-diabetic hyperglycaemia.

We found evidence on the effects of bariatric surgery on non-diabetic hyperglycaemia, which was not covered in the guideline. This evidence was considered to be insufficient to add new recommendations in this area at this time.

We did not find any new evidence related to the following areas of the guideline:

- content of quality-assured, intensive lifestyle-change programmes
- raising awareness of the importance of physical activity
- weight management advice
- information and services for vulnerable groups
- quality assurance of intensive lifestyle-change programmes
- training and professional development

### Ongoing research

During surveillance, Public Health England noted that evaluation data from the NHS Diabetes Programme are expected from 2020. We will check for publications from this programme, including:

- Delivering a realistic Diabetes Prevention Programme in a UK community
- Delivering the Diabetes Prevention Programme in a UK community setting
- Evaluating the NHS Diabetes Prevention Programme (NHS DPP): the DIPLOMA research programme (Diabetes Prevention Long term Multimethod Assessment)

Additionally, ongoing studies identified by topic experts and stakeholders were assessed for the potential to impact on the guideline. The following 3 studies will be monitored by the surveillance programme:

- <u>Norfolk Diabetes Prevention Study</u>
- <u>The PRomotion Of Physical activity through structured Education with differing</u> <u>Levels of ongoing Support for those with prediabetes (PROPELS): randomised</u> <u>controlled trial in a diverse multi-ethnic community</u>
- Development and evaluation of very brief behaviour change interventions to reduce the risk of chronic disease in primary care

When publications relating to these studies are identified, the impact of the results on recommendations, and any associated need to update the guidelines will be assessed.

### **Equalities**

No equalities issues were identified during the surveillance process for either of the guidelines.

### Overall proposed decision

After considering all the evidence and views of topic experts, we propose to not update the guidelines on preventing diabetes.

The next planned surveillance is expected in 5 years. However, new evidence from the ongoing studies noted above, and any other major developments in this area may result in the surveillance review being brought forward.

# **Further information**

See <u>appendix A</u>: summary of evidence from surveillance below for further information.

For details of the process and update decisions that are available, see <u>ensuring that</u> <u>published guidelines are current and accurate</u> in developing NICE guidelines: the manual.

# Appendix A: Summary of evidence from surveillance

# 2018 surveillance of <u>Type 2 diabetes: prevention in people at high risk</u> (2012) NICE guideline PH38

### Summary of evidence from surveillance

Studies identified in searches are summarised from the information presented in their abstracts. Full texts are consulted in specific circumstances, for example if the full text is necessary to make a definitive statement about the impact of the study on current recommendations. For this surveillance review we looked for new evidence relating to the whole guideline.

Feedback from topic experts who advised us on the approach to this surveillance review, and from stakeholders if public consultation was conducted, was considered alongside the evidence to reach a final decision on the need to update each section of the guideline.

This document follows the structure of the guideline, with the recommendations cited at the start of each section, and the new evidence discussed below the relevant recommendations.

#### Preamble to the recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in <u>your care</u>.

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

#### **Risk assessment**

- 1.1.1 GPs and other health professionals and community practitioners in health and community venues should implement a two-stage strategy to identify people at high risk of type 2 diabetes (and those with undiagnosed type 2 diabetes). First, a risk assessment should be offered (see recommendation 1.1.3). Second, where necessary, a blood test should be offered to confirm whether people have type 2 diabetes or are at high risk (see recommendation 1.1.4). [2012]
- 1.1.2 Service providers including pharmacists, managers of local health and community services and voluntary organisations, employers and leaders of faith groups should offer validated self-assessment questionnaires or validated web-based tools (for examples, see the <u>Diabetes UK website</u>). They should also provide the information needed to complete and interpret them. The tools should be available in local health, community and social care venues. Examples of possible health venues include: community pharmacies, dental surgeries, NHS walk-in centres and opticians. Examples of community and social care venues include: workplaces, job centres, local authority leisure services, shops, libraries,

faith centres, residential and respite care homes and day centres (for older adults and for adults with learning disabilities). **[2012]** 

- 1.1.3 Public health, primary care and community services should publicise local opportunities for risk assessment and the benefits of preventing (or delaying the onset of) type 2 diabetes. The information should be up-to-date and provided in a variety of formats. It should also be tailored for different groups and communities. For example, by offering translation services and information in languages used locally. [2012]
- 1.1.4 Where risk assessment is conducted by health professionals in NHS venues outside general practice (for example, in community pharmacies) the professionals involved should ensure the results are passed on to the person's GP. [2012]
- 1.1.5 GPs should keep records of all risk assessment results to ensure appropriate follow-up and continuity of care. [2012]
- 1.1.6 Where self-assessment is offered in community venues, health professionals and community practitioners in those venues should encourage people with an intermediate or high risk score to visit their GP to discuss how to manage their risk. Those at high risk should be offered a blood test by their GP. [2012]
- 1.1.7 Ensure health professionals and community practitioners involved with risk assessments in community venues communicate closely with, and receive support from, NHS diabetes risk-assessment and prevention services. They should aim to ensure continuity of care and avoid unnecessary duplication of risk assessments. [2012]
- 1.1.8 Managers in primary and secondary healthcare should ensure staff actively seek out and offer risk assessments to people who might not realise they could be at high risk. This includes people with particular conditions that can increase the risk such as: cardiovascular disease, hypertension, obesity, stroke, polycystic ovary syndrome, a history of gestational diabetes and mental health problems. In addition, people with learning disabilities and those attending accident and emergency, emergency medical admissions units, vascular and renal surgery units and ophthalmology departments may be at high risk. [2012]

#### Surveillance decision

No new information was identified at any surveillance review.

#### Encouraging people to have a risk assessment

- 1.2.1 Encourage the following to have a risk assessment:
  - all eligible adults aged 40 and above, except pregnant women
  - people aged 25–39 of South Asian, Chinese, African-Caribbean, black African and other high-risk black and minority ethnic groups, except pregnant women
  - adults with conditions that increase the risk of type 2 diabetes\*. [2012]

\*Particular conditions can increase the risk of type 2 diabetes. These include: cardiovascular disease, hypertension, obesity, stroke, polycystic ovary syndrome, a history of gestational diabetes and mental health problems. In addition, people with learning disabilities and those attending accident and emergency, emergency medical admissions units, vascular and renal surgery units and ophthalmology departments may be at high risk.

- 1.2.2 Explain to people why, even though they feel healthy, they can still be at risk of developing type 2 diabetes. Explain the implications of being at risk and that this can be reduced by making lifestyle changes. [2012]
- 1.2.3 Tell people how and where they can be assessed, including at their GP surgery or community pharmacy. Make people aware that they can use a validated self-assessment questionnaire or validated web-based tools (for examples, see the <u>Diabetes UK website</u>). Explain that those who are eligible can be assessed by the <u>NHS Health Check programme</u>. (This programme is for people aged 40–74 who are not on a disease register and have not been diagnosed with coronary heart disease, hypertension, atrial fibrillation, stroke, transient ischaemic attack, type 2 diabetes or kidney disease\*.) [2012]

\*They will be treated and managed using established health care pathways.

- 1.2.4 Encourage people who are less likely to attend a GP surgery to go elsewhere for a risk assessment. Possibilities include community pharmacies, dental surgeries, NHS walk-in centres and opticians. Assessments may also be offered in community venues. Examples include: workplaces, job centres, local authority leisure facilities, shops, libraries, faith centres, residential and respite care homes and day centres (for older adults and for adults with learning disabilities). [2012]
- 1.2.5 Advise people with type 2 diabetes to encourage family members to have their risk assessed. [2012]

#### Surveillance decision

This section of the guideline should not be updated.

#### Alternative settings for risk assessment

#### 2018 surveillance summary

A cohort study(1) assessed routine HbA1c testing in an urban Australian public hospital emergency department. All patients (n=4,580) having blood samples taken over a 6-week period had random blood glucose testing (n=2,652), if this indicated non-diabetic hyperglycaemia (NDH), HbA1c was measured on the same sample (n=1,267). Including people with previous diagnoses, 38% had type 2 diabetes, and 32% of these cases were new diagnoses. NDH was identified in 27% of people.

A cohort study(2) investigated use of a 'free public health station' for assessing hypertension and diabetes in a government medical centre in Israel. Of the participants (total number not reported in the abstract), 868 had a random blood glucose result indicating NDH, and 341 (39%) responded to a telephone follow-up survey. Almost all of these participants (n=313, 92%) visited their health service for fasting blood glucose measurement, and about a third of those results indicated NDH. Half of the respondents (n=173) started interventions including antidiabetic treatment, low-sugar diets, or physical activity programmes. About two-thirds of participants (n=216) found the station to be effective and 80% (n=273) would recommend it.

A retrospective study(3) assessed risk of type 2 diabetes in people attending a community hospital in the USA, who did not have health insurance or a primary care physician. Participants underwent risk assessment according to ADA criteria, and eligible people had HbA1c and fasting plasma glucose testing. Overall, 460 people had risk assessment, and 92 people were analysed. Of these, 9% had diabetes and 39% had NDH. Age and presence of hypertension were positively correlated with increased risk of diabetes.

A study(4) assessed opportunistic risk assessment and blood glucose testing events in local faith centres for people of South Asian origin in the UK. People at high risk of diabetes were offered an intervention (Walking Away from Diabetes). Over 4 events, 252 people had risk assessment, 202 of whom gave consent for inclusion in the analysis. Overall, 72% of participants had high risk of type 2 diabetes. An HbA1c result indicating NDH was seen in 16% of participants, and in 4% the result indicated type 2 diabetes. Of those eligible for the diabetes prevention programme, 56% attended.

#### **Topic expert feedback**

Topic experts highlighted a study(4) indicating that risk assessment and blood glucose testing in faith centres in the UK successfully identified people at high risk of type 2 diabetes, and identified a number of people with undiagnosed type 2 diabetes.

#### Impact statement

New evidence on assessing risk of type 2 diabetes in non-standard settings primarily used a type of healthcare service other than during a primary care consultation. However, in one study, risk assessment and blood glucose testing in faith centres appeared to be effective, and importantly may reach people who do not engage with standard health services.

The Australian study of blood-glucose testing in emergency health settings, indicates that targeting people using emergency health services may be feasible to implement in the UK.

Overall, the new evidence supports the recommendations to undertake risk assessments in a range of settings.

New evidence is unlikely to change guideline recommendations.

#### Views of diabetes risk

A qualitative study(5) assessed factors affecting enrolment and participation in a purposeful sample (n=24) from a cluster RCT of dietitian-delivered lifestyle advice in people of South Asian origin living in Scotland. The authors noted that the intervention resulted in modest weight loss, but did not significantly reduce the incidence of type 2 diabetes. Many participants were motivated to participate because of: known family history of diabetes and the desire to better understand diabetesrelated risks to their own and their family's health; ways to mitigate these risks and to benefit from personalised monitoring. Homebased interventions, communication in the participant's chosen language and continuity in dietitians supported their continuing

engagement with the trial. Adaptations in food choices were initially accommodated by participants, although social and faith-based responsibilities were reported as important barriers to persevering with agreed dietary goals. Many participants reported that increasing their level of physical activity was difficult because of long working hours, physically demanding employment and domestic commitments; participants were also reluctant to undertake outdoor physical activity.

A qualitative study(6) investigated how people with NDH perceive their risk of developing type 2 diabetes, and their preferences for preventative interventions (n=35). The sample consisted of 'middle aged' people, 77% of whom were non-white. Knowledge gaps about NDH and its medical management were pervasive. Most patients overestimated the risk of developing diabetes and were not familiar with evidence-based treatment options for NDH. They suggested that receiving brief, yet specific information about these topics during the study interview motivated them to act. The majority of participants considered both intensive lifestyle intervention and metformin acceptable treatment options. Many preferred initial treatment with intensive lifestyle intervention but would take metformin if their efforts at lifestyle change failed and their primary care physician recommended it. Some participants expressed wanting to combine both treatments.

A qualitative study(7) investigated how people aged 40-64 years with NDH perceive their risk of developing diabetes, and the effects on uptake of physical activity (n=14). Interviews were conducted twice, with a 2-year interval between interviews. Two themes of risk perception emerged from the data 'threatening' and 'rejecting'. The 'threatening' risk perception occurred when the risk was unexpected by the participant. The 'threatening' perception also involved a commitment to increase physical activity to prevent type 2 diabetes. However, short-term anxiety and subsequently emerging hopelessness were also part of this perception. The 'rejecting' risk perception involved indifference and scepticism regarding the risk.

Here, physical activity behaviour and cognitions appeared to remain unchanged. Rejection also involved difficulties in accepting one's high-risk identity. The 'rejecting' group lacked motivation for increased physical activity, while the 'threatening' group showed determination regarding increased physical activity, often leading to success.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

The evidence suggests that people's views of their diabetes risk, can affect their motivation to make lifestyle changes. However, there are other barriers to making lifestyle changes, such as family responsibilities, work commitments, and reluctance to undertake outdoor physical activity.

These findings support current recommendations to explain that risk of diabetes can be reduced by making lifestyle changes, and to advise people with type 2 diabetes to encourage family members to have risk assessment.

New evidence is unlikely to change guideline recommendations.

#### **Risk identification (stage 1)**

- 1.3.1 GPs and other primary healthcare professionals should use a validated <u>computer-based</u> <u>risk-assessment tool</u> to identify people on their practice register who may be at high risk of type 2 diabetes. The tool should use routinely available data from patients' electronic health records. If a computer-based risk-assessment tool is not available, they should provide a validated self-assessment questionnaire, for example, the Diabetes Risk Score assessment tool. This is available to health professionals on request from <u>Diabetes UK</u>. [2012]
- 1.3.2 GPs and other primary healthcare professionals should not exclude people from assessment, investigation or intervention on the basis of age, as everyone can reduce their risk, including people aged 75 years and over. [2012]

1.3.3 Pharmacists, opticians, occupational health nurses and community leaders should offer a validated self-assessment questionnaire to adults aged 40 and over, people of South Asian and Chinese descent aged 25–39, and adults with conditions that increase the risk of type 2 diabetes\*, other than pregnant women. Or they should tell people how to access specific, validated online self-assessment tools, such as the Diabetes Risk Score featured on the <u>Diabetes UK website</u>. [2012]

\*Particular conditions can increase the risk of type 2 diabetes. These include: cardiovascular disease, hypertension, obesity, stroke, polycystic ovary syndrome, a history of gestational diabetes and mental health problems. In addition, people with learning disabilities and those attending accident and emergency, emergency medical admissions units, vascular and renal surgery units and ophthalmology departments may be at high risk.

