

Preventing type 2 diabetes: risk identification and interventions for individuals at high risk

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Introduction: scope and purpose of this guidance

What is this guidance about?

This guidance focuses on identifying people at high risk of type 2 diabetes and the provision of effective, cost effective and appropriate interventions for them.

The guidance is not advocating a national screening programme for type 2 diabetes, rather the recommendations remind practitioners that age is no barrier to being at high risk of, or developing, type 2 diabetes. The recommendations can be used alongside the NHS Health Check programme. They cover:

- risk assessment
- encouraging people to have a risk assessment
- risk identification (stage 1)
- risk identification (stage 2)
- matching interventions to risk
- reassessing risk
- commissioning risk identification and intensive lifestyle-change programmes
- intensive lifestyle-change programmes:
 - design and delivery
 - content
 - evaluation
- physical activity:
 - awareness-raising
 - providing tailored advice
- weight management advice

- dietary advice
- vulnerable groups:
 - information and services
 - supporting lifestyle change
- intensive lifestyle-change programmes: quality assurance
- training and professional development
- metformin
- orlistat.

Who is this guidance for?

This guidance is for everyone who has a direct or indirect role in, and responsibility for, preventing or delaying the onset of type 2 diabetes. This includes GPs, nurses and other health professionals, as well as commissioners and managers within the NHS, local authorities and the wider public, private, voluntary and community sectors.

It is also for pharmacists, occupational health specialists, optical practitioners, those involved in the NHS Health Check programme and all those who deliver dietary, physical activity and weight management services.

In addition, it may be of interest to people at high risk of developing type 2 diabetes, their families and other members of the public.

Why is this guidance being produced?

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce public health guidance on the prevention of type 2 diabetes among high-risk groups. The referral was divided into two separate pieces of complementary guidance.

Originally, this guidance focused on preventing or delaying the progression from '[pre-diabetes](#)' to type 2 diabetes among individuals at high risk. The other guidance originally set out to address

the prevention of 'pre-diabetes' among adults aged 18–74 years in communities at high risk of developing type 2 diabetes.

However, in January 2011 the World Health Organization (WHO) recommended that glycated haemoglobin (HbA_{1c}) could be used as an alternative to standard glucose measures to diagnose type 2 diabetes among non-pregnant adults. HbA_{1c} levels of 48 mmol/mol (6.5%) or above indicate that someone has type 2 diabetes – but there is no fixed point to indicate when someone has 'pre-diabetes'. A UK expert group has also recommended HbA_{1c} for diagnosis of diabetes according to the WHO criteria. The group also recommended an HbA_{1c} of 42–47 mmol/mol (6.0–6.5%) to classify someone as being at high risk of diabetes (John et al. 2012). The titles of the two, complementary pieces of guidance were changed to reflect a move away from describing 'pre-diabetes' as a separate condition. However, their overall range and scope remains the same.

The other guidance, published in May 2011, focuses on interventions aimed at shifting the degree of risk within the wider population. This guidance focuses on identifying people aged 18 years and over at high risk of type 2 diabetes and offering them effective lifestyle-change programmes to prevent or delay the condition. Together they provide a comprehensive approach which combines population-based primary prevention with interventions targeted at those who are at high risk.

This guidance can be used alongside the NHS Health Check programme, the national vascular risk assessment and management programme for those aged 40–74. This is an integrated approach to identifying and preventing four diseases: diabetes, cardiovascular disease, stroke and kidney disease (NHS Health Check Programme 2009). The programme is being rolled out throughout England. The aim is to ensure everyone aged 40–74 who has not already been diagnosed with one of these conditions is offered a risk assessment and given advice and support to help them reduce and manage that risk.

This guidance should be implemented alongside other guidance and regulations (for more details see sections [4](#) and [7](#) on implementation and related NICE guidance respectively).

How was this guidance developed?

The recommendations are based on the best available evidence. They were developed by the Programme Development Group (PDG).

Members of the PDG are listed in [appendix A](#).

The guidance was developed using the NICE public health programme process. See [appendix B](#) for details.

Supporting documents used to prepare this document are listed in [appendix E](#).

What evidence is the guidance based on?