- 1.3.4 Pharmacists, opticians, occupational health nurses and community leaders involved in risk assessments should advise people with a high risk score to contact their GP or practice nurse for a blood test. The aim is to check if they have type 2 diabetes or to confirm their level of risk and discuss how to reduce it. [2012]
- 1.3.5 All providers of risk assessments should explain to those attending for a type 2 diabetes risk assessment the implications of being at high risk and the consequences of developing the condition. [2012]
- 1.3.6 All providers of risk assessments should discuss with those attending for a type 2 diabetes risk assessment how to prevent or delay the onset of the condition. This includes being more physically active, achieving and maintaining a healthy weight, eating less fat and eating more dietary fibre. They should also tell people where to get advice and support to maintain these lifestyle changes in the long term. **[2012]**

#### Surveillance decision

This section of the guideline should not be updated.

#### Diabetes risk assessment

#### 2018 surveillance summary

# Comparative effectiveness of risk assessment tools

A cohort study(8) assessed 3 validated type 2 diabetes risk assessment tools: QDiabetes, the Leicester Risk Assessment, FINDRISC, and the Cambridge Risk Score in 676 people who participated in a workplace-based diabetes risk assessment in South Wales, UK. From highest to lowest, the proportion of people categorised at high risk by each tool were Cambridge Risk Score (13.6%) FINDRISC (6.6%), QDiabetes (6.1%), and Leicester Risk Assessment (3.1%). The authors concluded that changing to a different risk assessment tool could alter the predicted risk of an individual.

#### QDiabetes-2018

A derivation and validation study(9) assessed the QDiabetes-2018 risk prediction tool. Data from 1,457 general practices in England, 1094 of which provided data to derive the scores (n=8.87 million) and 363 of which were used to validate the scores (n=2.63 million). Risk factors considered in model A included those already in QDiabetes (age, ethnicity, deprivation, body mass index [BMI], smoking, family history of diabetes in a first degree relative, cardiovascular disease, treated hypertension, and regular use of corticosteroids) and new risk factors: atypical antipsychotics, statins, schizophrenia or bipolar affective disorder, learning disability, gestational diabetes, and polycystic ovary syndrome. Additional models included fasting blood glucose (model B) and glycated

haemoglobin (HBA1c; model C). Model B explained 63.3% of the variation in time to diagnosis of type 2 diabetes in women and 58.4% of the variation in time to diagnosis in women. Model B also had the highest sensitivity compared with current recommended practice in the NHS based on bands of either fasting blood glucose or HBA1c. However, the authors noted that additional external validation with datasets with more complete data on blood glucose would be valuable before the models are used in clinical practice because complete data for blood glucose, smoking and BMI were available for only 16% of the patients in the dataset.

# Risk assessment tools based on the Leicester score

A validation study(10) assessed the Leicester self-assessment score for detecting risk of developing type 2 diabetes within 10 years using data from the English Longitudinal Study of Ageing. The size of the entire dataset was not reported in the abstract. The Leicester selfassessment tool had an area under the curve (AUC) of 69.4% in people with a baseline HbA1c measurement indicating NDH or diabetes (n=3,203). The tool had an AUC of 74.9% in people with diabetes status recorded at 10 years (n=3,550). The score threshold of 16 had sensitivity of 89.2% and specificity of 42.3% for detecting a diagnosis of type 2 diabetes at 10 years. The authors concluded that people with a high score are at high risk of developing diabetes in the future.

A validation study(11) assessed Leicester Practice Risk Score and the Leicester Risk Assessment Score in people of South Asian origin aged 25–39 years. Of 331 participants in a population-based screening study, 2% had undiagnosed type 2 diabetes and 9% had NDH. The Leicester Practice Risk Score had an AUC of 91% for undiagnosed diabetes and 72% for NDH. The result were noted to be similar for the Leicester Risk Assessment Score, but the values were not reported in the abstract. An RCT(12) assessed the computerised Leicester Practice Risk Score for health care professionals and the patient-administered Leicester Self-Assessment Score in people aged 40–75 years with no previous diagnosis of diabetes (n=577). The rate of self-referral blood tests was significantly higher when the Leicester Practice Risk Score was used, however the rate of diagnosis of type 2 diabetes or NDH was similar in the two groups. The cost per new case of type 2 diabetes diagnosed was lower for the Leicester Practice Risk Score compared with the Leicester Self-Assessment Score.

#### FINDRISC

A cohort study(13) assessed a modified FINDRISC tool in a cohort of black and white middle-aged participants in the US-based Atherosclerosis Risk in Communities study (n=9,754) who did not have diabetes at baseline. The modified FINDRISC used comprised age, BMI, waist circumference, blood pressure medication and family history. The mean FINDRISC score was higher for black women than for white women or black men or white men. However, no statistical comparison of these values was reported in the abstract. The AUC was highest for white women (77%) and lowest for black men (70%)

A study in a cohort of participants recruited for an RCT(14) assessed a FINDRISC threshold of 12 in a population of obese and overweight people in New Zealand who participated in the PREVention of diabetes through lifestyle Interventions in Europe and Worldwide (PREVIEW) study (n=424). Overall, 65% of those assessed had NDH and 7% had undiagnosed type 2 diabetes. Higher FINDRISC scores were significantly associated with NDH. Increasing the FINDRISC cut-off score to 15 did not significantly increase accuracy of detecting NDH (AUC=60%, sensitivity=60.3%, specificity=55.4%).

#### Other risk assessment tools

A validation study(15) assessed a newlydeveloped risk assessment tool for detecting NDH in an Indonesian population. The validation dataset included 21,730 people with fasting plasma glucose test results. A random sample of 6,933 people were selected for validation of the risk assessment tool. In the validation sample, the AUC was 64.6%; and at a threshold score of 12, it had a sensitivity of 55.1% and specificity of 65.8%.

A retrospective analysis(16) assessed the United States Preventive Services Task Force recommendations on risk assessment to target blood-glucose testing. Electronic health record data from 50,515 patients with a first office visit between 2008 and 2010 were identified and followed for 3 years. People with NDH at baseline and those with fewer than 2 visits during the follow-up period were excluded. The primary outcome was diagnosis of NDH or type 2 diabetes. Overall, 29,946 people had a blood glucose test within the study period, of whom, 8,478 had NDH. The United States **Preventive Services Task Force** recommendations, for identifying people at high risk of type 2 diabetes, and therefore eligible for blood-glucose testing had sensitivity of 45% and specificity of 72% for detecting NDH. Racial and ethnic minority populations were significantly less likely to be eligible for blood-glucose testing, but had higher odds of developing NDH than white people.

A derivation and validation study(17) used a population-based dataset to develop and 3 additional population-based datasets to validate a diabetes risk assessment tool developed for the southern Chinese population. Age, waist circumference, BMI and family history of diabetes were included in the risk score for both men and women, with the additional factor of hypertension for men. The AUC was 70% for men and women. A threshold of 28 for men resulted in sensitivity of 56.6%, specificity of 71.7%, positive predictive value of 13.0% and negative predictive value of 96.0%. A threshold of 18 in women resulted in sensitivity of 68.7%, specificity of 60.2%, positive predictive value of 11% and negative predictive value of 96.0% for women in the derivation population. In the validation datasets, the score performed well in 2, and poorly in the other. No data for these findings were reported in the abstract. Additionally, a risk assessment tool from the USA and 2 other Chinese tools were also noted to perform poorly in the study population.

#### Genetic testing

One RCT(18) examined the clinical utility of supplementing type 2 diabetes risk counselling with genetic testing (n=601). Non-diabetic overweight or obese veteran outpatients aged 21 to 65 years received risk estimates for lifetime risk of diabetes, including family history and fasting plasma glucose. Participants were randomly assigned to genetic testing or control (eye disease counselling). All participants received brief lifestyle counselling encouraging weight loss to reduce the risk of diabetes. There was no difference between groups in weight, insulin resistance, perceived risk, or physical activity at 3 or 6 months.

#### **Topic expert feedback**

Topic experts highlighted studies showing further validation of the Leicester diabetes risk assessment tools.(10,11)

#### Impact statement

# Comparative effectiveness of risk assessment tools

Evidence suggests that different tools categorise differing proportions of people as at high risk of type 2 diabetes. In practice, changing to a different risk score could change the predicted risk of an individual.

#### QDiabetes-2018

Evidence suggests that the QDiabetes tool may have potential for predicting 10-year risk of type 2 diabetes. However, the authors concluded that their models should undergo additional external validation before being used in clinical practice. Therefore, an update to assess the role of QDiabetes is not thought to be necessary at this time.

# Risk assessment tools based on the Leicester score

Although there are several versions of the Leicester risk score, and they are known by many names, the evidence suggests that the Leicester risk scores have high sensitivity and the risk assessment should select most people at high risk of type 2 diabetes for further investigation. This supports current recommendations, which list a tool provided by Diabetes UK as an example of a validated computerised tool as an option for risk assessment. The Diabetes UK tool is based on the Leicester risk tool. Additionally, the sensitivity of this score was similar in the general population and in people of South-Asian origin. However, people may be less likely to attend for blood testing after selfassessment than if the tool is administered by a health care professional.

#### FINDRISC

Evidence suggests that the FINDRISC tool may have differing effectiveness by gender and by ethnicity. Additionally, altering the cut-off score that determines a high risk status may not improve its diagnostic accuracy.

#### Other risk assessment tools

Evidence for other risk assessment tools indicates that new tools that may be more applicable in specific populations may help to increase accuracy in different ethnic groups. However, none of the studies indicated a clear need to update current recommendations in this area.

#### Genetic testing

New evidence, suggest that knowledge of genetic risk factors does not result in improvement in risk factors to a greater degree than standard risk counselling, which does not support a role for genetic testing in diabetes risk assessment at this time.

# Overall message from studies of risk assessment.

Evidence suggests that several tools are available for assessing risk of type 2 diabetes, but they result in notable differences in the proportion of people classed as at high risk. The development of population-specific tools may offer better accuracy for racial and ethnic minority populations in the UK. However, none of the studies indicated a clear need to update current recommendations in this area at this time.

New evidence is unlikely to change guideline recommendations.

### Risk identification (stage 2)

- 1.4.1 Trained healthcare professionals should offer venous blood tests (fasting plasma glucose [FPG] or HbA1c) to adults with high risk scores (stage 2 of the identification process). They should also consider a blood test for those aged 25 and over of South Asian or Chinese descent whose body mass index (BMI) is greater than 23 kg/m<sup>2</sup>. The aim is to:
  - determine the risk of progression to type 2 diabetes (a fasting plasma glucose of 5.5–6.9 mmol/I or an HbA1c level of 42–47 mmol/mol [6.0–6.4%] indicates high risk) or

- identify possible type 2 diabetes by using fasting plasma glucose, HbA1c or <u>an oral</u> <u>glucose tolerance test</u> (OGTT), according to <u>World Health Organization (WHO)</u> <u>criteria</u>. [2012]
- 1.4.2 Ensure HbA1c tests, including point-of-care tests, conform to expert consensus reports on appropriate use and national quality specifications (see <u>NHS Diabetes website</u> and <u>WHO guidance</u>). The tests should only be carried out by trained staff. [2012]

#### Surveillance decision

This section of the guideline should not be updated.

# Diagnostic performance of blood glucose tests

#### 2018 surveillance summary

#### Performance using standard thresholds

A systematic review(19) assessed 99 studies (number of participants not reported in the abstract) of blood glucose tests for detecting NDH. To be included in the systematic review, studies needed to assess interventions with a control group in people identified through 'screening'. HbA1c had a mean sensitivity of 49% and specificity of 79%, but studies used differing threshold values. Fasting plasma glucose had mean sensitivity of 25% and specificity of 94%.

A diagnostic performance study(20) assessed a 50 g oral glucose challenge test with blood glucose measurement after 1 hour, random blood glucose, and HbA1c with a 75 g glucose tolerance test used as the gold standard (n=1,535). The study population had obesity and consisted of 94% men and 74% black people. The gold standard oral glucose tolerance test detected type 2 diabetes in 10% of participants and NDH in 22% of participants. Diagnostic performance of the other tests was:

 glucose challenge test (plasma) AUC was 85% to detect diabetes and 76% to detect NDH

- glucose challenge test (capillary) AUC was 82% to detect type 2 diabetes and 73% to detect NDH
- random glucose (plasma) AUC was 76% to detect type 2 diabetes and 66% to detect NDH
- random glucose (capillary) AUC was 72% to detect type 2 diabetes and 64% to detect NDH
- HbA1c AUC was 67% to detect type 2 diabetes and 63% to detect NDH.

#### Optimum thresholds for blood glucose tests

#### Japanese population

A diagnostic performance study(21) assessed HbA1c for detecting type 2 diabetes and NDH in a Japanese population (n=1,372) with a 75 g oral glucose tolerance test used as the gold standard. HbA1c had an AUC of 91.8% for detecting type 2 diabetes and 71.4% for detecting NDH. The optimum HbA1c cut-off for diagnosing type 2 diabetes was 6.0% with sensitivity of 83.7%, and specificity of 87.6%. The optimum HbA1c cut-off for detecting NDH was 5.7% with sensitivity of 60.6% and specificity of 72.1%. However, the authors noted that the cut-off for NDH showed a low accuracy of 67.6% and a high false-negative rate of 39.4%. Agreement between HbA1c categorisation and OGTT-based diagnosis was low for type 2 diabetes and NDH.

#### Swedish and Middle Eastern populations

A diagnostic performance study(22) assessed HbA1c after an oral glucose tolerance test as a predictor for NDH and type 2 diabetes in Swedish and Middle-Eastern populations (n=3,954). HbA1c of 48 mmol/mol or higher for detecting type 2 diabetes had:

- sensitivity of 31%, positive predictive value of 70% and negative predictive value of 96% in people of Middle-Eastern origin
- sensitivity of 25%, positive predictive value of 96% and negative predictive value of 98% in people of Swedish origin.

A cut-off for HbA1c of 42 mmol/mol as a predictor for NDH had:

- sensitivity of 17% in people of Middle-Eastern origin
- sensitivity of 15% in people of Swedish origin.

A cut-off for HbA1c of 39 mmol/mol as a predictor for NDH had:

- sensitivity of 36% in people of Middle-Eastern origin
- sensitivity of 34% in people of Swedish origin.

The authors concluded that HbA1c was insensitive for detecting type 2 diabetes and is inefficient for detecting NDH in these populations.

#### **Chinese populations**

A diagnostic performance study(23) assessed HbA1c thresholds in a Chinese population aged over 40 years (n=8,239). Overall, 10.7% of the sample had newly diagnosed type 2 diabetes and 19.0% had NDH. Fasting plasma glucose and postprandial plasma glucose were significantly positively correlated with HbA1c level. And the AUC for diagnosing type 2 diabetes was 85.7% and for detecting NDH was 68.1%. The optimum HBA1c cut-off for diagnosing type 2 diabetes was 6.3% and for detecting NDH was 5.9%. A diagnostic performance study(24) assessed HbA1c for diagnosing type 2 diabetes in a Chinese population (n=4,325). The current threshold of HbA1c (6.5% or 48 mmol/mol) showed low sensitivity (35.6%) and high specificity (98.9%) for diagnosing type 2 diabetes. The diagnostic efficiency of HbA1c in the people older than 75 years (AUC 75.5%) was significantly lower than that in people aged 45–54 years (87.8%). The AUC of HbA1c was negatively correlated with age. When adjusting for red blood cell count (lower values more common with increased age) the association between age and AUC disappeared.

A diagnostic performance study(25) assessed fasting blood glucose, 2-hour oral glucose tolerance test and glycosylated haemoglobin for diagnosing type 2 diabetes and detecting NDH in a Chinese population aged 40 years or older (n=7,611). The prevalence of newly diagnosed type 2 diabetes was 12.7% and NDH was 29.4%. The AUC for detecting diabetes was 83.7% for fasting plasma glucose, 93.3% for 2-hour oral glucose tolerance test and was 80.6% for HbA1c. For NDH, the AUC was 80.2% for fasting plasma glucose, 92.9% for 2-hour oral glucose tolerance test, and 69.0% for HbA1c. The optimum HbA1c thresholds were 6.3% for detecting type 2 diabetes and 5.8% for detecting NDH.

A cross-sectional study(26) assessed HbA1c for diagnosing type 2 diabetes in a Chinese population with impaired fasting glucose (n=1,128). Overall, 20% of participants had diabetes. The sensitivity of HbA1c levels of 6.5% or more for diagnosing type 2 diabetes was 33.2%, the specificity was 93.5%, and the AUC was 77%, indicating HbA1c had fair discriminatory power. The optimum cut-off threshold of HbA1c for discriminating type 2 diabetes from NDH was 6.3% with sensitivity of 56.3% and specificity of 85.5%. A threshold HbA1c of 5.6% had the highest sensitivity, at 96.1% and the highest negative predictive value at 94.5%.

# Diagnostic strategies – risk assessment or initial blood glucose testing

A systematic review and meta-analysis(27) assessed 47 studies (n=422,754) of caseidentification or screening strategies to detect NDH, to determine the response rate and diagnostic yield. The populations included in these studies were not reported in the abstract. Studies were categorised as a onestep strategy (29 studies) if participants were invited directly for an oral glucose tolerance test and two-step (11 studies), or three-fourstep (7 studies) if participants were screened at one or more levels before being invited for an oral glucose tolerance test. The pooled response to invitation to the oral glucose tolerance test was 65.5% for one-step strategies, 63.1% in 2-step strategies, and 85.4% in 3-4-step strategies. The number needed to invite to the oral glucose tolerance test was 15 for one-step strategies, 7.6 in 2-step strategies, and 3.6 in 3-4-step strategies.

A US cross-sectional study(28) of data from NHANES (n=7,161) in adults without a diagnosis of NDH or type 2 diabetes assessed strategies to select people for testing for diabetes (confirmed with HbA1c). The authors aimed to assess the use of random blood glucose for case-finding, with consideration of current risk assessment. Random blood glucose levels of more than 100 mg/dL (5.6 mmol/l) had sensitivity of 81.6% and specificity of 78% for selecting people for diabetes testing, with an AUC of 80%. Recommendations from the American Diabetes Association (ADA) had an AUC of 59%, and the US Preventive Services Task Force 2015 recommendations had an AUC of 64%. The authors noted that random glucose testing needed to screen 14 people to detect 1 case of undiagnosed type 2 diabetes, whereas the number needed to screen was 33 for the ADA recommendations and 32 for the US Preventive Services Task Force 2015 recommendations.

A prospective longitudinal study(29) assessed systematic HbA1c testing compared with

standard care (n=488) in people aged 45 years or older. However, standard care was not defined in the abstract. Systematic screening identified significantly more people with NDH (53%) than standard care (33% of 22% who were tested).

#### Oral glucose tolerance versus HbA1c testing

A diagnostic performance study(30) assessed the performance of the oral glucose tolerance test and HbA1c in overweight and obese people without a previous diagnosis of diabetes (n=1,241). Overall, 47% had NDH and 12% had newly diagnosed type 2 diabetes according to American Diabetes Association criteria. Testing HbA1c only would result in 47% of new diagnoses of type 2 diabetes and 44.2% of diagnoses of NDH being missed.

An analysis of data from the NHANES crosssectional study(31) assessed the 2-hour glucose tolerance test for diagnosing diabetes in people who would be categorised as having NDH on the basis of HbA1c and fasting blood glucose levels (n=3,644). The 2-hour oral glucose tolerance test would result in 6.9% of participants being diagnosed with type 2 diabetes. These participants had greater odds of a diabetes diagnosis if they had hypertension, high triglycerides, low highdensity lipoprotein cholesterol, albuminuria, and raised alanine aminotransferase.

A diagnostic study(32) assessed the uptake and yield of HbA1c and oral glucose tolerance testing in a South Asian population (n=3,173) living in the Netherlands. Significantly more people who were invited attended for HbA1c testing than for oral glucose tolerance testing. Overall, HbA1c identified a similar proportion of type 2 diabetes cases as the oral glucose tolerance test, but identified a higher proportion of cases of NDH.

# Finding an optimum threshold for NDH and type 2 diabetes

A diagnostic performance study(33) assessed HbA1c for predicting NDH in a Chinese population aged over 45 years who had a FINDRISC score of 9 or higher (n=619). The optimum cut-off for HbA1c was 5.4% for NDH (AUC=62%) and 5.8% for type 2 diabetes (AUC=85%). The combination of FINDRISC score and HBA1c result had better discrimination than either assessment alone (NDH AUC=75%, type 2 diabetes AUC=88%), but this difference was not significant.

A diagnostic performance study(34) assessed FINDRISC plus HbA1c in people without known diabetes who participated in the US NHANES study (n=3,886). The prevalence of NDH was 43% and of undiagnosed type 2 diabetes was 7%. At a cut-off of 6.5% for detecting diabetes, HbA1c had sensitivity of 24.2% and specificity of 99.6%. FINDRISC (threshold of 9 or higher) had sensitivity of 79.1% and specificity of 48.6% for detecting diabetes. Combining FINDRISC and HbA1c had sensitivity of 84.2% and specificity of 48.4% for detecting diabetes. At a cut-off for detecting NDH of 5.7%, HBA1c had sensitivity of 35.2% and specificity of 86.4%. FINDRISC had sensitivity of 60.2% and specificity of 61.4% for detecting NDH. Combining FINDRISC and HbA1c had had sensitivity of 74.2% and specificity of 53.0%

A diagnostic performance study(35) assessed serum glycated albumin to determine the need for an oral glucose tolerance test in people without diabetes (n=1,559). Serum glycated albumin was significantly correlated with age, serum albumin, BMI, waist circumference and plasma glycated albumin, but not with diet. A threshold of glycated albumin of 15% for diagnosing type 2 diabetes had sensitivity of 74%, specificity of 85%, and AUC of 86%. Fasting plasma glucose of 100 to 126 mg/dL had sensitivity of 78.8% and a specificity of 100% and indicated that 14.4% of the study population needed an oral glucose tolerance test. When serum glycated albumin values of 14% and 17% were used to exclude and diagnose diabetes, respectively, the sensitivity improved to 83.3%, with a slight decrease in specificity to 98.2%, but led to a significant increase in oral glucose tolerance tests. Using

combined fasting plasma glucose and serum glycated albumin serum, the need for oral glucose tolerance testing was reduced to 22.5% and the sensitivity increased to 85.6% with no change in specificity (98.2%).

#### Record keeping on the provenance of bloodglucose samples

A cross-sectional study(36) assessed the proportion of glucose tests with unrecorded provenance in routine primary care data in England and Wales (n=2,137,098). All blood glucose results recorded during 2013 were identified (n=203,350). Tests were grouped by provenance (fasting, oral glucose tolerance test, random, none specified and other). A clinical audit in a single primary care practice was also performed to identify the impact of failing to record glucose provenance on diabetes diagnosis. Overall, 58% of tests did not have provenance information. The most commonly reported provenance was fasting glucose (37%). The distribution of glucose values where provenance was not recorded was most similar to that of fasting samples. The glucose measurements of 256 people with diabetes in the audit practice (size 11,514 people) were analysed. The initial glucose measurement had no provenance information in 64.1% of cases. A clinician guestioned the provenance of a result in 41 cases (16.0%); of these, 14 (34.1%) required repeating. Lack of provenance led to a median delay in the diagnosis of diabetes of 30 days, ranging from 3 days to 614 days.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

#### Performance using standard thresholds

Evidence suggests that blood glucose testing may have fairly low sensitivity but high specificity. Diagnostic accuracy of blood glucose tests appears to be moderate-to-high. However, evidence indicates that tests should not be used in isolation, which is consistent with the recommended 2-stage process for risk identification.

#### Optimum thresholds for blood glucose tests

Evidence suggested that Middle-Eastern, Japanese, and Chinese populations may need lower blood-glucose thresholds than other populations, which is broadly consistent with current recommendations, which note that people of South Asian or Chinese descent are regarded as at high risk of diabetes at lower thresholds than other populations.

#### Diagnostic testing strategies – risk assessment or initial blood glucose testing

Evidence suggests that blood-glucose testing may be an effective strategy for detecting NDH or type 2 diabetes. Other studies suggested that combining HbA1c with a risk assessment was better than either strategy alone. Practically, if a risk-assessment is not done, the person will not have the benefit of knowing how they can reduce their personal risk in the future. It is unclear whether strategies using multiple different blood tests would be more useful than repeating the same test.

#### Oral glucose tolerance versus HbA1c testing

There is evidence to suggest that oral glucose tolerance testing may be more effective than HbA1c testing, but participation in oral glucose tolerance testing may be low, Participation in oral glucose tolerance testing may be increased if offered after other risk identification methods, which is consistent with current recommendations.

# Finding an optimum threshold for NDH and type 2 diabetes

Several studies investigated different cut-offs for risk assessment and blood-glucose testing separately and combined. Generally, the diagnostic performance improved when risk assessment and blood-glucose testing were used together. Risk assessment tends to have high sensitivity and lower specificity, but blood glucose testing tends to have high specificity with lower sensitivity, which provides some support for the current 2-stage case identification process.

#### Record keeping on the provenance of bloodglucose samples

One study suggested that recording of the type of glucose test performed could be improved in England and Wales. However, this study did not provide information about the effectiveness of the different tests.

Overall, evidence does not suggest a need to update guidance on stage 2 risk identification.

New evidence is unlikely to change guideline recommendations.

#### Matching interventions to risk

- 1.5.1 For people at low risk (that is, those who have a low or intermediate risk score), tell the person that they are currently at low risk, which does not mean they are not at risk or that their risk will not increase in the future. Offer them <u>brief advice</u>. [2012]
- 1.5.2 As part of brief advice:
  - Discuss people's risk factors and how they could improve their lifestyle to reduce overall risk.
  - Offer encouragement and reassurance.