The evidence that the PDG considered included: reviews of the evidence, economic modelling, the testimony of experts, commissioned reports, stakeholder comments and fieldwork. Further detail on the evidence is given in the considerations section ([section 3](#)) and appendices [B](#) and [C](#).

In some cases the evidence was insufficient and the PDG has made recommendations for future research.

More details of the evidence on which this guidance is based, and NICE's processes for developing public health guidance, are on the [NICE website](#).

The recommendations support, but do not replace, the clinical assessment of someone's risk of type 2 diabetes taking into account of all their conditions and personal circumstances, and the provision of appropriate advice and monitoring.

The guidance complements, but does not replace, other NICE guidance on how to prevent or manage type 2 diabetes. It also complements NICE guidance on: behaviour change, cardiovascular disease, community engagement, obesity, physical activity and weight management before, during and after pregnancy (for further details, see [section 7](#)).

Terms in **bold** are explained in the glossary.

1 Recommendations

The evidence statements underpinning the recommendations are listed in [appendix C](#).

The Programme Development Group (PDG) considers that the recommended interventions are cost effective.

For the research recommendations and gaps in research, see [section 5](#) and [appendix D](#) respectively.

Background

In January 2011, the World Health Organization (WHO) recommended that [glycated haemoglobin \(HbA_{1c}\)](#) could be used as an alternative to standard glucose measures to diagnose type 2 diabetes among non-pregnant adults.

HbA_{1c} levels of 48 mmol/mol (6.5%) or above indicate that someone has type 2 diabetes. However, WHO did not provide specific guidance on HbA_{1c} criteria for people at increased risk of type 2 diabetes (WHO 2011).

A report from a UK expert group on the implementation of the WHO guidance recommends using HbA_{1c} values between 42 and 47 mmol/mol (6.0–6.4%) to indicate that a person is at high risk of type 2 diabetes. The group also recognised that there is a continuum of risk across a range of subdiabetic HbA_{1c} levels – and that people with an HbA_{1c} below 42 mmol/mol (6.0%) may also be at risk (John et al. 2012).

Focus of the recommendations

The recommendations focus on two major activities:

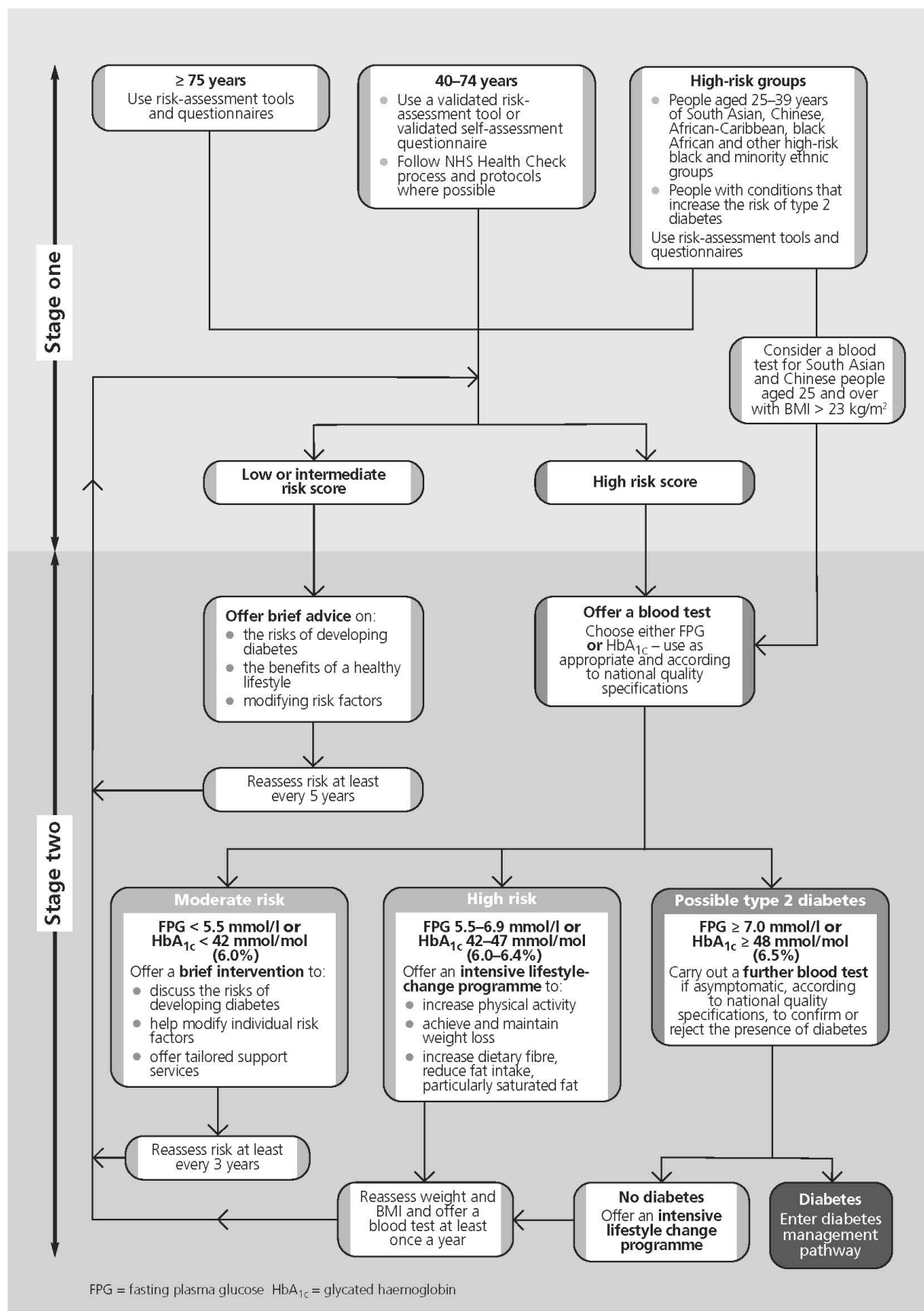
- Identifying people at risk of developing type 2 diabetes using a staged (or stepped) approach. This involves a validated risk-assessment score and a blood test – either the fasting blood glucose or the HbA_{1c} test to confirm high risk.
- Providing those at high risk with a quality-assured, evidence-based, intensive lifestyle-change programme to prevent or delay the onset of type 2 diabetes.