- Offer verbal and written information about culturally appropriate local services and facilities that could help them change their lifestyle. Examples could include information or support to: improve their diet (including details of any local markets offering cheap fruit and vegetables); increase their physical activity and reduce the amount of time spent being sedentary (including details about walking or other local physical activity groups and low-cost recreation facilities). The information should be provided in a range of formats and languages. [2012]
- 1.5.3 For people with a moderate risk (a high risk score, but with a fasting plasma glucose less than 5.5 mmol/l or HbA1c of less than 42 mmol/mol [6.0%]):
  - Tell the person that they are currently at moderate risk, and their risks could increase in the future. Explain that it is possible to reduce the risk. Briefly discuss their particular risk factors, identify which ones can be modified and discuss how they can achieve this by changing their lifestyle.
  - Offer them a <u>brief intervention</u> to help them change their lifestyle: give information about services that use evidence-based behaviour-change techniques that could help them change, bearing in mind their risk profile. Services cited could include walking programmes, slimming clubs or structured <u>weight-loss programmes</u>. (See recommendations 1.11.1–1.14.3.)
  - Discuss whether they would like to join a structured weight-loss programme. Explain that this would involve an individual assessment and tailored advice about diet, physical activity and behaviour change. Let them know which local programmes offer this support – and where to find them. [2012]
- 1.5.4For people confirmed as being at high risk (a high risk score and fasting plasma glucose of<br/>5.5-6.9 mmol/l or HbA1c of 42-47 mmol/mol [6.0-6.4%]):
  - Tell the person they are currently at high risk but that this does not necessarily mean they will progress to type 2 diabetes. Explain that the risk can be reduced. Briefly discuss their particular risk factors, identify which ones can be modified and discuss how they can achieve this by changing their lifestyle.
  - Offer them a referral to a local, evidence-based, quality-assured intensive lifestylechange programme (see recommendations 1.8.1–1.10.2). In addition, give them details of where to obtain independent advice from health professionals. [2017]
- 1.5.5 When commissioning local or national services to deliver intensive lifestyle-change programmes (see recommendations 1.8.1–1.10.2) where the availability of places is limited, prioritise people with a fasting plasma glucose of 6.5–6.9 mmol/l or HbA1c of 44–47 mmol/mol [6.2–6.4%]. [2017]
- 1.5.6 Ensure that intensive lifestyle-change programmes are designed to help as many people as possible to access and take part in them (see sections 1.1.5 and 1.16 for recommendations on providing information and services, and supporting lifestyle change in people who may need particular support). [2017]
- 1.5.7 For people with possible type 2 diabetes (fasting plasma glucose of, 7.0 mmol/l or above, or HbA1c of 48 mmol/mol [6.5%] or above, but no symptoms of type 2 diabetes):
  - Carry out a second blood test. If type 2 diabetes is confirmed, treat this in accordance with NICE guidance on <u>type 2 diabetes</u>. Ensure blood testing conforms to national quality specifications.

- If type 2 diabetes is not confirmed, offer them a referral to a local, quality-assured, intensive lifestyle-change programme (see recommendations 1.8.1–1.10.2). [2012]
- 1.5.8 For people with a high risk score who prefer not to have a blood test, or who do not use primary healthcare services, discuss the importance of early diagnosis to help reduce the risk of long-term complications. Use clinical judgement, based on the person's risk score, to decide whether to offer them a brief intervention or a referral to an intensive lifestyle-change programme (see recommendations 1.8.1–1.10.2). [2012]

#### Surveillance decision

No new information was identified at any surveillance review.

#### Changing diabetes risk

#### 2018 surveillance summary

A UK cross-sectional study(37) assessed type 2 diabetes risk and knowledge about type 2 diabetes risk in 59 people who attended a risk assessment to determine eligibility for a diabetes prevention study. After an initial telephone screening step, participants completed the Diabetes UK Risk Score. The risk of type 2 diabetes was: 44% high risk, 42% moderate risk, and 14% increased risk. People who had previously been informed of their risk of developing type 2 diabetes (42% of participants) had significantly higher perceived risk scores, higher knowledge scores, and reduced optimism scores. However, they did not have increased knowledge that diet and weight management have a role in preventing diabetes.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

The evidence suggests that people who know their risk of developing diabetes may not know that they can modify their risk with diet and weight management. This finding supports current recommendations, which include brief advice for people at low risk, a brief intervention for people ad moderate risk and, lifestyle intervention for people at high risk of diabetes. All these interventions should include advice on reducing their risk of diabetes with diet, weight management and physical activity.

New evidence is unlikely to change guideline recommendations.

#### **Reassessing risk**

- 1.6.1 Keep an up-to-date register of people's level of risk. Introduce a recall system to contact and invite people for regular review, using the two-stage strategy (see recommendations 1.1.3 and 1.1.4). [2012]
- 1.6.2 Offer a reassessment based on the level of risk. Use clinical judgement to determine when someone might need to be reassessed more frequently, based on their combination of risk factors (such as their body mass index [BMI], relevant illnesses or conditions, ethnicity and age). [2012]

- 1.6.3 For people at low risk (with a low or intermediate risk score) offer to reassess them at least every 5 years to match the timescales used by the NHS Health Check programme. Use a validated risk-assessment tool. [2012]
- 1.6.4 For people at moderate risk (a high risk score, but with a fasting plasma glucose less than 5.5 mmol/l, or HbA1c less than 42 mmol/mol [6.0%]), offer to reassess them at least every 3 years. [2012]
- 1.6.5 For people at high risk (a high risk score and fasting plasma glucose of 5.5–6.9 mmol/l, or HbA1c of 42–47 mmol/mol [6.0–6.4%]), offer a blood test at least once a year (preferably using the same type of test). Also offer to assess their weight or BMI. This includes people without symptoms of type 2 diabetes whose:
  - first blood test measured fasting plasma glucose at 7.0 mmol/l or above, or an HbA1c of 48 mmol/mol (6.5%) or greater, but
  - whose second blood test did not confirm a diagnosis of type 2 diabetes. [2012]
- 1.6.6 At least once a year, review the lifestyle changes people at high risk have made. Use the review to help reinforce their dietary and physical activity goals, as well as checking their risk factors. The review could also provide an opportunity to help people 'restart', if lifestyle changes have not been maintained. **[2012]**

#### Surveillance decision

This section of the guideline should not be updated.

### Changing diabetes risk

#### 2018 surveillance summary

A cluster RCT(38) (n=1,092) assessed a diabetes prevention intervention in community pharmacies involving 3 individual counselling sessions and 5 group-based sessions compared with control (standard written information) over 1 year. The FINDRISC diabetes risk assessment tool was used to assess risk of type 2 diabetes before and after the intervention. The diabetes prevention intervention was associated with significant reductions in FINDRISC score. The authors noted that this was attributed to improvements in the following risk factors: waist circumference, physical activity, high-fibre diet and body-mass index; however no statistical analysis of these outcomes was reported in the abstract.

#### Topic expert feedback

No topic expert feedback was relevant to this evidence.

#### Impact statement

The evidence suggests that interventions to prevent diabetes may result in reductions in diabetes risk score, which supports the recommendation to check risk factors in an annual review of the lifestyle changes the person has made.

New evidence is unlikely to change guideline recommendations.

### Commissioning risk identification and intensive lifestyle-change programmes

- 1.7.1 Health and wellbeing boards and public health commissioners should make type 2 diabetes prevention a priority in the joint health and wellbeing strategy. They should identify local needs by:
  - Using anonymised, regional and local health data and routinely collected surveillance data on specific population groups or geographical areas to inform the joint strategic needs assessment.
  - Mapping local diet, <u>weight management</u> and physical activity services and interventions (for example, slimming clubs). This should include details about locations, opening times and accessibility, staffing levels and the range of professional skills available. It should also include details of any tailored support provided by trained personnel. [2012]
- 1.7.2 Health and wellbeing boards and public health commissioners, working with clinical commissioning groups, should develop a comprehensive and coordinated type 2 diabetes prevention commissioning plan, based on the data collated. This should include:
  - Action to raise awareness of the risks of type 2 diabetes.
  - A proactive, two-stage approach to identifying people at high risk (and those with undiagnosed type 2 diabetes).
  - Evidence-based, quality-assured intensive lifestyle-change programmes. [2012]
- 1.7.3 Health and wellbeing boards and public health commissioners, working with clinical commissioning groups, should ensure the commissioning plan:
  - Sets out organisational responsibilities for local type 2 diabetes risk assessments. These could take place in primary care or community pharmacies as part of, or as a local addition to, the <u>NHS Health Check programme</u>, or as a self-assessment in community venues and workplaces.
  - Establishes arrangements to invite people of South Asian and Chinese descent aged 25 and over for a risk assessment at least once every 5 years. (Invitations and follow-up could be integrated within the NHS Health Check programme.)
  - Encourages employers in public and private sector organisations to include risk assessments in their occupational health service contracts.
  - Supports the development of coordinated referral pathways for evidence-based and quality-assured intensive lifestyle-change programmes that cover physical activity, weight management and diet, and which teach <u>behaviour-change</u> techniques.
  - Makes it clear that everyone (including older people, those from minority ethnic groups and vulnerable or socially disadvantaged people) should be offered risk assessments and intensive lifestyle-change programmes at times, and in locations, that meet their needs.
  - Makes provision for people who may have difficulty accessing, or are unlikely to access, services in conventional healthcare venues.

- Makes it clear that risk-assessment services and intensive lifestyle-change programmes should be delivered by trained practitioners (see recommendations 1.18.1–1.18.5). [2012]
- 1.7.4 Health and wellbeing boards and public health commissioners, working with clinical commissioning groups, should integrate the commissioning plan with the joint health and wellbeing strategy. They should ensure it is delivered through services operating across the NHS, local authorities and other organisations in the private, community and voluntary sectors. [2012]
- 1.7.5 Health and wellbeing boards and public health commissioners should regularly evaluate services in the context of these recommendations and changing local needs. They should use local accountability mechanisms (for example, health scrutiny reports) to examine specific issues. [2012]
- 1.7.6 Health and wellbeing boards and public health commissioners should evaluate or compare the different service options and make the findings publicly available. Assessments should focus on changes in participants' physical activity levels, weight and dietary intake (of fat, saturated fat and fibre) over 12–24 months. **[2012]**

#### Surveillance decision

No new information was identified at any surveillance review.

# Quality-assured, intensive lifestyle-change programmes: design and delivery

- 1.8.1 Provide specially designed and quality-assured intensive lifestyle-change programmes for groups of 10–15 people at high risk of developing type 2 diabetes. **[2012]**
- 1.8.2 Involve the target community (including community leaders) in planning the design and delivery of the programme to ensure it is sensitive and flexible to the needs, abilities and cultural or religious norms of local people. For example, the programme should offer practical learning opportunities, particularly for those who have difficulties with communication or literacy or whose first language is not English. **[2012]**
- 1.8.3 Ensure programmes are delivered by practitioners with relevant knowledge and skills who have received externally accredited training (see recommendations 1.18.1–1.18.5). Where relevant expertise is lacking, involve health professionals and specialists (such as dietitians and health psychologists) in the design and delivery of services. [2012]
- 1.8.4 Ensure programmes adopt a person-centred, empathy-building approach. This includes finding ways to help participants make gradual changes by understanding their beliefs, needs and preferences. It also involves building their confidence and self-efficacy over time. [2012]
- 1.8.5 Ensure programme components are delivered in a logical progression. For example: discussion of the risks and potential benefits of lifestyle change; exploration of someone's motivation to change; action planning; self-monitoring and self-regulation. [2012]
- 1.8.6 Ensure groups meet at least eight times over a period of 9–18 months. Participants should have at least 16 hours of contact time either within a group, on a one-to-one basis or using a mixture of both approaches. [2012]

1.8.7	Offer more intensive support at the start of the programme by delivering core sessions frequently (for example, weekly or fortnightly). Reduce the frequency of sessions over time to encourage more independent lifestyle management. <b>[2012]</b>
1.8.8	Allow time between sessions for participants to make gradual changes to their lifestyle – and to reflect on and learn from their experiences. Also allow time during sessions for them to share this learning with the group. <b>[2012]</b>
1.8.9	Deliver programmes in a range of venues such as workplaces, leisure, community and faith centres, and outpatient departments and clinics. Run them at different times, including during evenings and at weekends, to ensure they are as accessible as possible. [2012]
1.8.10	As part of the programme, offer referral to, or seek advice from, people with specialist training where necessary. For example, refer someone to a dietitian for assessment and specialist dietary advice if required. <b>[2012]</b>
1.8.11	Offer follow-up sessions at regular intervals (for example, every 3 months) for at least 2 years following the initial intervention period. The aim is to reinforce the positive behaviour change and to provide support, in case of relapse. Larger group sizes may be feasible for these maintenance sessions. <b>[2012]</b>
1.8.12	Link the programmes with weight management and other prevention initiatives that help people to change their diet or become more physically active. <b>[2012]</b>

#### Surveillance decision

This section of the guideline should not be updated.

### Lifestyle interventions

#### 2018 surveillance summary

We identified 5 systematic reviews that assessed the efficacy of lifestyle interventions for preventing type 2 diabetes.(42–47)

Overall, compared with control, lifestyle interventions were associated with:

- reduced incidence of type 2 diabetes(42,43,45)
- reduced blood glucose levels (fasting blood glucose, HbA1c, or 2-hour glucose tolerance)(42–47)
- increased weight loss.(42,44,46)

In studies conducting additional subgroup analyses:

- interventions delivered by a dietitian were associated with greater weight loss than those delivered by non-dietitians(44)
- interventions delivered in person did not have significantly different effects to those delivered by technology(44)
- treatment effects showed no significant differences between men and women for any outcomes(45)
- interventions with a maintenance component were associated with greater weight loss and improvements in blood glucose (although statistical analysis of this finding was not reported in the abstract)(46)
- compared with a lifestyle intervention consisting of diet and physical activity, physical activity alone was not effective for reducing blood glucose levels.(47)

A systematic review(48) assessed 27 health economic evaluations of lifestyle interventions

and metformin for preventing type 2 diabetes. Studies had considerable heterogeneity in definitions of NDH and in intensity and duration of lifestyle interventions. The components of included lifestyle interventions were not reported in the abstract. Lifestyle interventions and metformin appeared to be cost effective in preventing diabetes in highrisk individuals, but economic estimates varied widely between studies. Intervention-only programmes were generally more cost effective than programmes including a risk identification component. Interventions appeared to be more cost effective with longer periods of evaluation.

One systematic review(49) assessed patient outcomes after detection of NDH. In 16 studies, treatment of NDH (the abstract did not define 'treatment', but appeared to include lifestyle modification) resulted in delayed progression to diabetes. However, in 2 studies, strategies to identify type 2 diabetes had no mortality benefits at 10 years. Most trials of treatment of NDH found no effects on allcause or cardiovascular mortality, although lifestyle modification was associated with decreased risk of both outcomes after 23 years in 1 trial.

Additionally, 10 RCTs(50–59) and 1 quasiexperimental study(60) were identified of lifestyle interventions in people with NDH that had a follow-up period of at least 1 year; of which, 2 included metformin alongside the lifestyle intervention.(55,56) Lifestyle interventions were generally compared with standard care; however, one study(52) additionally included a comparator group receiving metformin and one study(57) used an 'evidence-based weight management programme as the comparator.

Overall, compared with control, lifestyle interventions were associated with:

- reduced incidence of type 2 diabetes(55,54)
- reduced blood glucose levels or insulin resistance (fasting blood glucose, HbA1c, glucose tolerance, or blood insulin)(53,58)

- increased weight loss(53,52,58,59)
- reduced cardiovascular events (including death from cardiovascular causes).(50,54)

The quasi-experimental study(60) assessed use of a commercial weight loss organisation (Weight Watchers) in the UK to deliver a diabetes prevention programme in obese people with NDH. Of 149 eligible participants, 79% attended an activation session and 77% started weekly sessions. The diabetes prevention programme was associated with reductions in weigh and HbA1c.

Lifestyle intervention (22 group-based sessions) did not significantly increase weight loss or improve blood glucose levels compared with an evidence-based weight management programme. However, the components of the weight management programme were not clear in the abstract.(57)

In studies conducting additional analyses:

- The constitution of the dietary component (moderate carbohydrate plus increased protein compared with high carbohydrate plus moderate protein) had no significant effect on the effectiveness of lifestyle intervention plus metformin (dose of metformin not reported in the abstract).(56)
- Weight loss was significantly higher with lifestyle intervention compared with either metformin 850 mg or standard care. However, blood glucose (HbA1c) did not differ significantly from metformin or standard care.(52)
- People with college-level education were more likely to have reduced type 2 diabetes incidence after lifestyle intervention than people without college-level education.(51)

A UK-based RCT(61) assessed a structured education (Let's Prevent) lifestyle intervention compared with standard care in people with NDH. People in the intervention arm had significantly greater gains in health-related quality of life than in the control arm. This resulted in the intervention having an incremental cost-effectiveness ratio of £3,643 per quality-adjusted life year, and 86% probability of being cost-effective at a threshold of  $\pm$ 20,000.

#### **Topic expert feedback**

Topic experts highlighted two studies of lifestyle interventions.(55,61) These studies were noted to add to the evidence base on lifestyle interventions, especially in a UK setting.(61)

#### Impact statement

Overall, the new evidence suggested that lifestyle interventions were beneficial, which supports current recommendations on the provision of lifestyle interventions. The sole study that found no significant effect of lifestyle interventions used an 'evidence-based' weight management programme, which suggests it was an effective active comparator, so a small between-group difference may be expected.

The finding that weight loss was greater when interventions were delivered by a dietitian supports the recommendations: 'Ensure programmes are delivered by practitioners with relevant knowledge and skills who have received externally accredited training (see recommendations 1.18.1–1.18.5). Where relevant expertise is lacking, involve health professionals and specialists (such as dietitians and health psychologists) in the design and delivery of services.' However, this finding was from a sub-group analysis of a systematic review and it could have been influenced by other factors in the design of included studies. Therefore, an update in this area is not thought to be necessary at this time.

New evidence is unlikely to change guideline recommendations

# Cultural adaptations of lifestyle interventions

#### 2018 surveillance summary

A systematic review(62) included 33 RCTs of culturally adapted health education interventions for diabetes. Meta-analysis of 28 studies showed that culturally adapted diabetes health education was associated with significant improvements in HbA1c and diabetes knowledge compared with conventional care.

A systematic review(63) included 6 studies of adaptations of the diabetes prevention programme for use in ethnic minority communities. Adaptations for the following populations were covered by the included studies: 'African American, Hispanic/Latino, Native Hawaiian and Other Pacific Islander, Arab American, and American Indian and Native Alaskan'. The most common translation strategies included group-based delivery and use of bilingual study personnel. Generally, these factors appeared to increase acceptability of the intervention within the populations reviewed.

A systematic review(64) included 34 studies of culturally adapted diabetes prevention interventions. The abstract did not define the populations included in the adapted interventions. The authors used thematic analysis to develop a framework to assess each study (Facilitating [that is, delivering] Interventions Through Language, Location, and Message). Overall, 25 of the studies showed significant improvements in HbA1c, fasting blood glucose or weight loss; 21 of these studies incorporated at least 3 culturally targeted domains. In all 7 studies using all 4 domains (facilitators, language, location, and messaging), positive results were seen. The domain 'facilitators' was the least often used.

A systematic review(65) included 12 studies of diabetes prevention programmes for in Hispanic populations in the USA. Eight of the studies included a mostly female population (more than 70%). All studies delivered the intervention in Spanish and took place in community settings. Effect sizes were small to moderate, study quality was moderate, and attrition was high in most trials. Nine studies showed significant effects of the intervention on blood glucose or weight loss, compared with control. Interventions with the largest effect sizes included one or more of the following adaptations: literacy modification, Hispanic foods/recipes, cultural diabetes beliefs, family/friend participation, structured community input, and innovative experiential learning.

A systematic review(66) assessed the effectiveness of components of cultural adaptations of diabetes prevention programmes. The abstract did not define the populations included in the adapted interventions. Overall, the type of modification or presence of a maintenance component had no significant effect on achieving significant reductions in weight or BMI. Programmes with fewer modifications reported significantly greater reduction in weight at 12 months and at the longest follow-up extracted from each study. Programmes with a maintenance component achieved significantly greater weight reduction at the longest follow-up extracted from each study.

A systematic review(67) included 44 studies of cultural adaptations of diabetes prevention programmes, 15 of which reported on cultural adaptations, and 38 explored implementation. The abstract did not define the populations included in the adapted interventions. Many studies shortened the program length and reported a group format. The most commonly reported cultural adaptation (13 of 15 studies) was of content. At the individual level, the most frequently assessed implementation outcome (n=30) was adoption. A qualitative study(68) assessed perspectives on behaviour change in 20 women of Pakistani origin who participated in a lifestyle intervention for preventing diabetes (New Life, New You) in an area of socioeconomic deprivation in the UK. Within the Theoretical Domains Framework (intentions and goals, reinforcement, knowledge, nature of the activity, social role and identity, social influences, capabilities and skills, regulation and decision, emotion and environment), we identified the importance of social factors relating to participants' own physical activity and dietary behaviour change. Benefits of the intervention included participants' 'psychological health'; 'responsibility' (for others' health, especially family members included in the new physical activity and diet regimens) and 'inclusion' (an ethos of accommodating differences).

A cohort study(69) assessed the effect of a diabetes prevention programme in Hispanic (n=567) compared with white participants (175). Overall, 45% of Hispanic participants selected the Spanish-language version of the programme. Mean attendance was 8.6 of 22 sessions. For each session attended, a significant weight loss of 0.3% was seen. Hispanic participants were half as likely to attend as white participants, and came to significantly fewer sessions. After adjusting for attendance, the intervention had similar effects in both populations.

An RCT(70) assessed a culturally adapted diabetes prevention programme compared with usual care in people of Iraqi origin living in Sweden. Of 636 people at high risk of diabetes who were invited to participate, 15% participated (n=96). The intervention group was offered seven group sessions addressing healthy diet and physical activity including one cooking class. About 30% of participants dropped out of the programme. The mean follow-up time was less than 4 months in both groups; however, significant increases in insulin sensitivity index and significant weight loss, and lower BMI was seen in the intervention group compared with usual care. A larger proportion of people in the intervention group achieved a weight loss of at least 5% of original bodyweight in the intervention group; however because none of the participants in the control group achieved this outcome, statistical analysis would not have been possible.

An RCT(71) assessed a culturally adapted lifestyle intervention for preventing diabetes in a population of South Asian origin (n=536) who were at high risk of diabetes. The culturally targeted intervention consisted of individual counselling using motivational interviewing (six to eight sessions in the first 6 months plus three to four booster sessions), a family session, cooking classes and a supervised physical activity programme. The control group received generic lifestyle advice. At 2 years, the change in amount of moderate to vigorous physical activity did not differ significantly between the intervention and control groups. No significant differences were found between the two groups in changes on any components of the diet or the social-cognitive determinants

of diet and physical activity. The authors concluded that this culturally-adapted intervention 'led to high drop-out and was not effective in promoting healthy behaviour among South Asians at risk for diabetes'.

#### Topic expert feedback

No topic expert feedback was relevant to this evidence.

#### Impact statement

Studies of cultural adaptations of lifestyle interventions suggest that some adaptations may be more successful than others. However, overall the evidence is broadly consistent with the recommendation to ensure that the programme is sensitive and flexible to cultural or religious norms, for example, practical learning opportunities, particularly for those who have difficulties with communication or literacy or whose first language is not English.

New evidence is unlikely to change guideline recommendations.

#### Quality-assured, intensive lifestyle-change programmes: content

- 1.9.1 Intensive lifestyle-change programmes should offer ongoing tailored advice, support and encouragement to help people:
  - undertake a minimum of 150 minutes of <u>'moderate-intensity' physical activity</u> per week
  - gradually lose weight to reach and maintain a BMI within the healthy range
  - increase their consumption of wholegrains, vegetables and other foods that are high in dietary fibre
  - reduce the total amount of fat in their diet
  - eat less saturated fat. [2012]
- 1.9.2 Established behaviour-change techniques should be used (see NICE guidance on <u>behaviour change</u>), including at least all of the following:
  - Information provision: to raise awareness of the benefits of and types of lifestyle changes needed to achieve and maintain a healthy weight, building on what participants already know.

- Exploration and reinforcement of participants' reasons for wanting to change and their confidence about making changes. This may include using motivational interviewing or similar techniques suitably adapted for use in groups.
- Goal setting: prompting participants to set achievable and personally relevant short- and long-term goals (for example, to lose 5–10% of their weight in 1 year is a realistic initial target, or to be more physically active).
- Action planning: prompting participants to produce action plans detailing what specific physical activity or eating behaviour they intend to change and when, where and how this will happen. They should start with achievable and sustainable short-term goals and set graded tasks (starting with an easy task and gradually increasing the difficulty as they progress towards their goal). The aim is to move over time towards long-term, lifestyle change.
- Coping plans and relapse prevention: prompting participants to identify and find ways to overcome barriers to making permanent changes to their exercise and eating habits. This could include the use of strategies such as impulse-control techniques (to improve management of food cravings). [2012]
- 1.9.3 Participants in intensive lifestyle-change programmes should be encouraged to involve a family member, friend or carer who can offer emotional, information, planning or other practical support to help them make the necessary changes. For example, they may be able to join the participant in physical activities, help them to plan changes, make or accept changes to the family's diet or free up the participant's time so they can take part in preventive activities. (It may sometimes be appropriate to encourage the participant to get support from the whole family.) [2012]
- 1.9.4 Participants should be encouraged to use self-regulation techniques. This includes selfmonitoring (for example, by weighing themselves, or measuring their waist circumference or both). They should also review their progress towards achieving their goals, identify and find ways to solve problems and then revise their goals and action plans, where necessary. The aim is to encourage them to learn from experience. **[2012]**

#### Surveillance decision

No new information was identified at any surveillance review.

### Quality-assured, intensive lifestyle-change programmes: evaluation

- 1.10.1 Evaluate intensive lifestyle-change programmes by recording people's health outcomes at 12 months, or more frequently, if appropriate (for example, every 6 months). As a minimum, include the following measures:
  - number and demographics of adults registered
  - level of attendance
  - changes in the amount of moderate to vigorous physical activity undertaken each week
  - changes in dietary intake, with a focus on total intake of fat, saturated fat and fibre

- changes in weight, waist circumference or BMI
- changes in fasting plasma glucose or HbA1c levels. [2012]
- 1.10.2 Conduct an annual audit of how the programme was delivered. For example\*, check the:
  - number of educators involved
  - level of training
  - number and demographics of adults registered
  - level of uptake for example, the percentage of those invited who attend the first session
  - programme content (for example, the use of behaviour-change techniques and empathy-building skills)
  - methods of delivery. [2012]

\*This is an edited version of recommendation 7 in the NICE guideline on <u>behaviour change</u>.

#### Surveillance decision

This section of the guideline should not be updated.

# Participation in diabetes prevention programmes

#### 2018 surveillance summary

A cohort study(72) assessed the factors associated with participants joining a diabetes prevention programme in the USA. People registered with one health system (n=1,249)referred to the diabetes prevention programme were included. The sample was mostly women (71%) and aged 45 years or older (71%). People aged 18-44 enrolled significantly less often than people older than 60 years. Enrolment was higher in the summer than in the winter, and people who preferred the sessions in Spanish were less often placed in the programme (although the abstract did not provide statistical data for these analyses). People who started sessions within 2 months of their referral were significantly more likely to participate than those who waited 4 or more months.

A before and after study(73) assessed the effects of a change to electronic medical records plus a provider education intervention to support patient referrals to a diabetes prevention programme. Before the change, 0 to 2 people were referred each month, which increased to 5 to 11 people per month.

A cross-sectional study(74) [Folling 2017] assessed characteristics associated with participating or not participating in a diabetes prevention programme in Norway (n=332). Overall, 86% declined to participate in the programme. Non-participating women had significantly fewer years of education than women who participated; however no such association was seen for men.

An analysis(75) of the Let's Prevent Diabetes cluster-RCT assessed engagement and retention in the intervention (n=880). Overall, 77% of people engaged with the intervention and 29% were described as 'retainers'. People who engaged or were 'retainers' were more likely to be older, leaner, and non-smokers; however, no statistical data for these outcomes was reported in the abstract. Participants who attended the initial session and at least one refresher session were less likely to develop type 2 diabetes compared with those in the control arm. People described as 'retainers' were also significantly less likely to develop type 2 diabetes than the control group.

A pragmatic quasi-RCT(76) (n=3,511) assessed attendance at The NHS Health Check programme (which includes diabetes risk assessment) using the standard national invitation template letter (control) compared with an enhanced invitation letter using insights from behavioural science (intervention).

The intervention letter included:

- simplification reducing letter content
- behavioural instruction action focused language
- personal salience appointment due rather than invited
- addressing implementation intentions with a tear off slip to record the date, time and location of the appointment.

Significantly more people who received the intervention letter attended their health check.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

Evidence has identified several factors that may reduce uptake of lifestyle interventions, for example winter rather than summer enrolment, or the level of education of the attendee.