The flowchart provides an overview of the recommendations on risk assessment, blood tests and interventions for people at different levels of risk.

Who will benefit?

The recommendations aim to help adults who are at high risk of developing type 2 diabetes. When a particular at-risk group is being targeted, this is cited in the recommendation.

Flowchart: identifying and managing risk of type 2 diabetes



Recommendation 1 Risk assessment

Who should take action?

- Providers of public health services.
- GPs, practice nurses and other health professionals and managers in primary and secondary healthcare and community venues. This includes those working in community pharmacies, dental surgeries, occupational health departments, optical practices, eye hospitals and prison health services.
- Staff delivering the NHS Health Check programme.
- Managers of adult social, residential and community services and local authority leisure services.
- Voluntary, not-for-profit and non-government organisations (including faith and community groups, diabetes support groups and charities).

What action should they take?

- 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 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 4](#)).
- 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 [Diabetes UK website](#)). 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).

- 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.
- 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.
- GPs should keep records of all risk assessment results to ensure appropriate follow-up and continuity of care.
- 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.
- 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.
- 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.

Recommendation 2 Encouraging people to have a risk assessment

Who should take action?

- Providers of public health services.

- GPs, practice nurses, and other health professionals in primary and secondary healthcare and community venues. This includes those working in community pharmacies, dental surgeries, occupational health departments, optical practices, eye hospitals and prison health services.
- Staff delivering the NHS Health Check programme.
- Managers of adult social, residential and community services and local authority leisure services.
- Voluntary, not-for-profit and non-government organisations (including faith and community groups, diabetes support groups and charities).

What action should they take?

- 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^[1].
- 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.
- 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 [Diabetes UK website](#)). Explain that those who are eligible can be assessed by the [NHS Health Check programme](#). (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^[2]).

- 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).
- Advise people with type 2 diabetes to encourage family members to have their risk assessed.

Recommendation 3 Risk identification (stage 1)

Who should take action?