One study focusing on invitation to the NHS Health Check, which includes diabetes risk assessment, found that a simplified, more direct invitation letter increased attendance.

Overall, these studies indicate that a diabetes prevention programme could have problems recruiting and retaining people because of environmental factors as well as individuals' characteristics. These factors could inform areas for improvement in the recommended regular evaluation of diabetes prevention programmes.

New evidence is unlikely to change guideline recommendations.

#### Adherence

#### 2018 surveillance summary

A cohort analysis(77) assessed the effects of a diabetes prevention programme over 4 years (n=14,747). Participants attended a median of 14 sessions over an average of 172 days. Overall, 35.5% achieved the 5% weight loss goal, and 42% met the physical activity goal of 150 min per week. For every additional session attended and every 30 min of activity reported, participants lost 0.3% of body weight.

An RCT(78) assessed a group-based adaptation of a diabetes prevention programme compared with brief counselling in people with low income. The diabetes prevention programme showed no evidence of an effect on moderate to vigorous physical activity or sedentary behaviour. Baseline physical activity and local crime levels were associated with lower levels of moderate to vigorous physical activity. Lower baseline sedentary behaviour, higher perceived health, and more green space were related to lower levels of continued sedentary behaviour.

A cohort study(79) assessed a scoring system for predicting attrition from a diabetes prevention programme in American Indian and Alaskan Native communities (a derivation cohort, n=1,600 and a validation cohort, n=801) were used. The factors predicting attrition were gender, age, household income, comorbidity, chronic pain, site's user population size, and average age of site staff. Long-term attrition was predicted by gender, age, marital status, chronic pain, site's user population size, and average age of site staff. The authors noted that the models had moderate to fair discriminatory power.

An RCT(80) assessed high-intensity compared with low intensity maintenance of a resistance training physical activity intervention in overweight and obese people with NDH aged 50-69 years (n=170). After the initial 3-month physical activity intervention, participants were randomly assigned to either the high-intensity or the low-intensity 6 month maintenance phase. The high-intensity intervention included continued tailored, interactive personal, and web-based check-ups focused on resistance training, self-regulation, and a barrier/strategies approach. Low-intensity maintenance included, generic personal, and web-based check-ups. Adherence to maintenance was about 74% in both groups.

#### Topic expert feedback

No topic expert feedback was relevant to this evidence.

#### Impact statement

Evidence suggests that in people who initially engage with a diabetes prevention programme, in the long term, adherence may be a problem. However, one study suggested that each additional session attended may have a small benefit. Therefore, re-engaging with participants who stop attending may be beneficial.

The guideline currently has no recommendations on strategies to increase adherence and attendance at programme sessions. Nevertheless, the evidence does not suggest a need to update recommendations in this area at this time, but provides useful information that could support the evaluation of diabetes prevention programmes.

New evidence is unlikely to change guideline recommendations.

#### Raising awareness of the importance of physical activity

- 1.11.1 Find out what people already know about the benefits of physical activity and the problems associated with a sedentary lifestyle. Where necessary, provide this information. In addition, explain that being more physically active can help reduce their risk of type 2 diabetes, even when that is the only lifestyle change they make. [2012]
- 1.11.2 Explain that the government recommends a minimum of 150 minutes of 'moderateintensity' activity per week which can be taken in bouts of 10 minutes or more. Explain that people can also meet the minimum recommendation by doing 75 minutes of 'vigorous-intensity' activity spread across the week – or by combining bouts of moderate and vigorous-intensity activity. Explain that this should include activities to increase muscle strength on 2 days a week. (See the full recommendations in <u>Start active, stay</u> <u>active</u> for examples.) [2012]
- 1.11.3 In cases where it is unrealistic to expect someone to meet the recommended minimum, explain that even small increases in physical activity will be beneficial and can act as a basis for future improvements. **[2012]**
- 1.11.4 Explain that people should also reduce the amount of time they spend sitting at a computer or watching TV. Encourage them to be more active during work breaks, for example, by going for a walk at lunchtime. **[2012]**

1.11.5 Explain that some people may need to be more physically active to help lose weight or maintain weight loss (see NICE guidance on <u>obesity</u>). [2012]

#### Surveillance decision

No new information was identified at any surveillance review.

### Providing tailored advice on physical activity

- 1.12.1 Help people to identify which of their activities involve 'moderate' or 'vigorous' physical activity and the extent to which they are meeting the national minimum recommendation on physical activity. Use a validated tool such as the Department of Health's <u>General practitioner physical activity questionnaire</u> or the <u>International physical activity</u> <u>questionnaire</u> (IPAQ). [2012]
- 1.12.2 Encourage people to choose physical activities they enjoy or that fit easily within their daily lives. For example, they may choose to do specific activities such as walking, cycling, swimming, dancing or aerobics. Or they could build physical activity into their daily life for example, by walking or cycling instead of using a car for short journeys, and by taking the stairs instead of the lift. **[2012]**
- 1.12.3 Encourage people to set short and long-term goals for example, on how far they walk or cycle, or the number or length of activities undertaken every week. In addition, encourage them to keep a record of their activity for example, by using a pedometer, and to record the things that make it easier or harder. Help them to find other ways to identify and overcome any barriers to physical activity. [2012]
- 1.12.4 Consider referring people who want structured or supervised exercise to an exercise referral scheme or supervised exercise sessions, as part of an intensive lifestyle-change programme. [2012]
- 1.12.5 Provide information on local opportunities for physical activity. [2012]

For more recommendations on increasing physical activity, see NICE guidance on <u>promoting physical</u> <u>activity in the workplace; physical activity and the environment</u> and <u>four commonly used methods to</u> <u>increase physical activity</u>.

#### Surveillance decision

This section of the guideline should not be updated.

#### Physical activity-only interventions

#### 2018 surveillance summary

We identified 2 systematic reviews of physical activity -only interventions for preventing diabetes,(81,82) of which 1 assessed walking interventions only.(82) Overall, physical activity interventions reduced blood glucose levels (fasting blood glucose, HbA1c, or glucose tolerance) or insulin resistance.(81,82) Supervised walking interventions or unsupervised walking interventions using motivational strategies appeared to be effective in reducing blood glucose, whereas unsupervised walking interventions were not effective.(82) We also identified 3 RCTs of physical activityonly interventions in people with NDH that had a follow-up period of at least 1 year.(83– 85)

In one UK-based cluster-RCT(83) (n=818), an exercise intervention (Walking Away from Diabetes) showed significant effects on daily steps and amount of vigorous physical activity at 12 months; however, these outcomes were not sustained at 3 years. The abstract did not report what the control consisted of. A further analysis(86) from this study suggested that increased time in moderate to vigorous physical activity was associated with reductions in blood glucose levels.

An RCT (n=170) assessed a social cognitive theory-based maintenance phase after a resistance training intervention(84). All participants completed 3 months of resistance training; then received either social cognitive theory-based maintenance or standard care for 6 months, with a further 6 months of follow-up. The initial resistance training component reversed NDH in around a third of participants. However, the assessed maintenance phases showed no significant differences between the groups.

An RCT(85) assessed a yoga intervention compared with active stretching in people with metabolic syndrome. Blood glucose levels were improved significantly more in the yoga group compared with the active stretching group at 6 months, which was maintained at 12 months.

An RCT(87) assessed the effects of unbroken sitting for 7.5 hours compared with either standing or walking for 5 minutes every 30 minutes in overweight or obese postmenopausal women with NDH (n=22). Participants undertook each intervention in a randomly allocated order on consecutive days. Compared with prolonged sitting, standing and walking both significantly reduced the incremental AUC for glucose, and insulin.

#### Topic expert feedback

Topic experts highlighted several studies of physical activity.(83,86) The finding that any increase in physical activity has beneficial effects was thought to be important.

#### Impact statement

Generally, the new evidence supports a variety of modes of physical activity as useful for preventing type 2 diabetes. This is consistent with current recommendations, including the recommendation to encourage people to choose physical activities they enjoy or that fit easily within their daily lives.

Although one study suggested that unsupervised walking programmes may not be effective, in a trial the participants in this group may have preferred a supervised intervention and thus could have been less motivated to walk than a person whose preference was for unsupervised activity.

Current recommendations also recognise that small increments in physical activity may be beneficial, for example choosing to take the stairs rather than the lift, or breaking up time spent sitting with small amounts of standing or walking.

New evidence is unlikely to change guideline recommendations.

#### Weight management advice

1.13.1 Advise and encourage overweight and obese people to reduce their weight gradually by reducing their calorie intake. Explain that losing 5–10% of their weight in 1 year is a

realistic initial target that would help reduce their risk of type 2 diabetes and also lead to other, significant health benefits. **[2012]** 

- 1.13.2 Use evidence-based behaviour-change techniques to help overweight and obese people eat less, be more physically active and make long term changes to their diet that result in steady weight loss (see recommendations 1.14.1–1.14.3). [2012]
- 1.13.3 Motivate and support overweight and obese people to continue to lose weight until they have achieved and can maintain a BMI within the healthy range. (For the general population, the healthy range is between 18.5 and 24.9 kg/m<sup>2</sup>. For people of South Asian or Chinese descent, the range is likely to be between 18.5 and 22.9 kg/m<sup>2</sup>.) [2012]
- 1.13.4 Encourage people to check their weight and waist measurement periodically. Provide brief advice about how to measure their waist correctly (for an example, visit the <u>British</u> <u>Heart Foundation website</u>). [2012]
- 1.13.5 Offer people with a BMI of 30 kg/m<sup>2</sup> or more (27.5 kg/m<sup>2</sup> or more if South Asian or Chinese) a structured weight-loss programme as part of, or to supplement, the intensive lifestyle-change programme. Or, if more appropriate, offer them a referral to a dietitian or another appropriately trained health professional. Ensure they are given a personal assessment and tailored advice about diet, physical activity and what techniques to use to help change their behaviour. **[2012]**
- 1.13.6 GPs and other health professionals should continue to monitor, support and care for people with a BMI of 30 kg/m<sup>2</sup> or more (27.5 kg/m<sup>2</sup> or more if South Asian or Chinese) who join slimming clubs or other weight-loss programmes. [2012]
- 1.13.7 GPs should consider offering orlistat, in conjunction with a low-fat diet, to help those who are unable to lose weight by lifestyle-change alone (see recommendations 1.20.1–1.20.6). [2012]
- 1.13.8 If the weight management interventions in recommendations 1.13.1–1.13.7 have been unsuccessful, refer people to a specialist obesity management service (see NICE guidance on <u>obesity</u>). [2012]

#### Surveillance decision

No new information was identified at any surveillance review.

### **Dietary advice**

- 1.14.1 Find out what people already know about the types and amounts of food and drink that can help reduce the risk of type 2 diabetes. Provide this information where necessary. Explain that increasing dietary fibre intake and reducing fat intake (particularly saturated fat) can help reduce the chances of developing type 2 diabetes. [2012]
- 1.14.2 Help people to assess their diet and identify where and how they could make it healthier, taking into account their individual needs, preferences and circumstances. (For example, take into account whether they need to lose weight or if they have a limited income.)
   [2012]
- 1.14.3 Encourage people to:
  - Increase their consumption of foods that are high in fibre, such as wholegrain bread and cereals, beans and lentils, vegetables and fruit.

- Choose foods that are lower in fat and saturated fat, for example, by replacing products high in saturated fat (such as butter, ghee, some margarines or coconut oil) with versions made with vegetable oils that are high in unsaturated fat, or using low-fat spreads.
- Choose skimmed or semi-skimmed milk and low-fat yoghurts, instead of cream and full-fat milk and dairy products.
- Choose fish and lean meats instead of fatty meat and processed meat products (such as sausages and burgers).
- Grill, bake, poach or steam food instead of frying or roasting (for example, choose a baked potato instead of chips).
- Avoid food high in fat such as mayonnaise, chips, crisps, pastries, poppadums (papads) and samosas.
- Choose fruit, unsalted nuts or low-fat yoghurt as snacks instead of cakes, biscuits, bombay mix or crisps. [2012]

#### Surveillance decision

This section of the guideline should not be updated.

#### **Dietary** advice

#### 2018 surveillance summary

#### **Dietary** advice

A Cochrane review(88) included 2 studies comparing dietary advice with control for preventing type 2 diabetes with follow-up of at least 1 year. The abstract did not provide details of the components of the dietary advice. In 1 of the studies the dietary intervention resulted in significantly lower incidence of type 2 diabetes after 6 years compared with control. In the other study, dietary intervention reduced blood glucose levels and insulin resistance

#### Effectiveness of following specific diets

One meta-analysis compared various healthy diets and their association to diabetes risk.(89) Healthy diets (such as Mediterranean and Dietary Approaches to Stop Hypertension [DASH]) are generally associated with a reduced risk of type 2 diabetes; however, there was no difference in results when comparing different healthy diets.

One meta-analysis considered diets low in advanced glycation end products (AGEs)(90). The authors concluded that low AGE diets significantly decreased insulin resistance, total cholesterol and LDL.

One study evaluated the effects of an advice intervention to increase fibre intake. Advice was given on dietary fibre or resistant starch.(91) Both types of intervention were found to decrease total cholesterol and non-HDL cholesterol and glucose regulation was significantly improved in the dietary fibre advice group.

One RCT compared two diets of varying monounsaturated fat and GI compared to a control.(92) There were no differences between groups for weight regain and body after 18 months, however the LDL/HDL ratio was more improved in the high monounsaturated fat group compared to the control group.

#### Including specific foodstuffs in diets

One meta-analysis considered the effect of dragon fruit.(93) The intervention was found to significantly lower fasting plasma glucose levels in people with NDH but not for people with type 2 diabetes.

Two meta-analyses considered the effect of aloe vera. Both studies found that aloe vera significantly improved fasting plasma glucose in people with NDH.(94,95) The effect of aloe vera on HbA1c is unclear, with one study reporting no effect in people with NDH(94) and one reporting a significant reduction(95) but it was not clear the proportion of people with NDH and type 2 diabetes in the included studies. For people with type 2 diabetes, there was a marginal significant improvement in fasting plasma glucose and a significant improvement in HbA1c with the intervention.(94)

# Dietary supplements and traditional or herbal remedies

14 studies were identified focusing on dietary supplements or traditional or herbal remedies for prevention of type 2 diabetes.