- GPs and practice nurses.
- Other practitioners and managers in primary, secondary and community care, including those working in:
 - community pharmacies
 - dental surgeries
 - occupational health departments
 - optical practices and eye hospitals
 - prison health services
 - services providing healthcare for people with conditions which increase the risk of type 2 diabetes^[1].
- Staff delivering the NHS Health Check programme.

What action should they take?

- GPs and other primary healthcare professionals should use a validated [computer-based risk-assessment tool](#) 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 [Diabetes UK](#).
- 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.
- 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^[1], 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 [Diabetes UK website](#).
- 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.
- 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.
- 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.

Recommendation 4 Risk identification (stage 2)

Who should take action?

- GPs and nurses working in primary care and the community.
- Health professionals in secondary care who treat particular conditions where the risk of type 2 diabetes is high^[1].

What action should they take?

- Trained healthcare professionals should offer venous blood tests (fasting plasma glucose [FPG] or HbA_{1c}) 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/m². The aim is to:
 - determine the risk of progression to type 2 diabetes (a fasting plasma glucose of 5.5–6.9 mmol/l or an HbA_{1c} level of 42–47 mmol/mol [6.0–6.4%] indicates high risk) **or**
 - identify possible type 2 diabetes by using fasting plasma glucose, HbA_{1c} or an oral glucose tolerance test (OGTT), according to World Health Organization (WHO) criteria.
- Ensure HbA_{1c} tests, including point-of-care tests, conform to expert consensus reports on appropriate use and national quality specifications (see NHS Diabetes website and WHO guidance). The tests should only be carried out by trained staff.

Recommendation 5 Matching interventions to risk

Who should take action?

- Health professionals and healthcare assistants carrying out diabetes risk assessments in NHS or non-NHS venues.
- Staff delivering the NHS Health Check programme.
- Local public health services, in partnership with primary and secondary healthcare teams and providers of intensive, lifestyle-change programmes.

What action should they take?

- 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 [brief advice](#).
- As part of brief advice:
 - Discuss their 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.
- For people with a moderate risk (a high risk score, but with a fasting plasma glucose less than 5.5 mmol/l or HbA_{1c} 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 [brief intervention](#) 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 [weight-loss programmes](#). (See recommendations [11–14](#).)
 - 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.

- For people confirmed as being at high risk (a high risk score and fasting plasma glucose of 5.5–6.9 mmol/l or HbA_{1c} 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 lifestyle-change programme (see recommendations [8](#), [9](#) and [10](#)). In addition, give them details of where to obtain independent advice from health professionals.
- For people with possible type 2 diabetes (fasting plasma glucose of, 7.0 mmol/l or above, or HbA_{1c} 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 [type 2 diabetes](#). 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 [8](#), [9](#) and [10](#)).
- 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 [8](#), [9](#) and [10](#)).

Recommendation 6 Reassessing risk

Who should take action?

GPs and other primary healthcare providers.

What action should they take?

- 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 [3](#) and [4](#)).

- 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).
- 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.
- For people at moderate risk (a high risk score, but with a fasting plasma glucose less than 5.5 mmol/l, or HbA_{1c} less than 42 mmol/mol [6.0%]), offer to reassess them at least every 3 years.
- For people at high risk (a high risk score and fasting plasma glucose of 5.5–6.9 mmol/l, or HbA_{1c} 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 HbA_{1c} of 48 mmol/mol (6.5%) or greater, but
 - whose second blood test did not confirm a diagnosis of type 2 diabetes.
- 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.

Recommendation 7 Commissioning risk identification and intensive lifestyle-change programmes

Who should take action?

- Commissioners of public health services.
- Health and wellbeing boards.
- Clinical commissioning groups.

What action should they take?

- 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, weight management 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.
- 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.

-
- 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 [NHS Health Check programme](#), 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 behaviour 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 [recommendation 18](#)).
 - 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.

- 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.
- 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.

Recommendation 8 Quality-assured, intensive lifestyle-change programmes: design and delivery

Who should take action?

Providers of intensive lifestyle-change programmes. This includes primary healthcare teams and specialists who provide advice and support on physical activity, weight management and diet in the NHS and other public, private, voluntary and community organisations.

What action should they take?