- Two studies considered zinc supplementation(96,97). Results were mixed, with a Cochrane review concluding that there was no evidence to support zinc supplementation in preventing type 2 diabetes (96) and an RCT which found that significantly fewer people developed type-2 diabetes with zinc supplementation compared to control.(97) Significant improvements were also found in blood glucose levels and insulin resistance, as well as beta-cell function.
- Three studies were identified that examined the effect of vitamin D supplementation in people with NDH.(98–100) All three studies reported that there was no significant effect of vitamin D supplementation on diabetes prevention and glycaemic control.
- One meta-analysis of investigated the association between selenium

supplementation and the risk of type 2 diabetes(101) and found that it did not have an effect on risk of type 2 diabetes.

- One RCT considered l-arginine supplementation.(102) There was no significant effect of the intervention on the probability of becoming diabetic; however, l-arginine could significantly delay the development of type 2 diabetes over a long period.
- One systematic review examined the effect of polyphenol supplementation.(103)
   Polyphenol supplementation was found to significantly reduce HbA1c in people with diabetes but no effect was found in people without diabetes or with NDH.
- Three systematic reviews(104–106) and three RCTs(107–109) of traditional Chinese medicines were identified. However these were considered to have no impact on the guideline because none of the preparations are licensed for use in the UK.

#### Topic expert feedback

No topic expert feedback was relevant to this evidence.

#### Impact statement

Dietary interventions: dietary advice, effectiveness of following specific diets and including specific foodstuffs in diets.

Overall, dietary advice interventions appear to reduce the risk of developing type 2 diabetes. Specific diets did not show effectiveness over other diets, but dragon fruit and aloe vera appear to be effective components of a healthy diet.

This is broadly consistent with the approach of the guideline which recommends increasing intake of dietary fibre, fruit and vegetables, and reducing intake of foods high in fats and sugar.

# Dietary supplements and traditional or herbal remedies

Evidence suggests that vitamin D, selenium, and polyphenol supplementation have no significant effects on preventing type 2 diabetes. Evidence appears to be mixed for zinc supplementation, but overall less than 400 people participated in the studies identified. Similarly, the study of I-arginine included fewer than 200 participants.

Therefore, it is unlikely that the available evidence is sufficient to add recommendations for these supplements.

New evidence is unlikely to change guideline recommendations.

# Vulnerable groups: information and services

- 1.15.1 Provide up-to-date information in a variety of formats about local opportunities for risk assessment and the benefits of preventing (or delaying the onset of) type 2 diabetes. This should be tailored for different groups and communities. For example, messages could be provided in a visual, Braille or audio format. [2012]
- 1.15.2 Provide integrated risk-assessment services and intensive lifestyle-change programmes for prisons and residential homes, as appropriate. **[2012]**
- 1.15.3 Offer longer appointment times or outreach services to discuss the options following a risk assessment and blood test. **[2012]**
- 1.15.4 Ensure intensive lifestyle-change programmes are delivered by sensitive, well trained and dedicated people who are also trained to work with vulnerable groups. [2012]
- 1.15.5 Offer to refer travellers and people from other mobile populations to prevention initiatives in the area they are moving to. Or use electronic communications (for example, telephone or text messages as appropriate) to deliver programmes or provide ongoing support. Ensure confidentiality is maintained. **[2012]**

#### Surveillance decision

This section of the guideline should not be updated.

### Use of technology

#### 2018 surveillance summary

Thirteen studies were identified focusing on technology for prevention of type 2 diabetes. Eight studies examined digital health programmes for prevention of diabetes.(110– 117)

 Results were mixed with some reporting improvements in weight(110–113,115,116) and glucose control(111,112,116) and other studies reporting no effect on glucose control.(113,114) Another study reported no improvement in weight loss following the intervention.(117)

Three studies evaluated telephone programmes including phone messaging services.(118–120)

• All 3 studies reported a benefit of the telephone programmes on measured outcomes including HbA1c,(119)

development of type 2 diabetes(118) and fasting plasma glucose.(120)

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

Evidence for digital health programmes showed, inconsistent results, whereas telephone programmes consistently showed effectiveness for preventing diabetes.

Electronic means of communication are currently recommended to help engage with mobile populations. However, the guideline does not recommend electronic delivery of the entire intervention.

NICE has guidance on <u>individual approaches to</u> <u>behaviour change</u> (NICE PH49), which is being updated to consider the use of technology such as apps, text messaging and the internet to drive improvements in behaviours such as physical activity, diet and weight. Therefore, the guideline on diabetes prevention should not be updated to cover technology-based interventions at this time.

New evidence is unlikely to change guideline recommendations.

### Vulnerable groups: supporting lifestyle change

- 1.16.1 Ensure all staff involved in the care of vulnerable groups understand the risk factors for type 2 diabetes and how they can help people reduce their risk. Staff should also be able to recognise and address (where possible) issues which mean someone gives their health a low priority. [2012]
  1.16.2 Make all staff aware of the benefits of physical activity and reducing the time spent being
- 1.16.2 Make all staff aware of the benefits of physical activity and reducing the time spent being sedentary. Where possible, encourage them to increase the opportunities for those in their care to be physically active. **[2012]**
- 1.16.3 Ensure staff offer to refer people to risk-assessment services and quality-assured, intensive lifestyle-change programmes in the community. Or, where necessary, arrange for them to be provided in convenient, familiar local venues such as residential care homes or day centres. (See also recommendations 1.1.1–1.10.2 for advice on risk assessment and intensive lifestyle-change programmes.) [2012]
- 1.16.4 Educate those involved in buying or preparing food in residential care, day centres and psychiatric units about what constitutes a healthy diet and how to prepare healthy meals\*. [2012]

\*This is from the NICE guideline on preventing type 2 diabetes – population and community interventions.

#### Surveillance decision

This section of the guideline should not be updated.

# Adaptations of lifestyle interventions for vulnerable groups

#### 2018 surveillance summary

A systematic review(39) included 54 RCTs of interventions for improving glycaemic control in people with severe mental illness (n=4,392). Drug treatments and behavioural interventions significantly lowered fasting blood glucose, but not HbA1c compared with usual care or placebo. In subgroup analysis of drug interventions, metformin and antipsychotic switching strategies improved HbA1c. Behavioural interventions of longer duration and those including repeated physical activity had greater effects on fasting glucose than those without these characteristics.

A single-group pre-test post-test pilot study(40) assessed a modified group-based diabetes prevention programme in 10 overweight or obese people with permanent disability. Participants received 15 conference calls to encourage reduced calorie and fat intake, and increasing physical activity. Overall, the programme retained 70% of participants, who attended an average of 79.3% of conference calls and self-monitored more than half of the weeks. Participants rated the program highly, with mean overall scores of 6.3 out of 7 for helpfulness and 6.2 out of 7 for satisfaction scales, respectively. Program completers experienced a significant mean weight loss, and reduced their BMI.

A study(41) assessed a multi-component lifestyle behaviour change intervention (STOP Diabetes) for adults with intellectual disabilities. The intervention was developed by evidence review plus qualitative stakeholder interviews. It was piloted in 2 cycles, with additional stakeholder interviews to refine the intervention. Qualitative data suggested that two educators and one support person delivering a programme of one carer session followed by seven sessions over 7 weeks was acceptable to service users, carers and educators and appeared to benefit the participants.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

The evidence suggest that lifestyle interventions to prevent type 2 diabetes can be effective in vulnerable groups such as people with physical and intellectual disabilities and people with severe mental health disorders). This finding supports the recommendation that everyone (including older people, those from minority ethnic groups and vulnerable or socially disadvantaged people should be offered risk assessments and lifestyle programmes at times and in locations that meet their needs.

New evidence is unlikely to change guideline recommendations.

#### Intensive lifestyle-change programmes: quality assurance

- 1.17.1 Set up a national accreditation body to benchmark, audit, accredit and share effective practice in type 2 diabetes prevention. This body should:
  - Conduct research to establish and implement effective practice.
  - Provide a national, quality-assured training programme and a central database of effective curriculum resources for intensive lifestyle-change programmes. The

programme and resources should meet criteria developed by the Department of Health and Diabetes UK <u>Patient Education Working Group</u> (PEWG).

• Evaluate the effectiveness of the national training and accreditation programme. This includes its impact on practice and outcomes for participants. **[2012]** 

#### Surveillance decision

No new information was identified at any surveillance review.

#### Training and professional development

1.18.1The national accreditation body for type 2 diabetes prevention (see recommendation<br/>1.17.1) should work with others\* to:

- ensure training about risk factors for type 2 diabetes and how to prevent or delay it, is part of the core curriculum for healthcare undergraduates and postgraduates
- provide training for health professionals and community practitioners on how to provide brief advice and brief interventions
- provide accredited training which meets nationally defined criteria for health professionals and community practitioners who are delivering risk assessments and intensive lifestyle-change programmes, and for other providers of advice on diet and physical activity who may wish to develop a type 2 <u>diabetes prevention</u> <u>programme</u>
- provide additional, specialised training for those working with vulnerable groups including, for example, people with mental health problems or learning disabilities, refugees and gypsy and traveller populations. **[2012]**
- 1.18.2 The national accreditation body for type 2 diabetes prevention and others\* should ensure training on delivering risk assessments, intensive lifestyle-change programmes, dietary and physical activity advice increases participants' understanding of type 2 diabetes and its complications. It should also cover: behaviour-change theories and techniques, awareness-raising, how to communicate risk and how to tailor interventions to meet individual need. In addition, participants should learn how to assess, audit and evaluate type 2 diabetes prevention programmes. [2012]
- 1.18.3 The national accreditation body for type 2 diabetes prevention and others\* should establish competencies for practice and provide accredited training for other potential providers such as lay educators or voluntary sector organisations. [2012]
- 1.18.4 Managers of type 2 diabetes risk assessment and prevention services should provide opportunities at least every 3 years for staff to attend accredited training and refresher courses on how to deliver an intensive lifestyle-change programme. Training should be cascaded down through the team(s) via formal and informal in-service training. In addition, peer review processes should be used to encourage sharing of good practice. [2012]
- 1.18.5 Managers of type 2 diabetes risk assessment and prevention services should offer training to community and faith leaders, staff in local authority leisure services, day centres,

residential and respite care homes and staff in occupational health departments. The training should cover:

- how to carry out an initial risk assessment using validated self-assessment risk questionnaires
- effective ways to communicate someone's level of risk, the consequences of type 2 diabetes and the benefits of change
- how to give brief advice on reducing the risk of type 2 diabetes
- how to refer on for appropriate interventions. [2012]

\*Commissioners and providers of public health services; managers of type 2 diabetes risk-assessment and prevention services; schools of medicine, healthcare faculties, royal colleges and professional associations offering professional healthcare qualifications such as dietetics, nursing, physiotherapy, podiatry and occupational health; voluntary organisations; commercial training organisations.

#### Surveillance decision

No new information was identified at any surveillance review.

### **Metformin**

- 1.19.1 Use clinical judgement on whether (and when) to offer metformin\* to support lifestyle change for people whose HbA1c or fasting plasma glucose blood test results have deteriorated if:
  - this has happened despite their participation in intensive lifestyle-change programmes **or**
  - they are unable to participate in an intensive lifestyle-change programme, particularly if they have a BMI greater than 35. [2017]
- 1.19.2 Discuss with the person the potential benefits and limitations of taking metformin, taking into account their risk and the amount of effort needed to change their lifestyle to reduce that risk. Explain that long-term lifestyle change can be more effective than drugs in preventing or delaying type 2 diabetes. Encourage them to adopt a healthy diet and be as active as possible. Where appropriate, stress the added health and social benefits of physical activity (for example, point out that it helps reduce the risk of heart disease, improves mental health and can be a good way of making friends). Advise them that they might need to take metformin for the rest of their lives and inform them about possible side effects. [2012]
- 1.19.3 Continue to offer advice on diet and physical activity along with support to achieve their lifestyle and weight-loss goals. **[2012]**
- 1.19.4 Check the person's renal function before starting treatment, and then twice yearly (more often if they are older or if deterioration is suspected). [2012]
- 1.19.5 Start with a low dose (for example, 500 mg once daily) and then increase gradually as tolerated, to 1500–2000 mg daily. If the person is intolerant of standard metformin consider using modified-release metformin. [2012]
- 1.19.6 Prescribe metformin for 6–12 months initially. Monitor the person's fasting plasma glucose or HbA1c levels at 3-month intervals and stop the drug if no effect is seen. [2012]

\*The large study of metformin included in the evidence review and on which this recommendation is based (the US Diabetes Prevention Programme) used standard-release metformin. At the time of publication (September 2017), one modified-release metformin product, Glucophage SR, had recently extended its marketing authorisation to include reducing the risk or delaying the onset of type 2 diabetes in overweight adults with impaired glucose tolerance and/or fasting glucose, and/or increased HbA1c who are at high risk of overt type 2 diabetes and are progressing towards this despite intensive lifestyle change for 3-6 months. Other standard-release and modified-release metformin products may similarly extend their marketing authorisations in the future. See the General Medical Council's <u>Prescribing guidance: prescribing unlicensed medicines</u> for information on off-label prescribing.

#### Surveillance decision

This section of the guideline should not be updated.

#### Drug treatment for NDH

#### 2018 surveillance summary

#### Insulin secretagogues

A Cochrane review(121) included 6 RCTs (n=10,018) assessed insulin secretagogues (sulphonylureas and meglitinide analogues) for preventing type 2 diabetes. Comparator groups were mostly placebo, however a small number of participants in the comparator groups received diet and physical activity or metformin. Most of the data came from one trial of nateglinide. None of the included studies were judged by the authors to have low risk of bias. In 2 studies (n=307), glimepiride showed no significant effect on incidence of diabetes. In 1 study, nateglintide showed no significant effect on incidence of diabetes. Nateglinide and glimepiride are not licenced in the UK for prevention of type 2 diabetes.