- Provide specially designed and quality-assured intensive lifestyle-change programmes for groups of 10–15 people at high risk of developing type 2 diabetes.
- 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.
- Ensure programmes are delivered by practitioners with relevant knowledge and skills who have received externally accredited training (see [recommendation 18](#)). Where relevant expertise is lacking, involve health professionals and specialists (such as dietitians and health psychologists) in the design and delivery of services.
- 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.

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Link the programmes with weight management and other prevention initiatives that help people to change their diet or become more physically active.

Recommendation 9 Quality-assured, intensive lifestyle-change programmes: content

Who should take action?

Providers of intensive lifestyle-change programmes. This includes primary healthcare teams and specialists who provide advice and support on physical activity, weight management and diet in the NHS and other public, private, voluntary and community organisations.

What action should they take?

- Intensive lifestyle-change programmes should offer ongoing tailored advice, support and encouragement to help people:
 - undertake a minimum of 150 minutes of 'moderate-intensity' physical activity 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.

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- Established behaviour-change techniques should be used (see NICE guidance on [behaviour change](#)), 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).
 - Participants 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.)
 - Participants should be encouraged to use self-regulation techniques. This includes self-monitoring (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.
-

Recommendation 10 Quality-assured, intensive lifestyle-change programmes: evaluation

Who should take action?

Managers and providers of intensive lifestyle-change programmes.

What action should they take?

- Evaluate 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 HbA_{1c} levels.
- Conduct an annual audit of how the programme was delivered For example^[3], 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.

Recommendation 11 Raising awareness of the importance of physical activity

Who should take action?

- Providers of intensive lifestyle-change programmes.
- Primary healthcare teams.

What action should they take?

- 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.
- Explain that the government recommends a minimum of 150 minutes of 'moderate-intensity' 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 Start active, stay active for examples.)
- 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.
- 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.
- Explain that some people may need to be more physically active to help lose weight or maintain weight loss (see NICE guidance on obesity).

Recommendation 12 Providing tailored advice on physical activity

Who should take action?

- Providers of intensive lifestyle-change programmes.
- Primary healthcare teams.

What action should they take?

- 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 [general practitioner physical activity questionnaire](#) or the [international physical activity questionnaire \(IPAQ\)](#).
- 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.
- 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.
- 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.
- Provide information on local opportunities for physical activity.

For more recommendations on increasing physical activity, see NICE guidance on [promoting physical activity in the workplace](#); [physical activity and the environment](#) and [four commonly used methods to increase physical activity](#).

Recommendation 13 Weight management advice

Whose health will benefit?

Adults at high risk of developing type 2 diabetes with a BMI of 25 kg/m² or more (23 kg/m² or more if the person is of South Asian or Chinese descent).

Who should take action?

- Providers of intensive lifestyle-change programmes.
- Primary healthcare teams.

What action should they take?

- 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.
- 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 [recommendation 14](#)).
- 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/m². For people of South Asian or Chinese descent, the range is likely to be between 18.5 and 22.9 kg/m².)
- 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 [British Heart Foundation website](#)).
- Offer people with a BMI of 30 kg/m² or more (27.5 kg/m² 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.

- GPs and other health professionals should continue to monitor, support and care for people with a BMI of 30 kg/m² or more (27.5 kg/m² or more if South Asian or Chinese) who join slimming clubs or other weight-loss programmes.
- 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 [recommendation 20](#)).
- If the above weight management interventions have been unsuccessful, refer people to a specialist obesity management service (see NICE guidance on [obesity](#)).

Recommendation 14 Dietary advice

Who should take action?

- Providers of intensive lifestyle-change programmes.
- Primary healthcare teams.

What action should they take?

- 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.
- 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.)

- 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.

Recommendation 15 Vulnerable groups: information and services

Whose health will benefit?

Adults from vulnerable groups whose risk of type 2 diabetes may be increased by a medical condition, or who may not realise they are at risk or who are less likely to access healthcare services. This includes people:

- with severe mental health problems
- with learning disabilities
- with physical or sensory disabilities

- who live in hostels, nursing and residential homes, residential mental health and psychiatric care units, secure hospitals, prisons and remand centres
- who are part of a mobile population such as travellers, asylum seekers and refugees.

Who should take action?

- Healthcare professionals working with people who have physical, sensory or learning disabilities or a mental health problem.
- Providers of intensive lifestyle-change programmes.

What action should they take?

- 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.
- Provide integrated risk-assessment services and intensive lifestyle-change programmes for prisons and residential homes, as appropriate.
- Offer longer appointment times or outreach services to discuss the options following a risk assessment and blood test.
- Ensure intensive lifestyle-change programmes are delivered by sensitive, well trained and dedicated people who are also trained to work with vulnerable groups.
- 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.

Recommendation 16 Vulnerable groups: supporting lifestyle change

Whose health will benefit?

See [recommendation 15](#).

Who should take action?

See [recommendation 15](#).

What action should they take?

- 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.
- 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.
- 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](#) to [10](#) for advice on risk assessment and intensive lifestyle-change programmes.)
- 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^[4].

Recommendation 17 Intensive lifestyle-change programmes: quality assurance

Who should take action?

Professional associations, royal colleges, academic centres, research institutes and community and voluntary sector organisations with an interest in type 2 diabetes prevention.

What action should they take?

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 [Patient Education Working Group](#) (PEWG).
- Evaluate the effectiveness of the national training and accreditation programme. This includes its impact on practice and outcomes for participants.

Recommendation 18 Training and professional development

Who should take action?

- National accreditation body for type 2 diabetes prevention (see [recommendation 17](#)).
- 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.

What action should they take?

- The national accreditation body for type 2 diabetes prevention (see [recommendation 17](#)) should work with those listed above 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 [diabetes prevention programme](#)
 - 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.
- All the above 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.
- All of the above should establish competencies for practice and provide accredited training for other potential providers such as lay educators or voluntary sector organisations.
- 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.

- 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.

Recommendation 19 Metformin

Whose health will benefit?

- Adults at high risk whose blood glucose measure (fasting plasma glucose or HbA_{1c}) shows they are still progressing towards type 2 diabetes, despite their participation in an intensive lifestyle-change programme.
- Adults at high risk who are unable to participate in lifestyle-change programmes because of a disability or for medical reasons.

Who should take action?

Doctors, non-medical prescribers and pharmacists in primary and secondary healthcare.

What action should they take?

- Use clinical judgement on whether (and when) to offer standard-release metformin^[5] to support lifestyle change for people whose HbA_{1c} or fasting plasma glucose blood test results have deteriorated if:
 - this has happened despite their participation in an intensive lifestyle-change programme, **or**
 - they are unable to participate in an intensive lifestyle-change programme.

- 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.
- Continue to offer advice on diet and physical activity along with support to achieve their lifestyle and weight-loss goals.
- Check the person's renal function before starting treatment, and then twice yearly (more often if they are older or if deterioration is suspected).
- 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.
- Prescribe metformin for 6– 12 months initially. Monitor the person's fasting plasma glucose or HbA_{1c} levels at 3-month intervals and stop the drug if no effect is seen.

Recommendation 20 Orlistat

Whose health will benefit?

Adults who have a BMI of 28.0 kg/m² or more, whose blood glucose measure (fasting plasma glucose or HbA_{1c}) shows they are still progressing towards type 2 diabetes. In particular, this includes those who are not benefiting from lifestyle-change programmes, or who are unable to participate in physical activity because of a disability or for medical reasons.

Who should take action?

- Doctors and non-medical prescribers in primary and secondary healthcare.
- Community pharmacists and pharmacists in secondary healthcare.

What action should they take?

- Use clinical judgement on whether to offer orlistat to people with a BMI of 28.0 kg/m² 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.
- Discuss the potential benefits and limitations of taking orlistat and its side effects.
- 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.
- Agree a weight-loss goal with the person and regularly review it with them^[6].
- 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.
- 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.

^[1] 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.

^[2] They will be treated and managed using established health care pathways.

^[3] This is an edited version of recommendation 7 in [Behaviour change](#). (NICE public health guidance 6)

^[4] This is from [Preventing type 2 diabetes – population and community interventions](#) (NICE public health guidance 35).

^[5] At the date of publication (July 2012), metformin did not have UK marketing authorisation for this indication. Informed consent should be obtained and documented.

^[6] This is part of a recommendation from [Obesity](#) (NICE clinical guideline 43).