# Dipeptidyl-peptidase (DPP)-4 inhibitors and glucagon-like peptide (GLP)-1 analogues

A Cochrane review(122) included 7 RCTs assessing dipeptidyl-peptidase (DPP)-4 inhibitors (n=98) and glucagon-like peptide (GLP)-1 analogues (n=1,620) for preventing diabetes. One RCT of liraglutide 3 mg contributed 85% of all participants. None of the studies were judged by the authors to have a low risk of bias. Liraglutide appeared to reverse NDH in more people (66%) than placebo (36%), but no statistical analysis of this outcome was reported in the abstract. In 1 study of vildagliptin, more people in the vildagliptin group had incident diabetes compared with placebo, but no statistical analysis of this outcome was reported in the abstract and the number of incident cases was very small, so would probably be

underpowered to detect a difference between groups. No diabetes-related data for 1 study of exenatide were reported in the abstract. Vildagliptin and exenatide are licensed in the UK for treating type 2 diabetes, but not for diabetes prevention.

An RCT(123) (n=3,731) assessed liraglutide 3 mg compared with placebo over in people with obesity (almost two-thirds of whom had NDH). All participants additionally received structured diet and physical activity. At 56 weeks, people in the liraglutide group had significantly greater weight loss, and lower blood glucose levels than those in the placebo group.

An RCT(124) (n=2,254) assessed liraglutide 3 mg compared with placebo in obese people with NDH. All participants additionally received structured diet and physical activity. By week 160, about half of participants in both groups withdrew from the study. At 160 weeks, the time to diagnosis of diabetes was significantly longer in people in the liraglutide group than those in the placebo group. However, the proportion of people who progressed to type 2 diabetes was low in both groups (2% on liraglutide and 6% on placebo). This may indicate that the diet and physical activity components were effective, so liraglutide has a small additive effect. People in the liraglutide group also had significantly greater weight loss. A further report from this study(125) noted that significantly more people in the liraglutide group reverted to normoglycaemia compared with placebo. Liraglutide 1.2-1.8 mg is licensed in the UK for treating diabetes and liraglutide 3 mg is licensed for treating obesity. However, liraglutide is not licensed in the UK for preventing type 2 diabetes. NICE has published Obese, overweight with risk factors: liraglutide (Saxenda)' (ES14), which summarises the

evidence base for use of liraglutide for weight management.

#### Thiazolidinediones

An RCT(127) (n=190) assessed rosiglitazone 8 mg compared with placebo in people with NDH. After 3.5 years, people on rosiglitazone had significantly more body fat, and abdominal fat than those on placebo. Rosiglitazone has been withdrawn from sale in the UK.

An RCT(128) (ACT NOW, n=293) assessed pioglitazone (dose not reported in the abstract) compared with placebo. At 12 months after stopping study drugs the cumulative incidence of type 2 diabetes was lower in the pioglitazone group. However, when analysing only the period after stopping the study drugs, there was no significant difference in incidence of diabetes between the pioglitazone and placebo groups. Pioglitazone is not licensed in the UK for preventing type 2 diabetes.

#### Lorcaserin

A post-hoc analysis(126) from 2 RCTs (BLOOM, BLOSSOM) assessed the weight-loss drug lorcaserin compared with placebo in people with NDH. Guidance on lorcaserin is the subject of an ongoing technology appraisal - <u>Obesity - lorcaserin</u>. This information will be passed onto the TA team for consideration.

#### Antihypertensives

An RCT(129) assessed losartan 50–100 mg daily and levamlodipine 2.5–5.0 mg daily in people with hypertension and NDH (n=244). After 24 and 36 months of treatment there was no significant difference between the groups in change in fasting insulin levels or insulin sensitivity index. However, both outcomes showed significant improvement from baseline. Losartan is not licensed in the UK for preventing type 2 diabetes and levamlodipine is not licensed for use in the UK.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

Overall, the new evidence suggests that there is limited or no evidence of effectiveness in preventing type 2 diabetes for these drugs.

New evidence is unlikely to change guideline recommendations

#### **Orlistat**

1.20.1	Use clinical judgement on whether to offer orlistat to people with a BMI of 28.0 kg/m <sup>2</sup> or more, as part of an overall plan for managing obesity. Take into account the person's risk and the level of weight loss and lifestyle change required to reduce this risk. [2012]
1.20.2	Discuss the potential benefits and limitations of taking orlistat and its side effects. [2012]
1.20.3	Advise the person to follow a low-fat diet that provides 30% of daily food energy as fat, distributed over three main meals a day. Offer information and regular support from a dietitian or another appropriate healthcare professional. <b>[2012]</b>
1.20.4	Agree a weight-loss goal with the person and regularly review it with them <sup>*</sup> . [2012]
1.20.5	Review the use of orlistat after 12 weeks. If the person has not lost at least 5% of their original body weight, use clinical judgement to decide whether to stop the orlistat. However, as with adults who have type 2 diabetes, those at high risk of the condition may

lose weight more slowly than average, so less strict goals may be appropriate. [2012]

1.20.6 Use orlistat for more than 12 months (usually for weight maintenance) only after discussing the potential benefits, limitations and side effects with the person concerned.[2012]

\*This is part of a recommendation from the NICE guideline on obesity.

#### Surveillance decision

No new information was identified at any surveillance review.

#### Areas not currently covered in the guideline

In surveillance, evidence was identified for areas not covered by the guideline. This new evidence has been considered for possible addition as a new section of the guideline.

#### New section considered in surveillance

What is the effectiveness of bariatric surgery in preventing diabetes?

#### Surveillance decision

This section should not be added.

#### **Bariatric surgery**

#### 2018 surveillance summary

Nine studies (6 observational studies, 2 systematic reviews and 1 follow-up of an RCT) were identified focusing on bariatric surgery as a tool for preventing type 2 diabetes in obese patients. The following interventions were considered: Roux-en-Y gastric bypass(130), partial ileal bypass(131), bariatric surgery (not otherwise specified),(132–135) sleeve gastrectomy,(136) gastric banding (137) and endoscopic sleeve gastroplasty.(138) In all studies, the surgical intervention had a beneficial impact on reducing the development of type 2 diabetes.

A cost-effectiveness analysis(132) suggested that bariatric surgery is cost-effective, with a cost per quality-adjusted life year gained (QALY) gained of £7,129.

#### **Topic expert feedback**

No topic expert feedback was relevant to this evidence.

#### Impact statement

Evidence consistently shows that bariatric surgery may prevent diabetes. Although NICE's guideline on preventing type 2 diabetes in people at high risk has no recommendations on bariatric surgery; this intervention is covered in 'Obesity: identification, assessment and management' (NICE CG189). In the abstracts that mentioned the BMI of participants, people would be eligible for bariatric surgery as recommended in NICE's obesity guideline. Therefore no new recommendations in this area are necessary in the guideline on preventing type 2 diabetes in people at high risk.

New evidence is unlikely to change guideline recommendations

# Editorial and factual corrections

During surveillance of the guideline we identified the following issues with the NICE version of the guideline that should be corrected.

NICE PH38 recommendations 1.11.5 and 1.13.8 have a cross-reference to the guideline on <u>obesity</u> <u>prevention</u> (NICE CG43), but the relevant sections have been updated in <u>obesity: identification</u>, <u>assessment and management</u> (NICE CG189). This is potentially confusing because the public health recommendations in NICE CG43 still exist. The cross-reference should be updated to take the reader directly to CG189.

NICE PH38 has a general cross reference to <u>four commonly used methods to increase physical activity</u> (NICE PH2) at the end of section 1.12. However, this guidelines has been updated and replaced by 3 new guidelines: <u>walking and cycling</u> (NICE PH41); <u>physical activity</u>: <u>brief advice for adults in primary</u> <u>care</u> (NICE PH44); and <u>exercise referral schemes to promote physical activity</u> (NICE PH54). This cross-reference should be updated.

# **Research recommendations**

### **Prioritised research recommendations**

At specified surveillance reviews of guidelines published after 2011, we assess progress made against prioritised research recommendations. We may then propose to remove research recommendations from the NICE version of the guideline and the <u>NICE database for research recommendations</u>. The research recommendations will remain in the full versions of the guideline. See NICE's <u>research recommendations process and methods guide 2015</u> for more information.

These research recommendations were deemed priority areas for research by the Guideline Committee; therefore, a decision will be taken on whether to retain the research recommendations or stand them down.

We applied the following approach:

- New evidence relevant to the research recommendation was found and an update of the related review question is planned.
  - The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database. If needed, a new research recommendation may be made as part of the update process.
- New evidence relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.
  - The research recommendation will be retained because there is evidence of research activity in this area.

- New evidence relevant to the research recommendation was found but an update of the related review question is not planned because evidence supports current recommendations.
  - The research recommendation will be removed from the NICE version of the guideline and the NICE research recommendations database because further research is unlikely to impact on the guideline.
- Ongoing research relevant to the research recommendation was found.
  - The research recommendation will be retained and evidence from the ongoing research will be considered when results are published.
- No new evidence relevant to the research recommendation was found and no ongoing studies were identified.
  - The research recommendation will be removed from the NICE version of guideline and the NICE research recommendations database because there is no evidence of research activity in this area.
- The research recommendation would be answered by a study design that was not included in the search (usually systematic reviews or randomised controlled trials).
  - The research recommendation will be retained in the NICE version of the guideline and the NICE research recommendations database.
- The new research recommendation was made during a recent update of the guideline.
  - The research recommendation will be retained in the NICE version of the guideline and the NICE research recommendations database.

#### Research recommendations considered in surveillance

RR - 01 Which combination of risk-assessment tools and blood tests (HbA1c or fasting plasma glucose [FPG]) are most cost effective and effective at identifying and assessing the risk of type 2 diabetes among populations at high risk? In addition, how frequently should testing take place to be efficient? How does effectiveness and cost effectiveness vary for different black and minority ethnic groups, for example, African-Caribbean and black African; people aged 18–40, people aged 75 and over, and for high-risk vulnerable adults? [2012]

#### Summary of findings

New evidence relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update. The new evidence includes further evidence on <u>risk assessment tools</u> and on <u>blood testing options</u>.

#### Surveillance decision

The research recommendation will be retained because there is evidence of research activity in this area.

RR - 02 What are the demographic characteristics and rates of progression to type 2 diabetes among people with a high risk score but normal blood glucose levels (fasting plasma

glucose of less than 5.5 mmol/l or HbA1c of less than 42 mmol/mol)? How does this compare with people who have both a high risk score and blood glucose levels that indicate impaired glucose regulation (fasting plasma glucose 5.5–6.9 mmol/l or HbA1c 42–47 mmol/mol (6.0–6.4%)? [2012]

#### **Summary of findings**

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

#### Surveillance decision

The research recommendation will be retained because the <u>NHS Diabetes Prevention Programme</u>, which is rolling out across the UK, may provide evidence relevant to this research recommendation when evaluation data are available from 2020.

RR - 03 What are the most effective and cost-effective methods of increasing uptake of type 2 diabetes risk assessments and monitoring among those at greatest risk? Those at greatest risk include people from lower socioeconomic and black and minority ethnic groups, and those aged 75 or over. [2012]

#### Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

#### Surveillance decision

The research recommendation will be retained because the <u>NHS Diabetes Prevention Programme</u>, which is rolling out across the UK, may provide evidence relevant to this research recommendation when evaluation data are available from 2020.

RR - 04 Which components of an intensive lifestyle-change programme contribute most to the effectiveness and cost effectiveness of interventions to prevent or delay type 2 diabetes in those at high risk? How does this vary for different black and minority ethnic groups, for people of different ages for example, aged 18–24, 25–39 and 75 and over, and for vulnerable adults? [2012]

#### Summary of findings

No new evidence relevant to the research recommendation was found and no ongoing studies were identified.

#### Surveillance decision

The research recommendation will be retained because the <u>NHS Diabetes Prevention Programme</u>, which is rolling out across the UK, may provide evidence relevant to this research recommendation when evaluation data are available from 2020.

RR - 05 How effective and cost effective are different types of dietary regime in reducing shortand long-term blood glucose levels and preventing or delaying type 2 diabetes? How does this vary for different subgroups, for example, African-Caribbean and black African and other minority ethnic groups and for people of different ages, for example, aged 18–24, 25–39 and 75 and over? [2012]

#### Summary of findings

New <u>evidence on diet</u> relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.

#### Surveillance decision

The research recommendation will be retained because there is evidence of research activity in this area.

RR - 06 How effective and cost effective are different types (and levels and frequency) of physical activity in reducing short- and long-term blood glucose levels and preventing or delaying type 2 diabetes? How does this vary for different subgroups, for example, different black and minority ethnic groups and people of different ages, for example, aged 18–24, 25–39 and 75 and over? [2012]

#### Summary of findings

New <u>evidence on physical activity</u> relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.

#### Surveillance decision

The research recommendation will be retained because there is evidence of research activity in this area.

RR - 07 What are the most effective and cost-effective methods for identifying, assessing and managing the risk of type 2 diabetes among high-risk, vulnerable adults? This group includes: frail older adults, homeless people, those with severe mental illness, learning or physical disabilities, prisoners, refugees, recent migrants and travellers. [2012]

#### **Summary of findings**

New evidence on <u>managing the risk of type 2 diabetes in vulnerable adults</u> relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.

#### Surveillance decision

The research recommendation will be retained because there is evidence of research activity in this area.

RR - 08 What is the effectiveness of providing digitally delivered intensive lifestyle-change programmes in preventing type 2 diabetes in adults at high risk of type 2 diabetes?

#### **Summary of findings**

New <u>evidence on digitally delivered interventions</u> relevant to the research recommendation was found but an update of the related review question is not planned because the new evidence is insufficient to trigger an update.

#### Surveillance decision

The research recommendation will be retained because there is evidence of research activity in this area.

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