2 Public health need and practice

Introduction

Diabetes is a chronic disease characterised by an inability to regulate blood glucose concentrations. In 2010 in England, the number of people aged 16 and older with diabetes (diagnosed and undiagnosed) was approximately 3.1 million, accounting for 7.4% of this population (Yorkshire and Humber Public Health Observatory 2010). That number is estimated to rise to 4.6 million – that is, nearly 10% of the population – by 2030. Around 90% of these people will have type 2 diabetes.

An estimated 850,000 people in England may have diabetes but have not been diagnosed (Diabetes UK 2012). Many more may have blood glucose levels above the normal range, but not high enough for a diabetes diagnosis (Danaei et al. 2011). Around 1 in 7 adults may have either impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), based on World Health Organization (WHO) criteria (Diabetes UK 2012).

Diabetes can lead to serious complications in the long term. It is the most common cause of visual impairment and blindness among people of working age. It is also the most common cause of kidney failure and non-traumatic lower limb amputations. People with diabetes are up to five times more likely to have cardiovascular disease and stroke, compared to those without diabetes. (Diabetes UK 2012).

In England, people aged between 20 and 79 with type 2 diabetes are 1.6 times as likely to die prematurely than those without the disease (The Healthcare Quality Improvement Partnership 2011). It is estimated that, generally, they die 10 years earlier than average (Diabetes UK 2012).

Treating type 2 diabetes and its complications currently costs the NHS £8.8 billion a year (Hex et al. 2012), just over 8% of its annual budget. The cost of prescribing drugs to treat diabetes rose from £513.9 million in 2005/06 to £725.1 million in 2010/11 (The NHS Information Centre for Health and Social Care 2011a). The indirect costs associated with type 2 diabetes, such as those related to an increase in premature deaths and illness, loss of productivity and the need for informal care, are estimated at £13 billion (Hex et al. 2012).

By 2035/06, the cost of direct care and other indirect costs for type 2 diabetes are estimated to rise to £15.1 billion and £20.5 billion respectively (Hex et al. 2012).

The growing burden of type 2 diabetes is due to obesity, sedentary lifestyles, dietary trends and an ageing population (Yorkshire and Humber Public Health Observatory 2010). However, lifestyle interventions targeting these risk factors have reduced its incidence by about 50% among high-risk individuals (Gillies et al. 2007).

People at high risk

People who are overweight or obese are more likely to develop type 2 diabetes – and the risk rises as body weight increases (The DECODE Study Group 2002). In 2010, almost a quarter of adults (26% of both men and women aged 16 or over) in England were classified as obese (body mass index [BMI] 30 kg/m² or over for the white population, or 27.5 kg/m² or higher for people of South Asian or Chinese descent).

A greater proportion of men than women (42% compared with 32%) in England were classified as overweight (BMI 25 kg/m² up to 29.99 kg/m²). However, women were more likely than men (46% and 34% respectively) to have a raised waist circumference (over 88 cm for women and over 102 cm for men) (The NHS Information Centre for Health and Social Care 2012).

Evidence suggests that a 1 kg/m² increase in BMI increases the risk of developing new-onset type 2 diabetes by 8.4%. The risk of impaired fasting glucose rises by 9.5%. A 1 cm increase in waist circumference increases the risk of type 2 diabetes and impaired fasting glucose by 3.5% and 3.2% respectively (Bombelli et al. 2011).

In the UK, type 2 diabetes is more prevalent among people of South Asian, Chinese, African–Caribbean and black African descent than among the white population. People in these groups tend to develop it at a younger age (DH 2006). They also tend to progress from impaired glucose tolerance to diabetes much more quickly (more than twice the rate of white populations) (Webb et al. 2011).

People with other health conditions may also be at increased risk. This includes:

- People with cardiovascular disease (those who have had myocardial infarction or a stroke) or polycystic ovary syndrome or have a history of gestational diabetes.
- People with mental health conditions or learning disabilities.

- Hospital in-patients and those attending accident and emergency, emergency medical admissions units, vascular and renal surgery units and ophthalmology departments.
- People taking certain medication such as steroids, anti-retrovirals and some antipsychotic drugs.

Risk factors for type 2 diabetes

Impaired glucose regulation signifies that someone has impaired glucose tolerance, impaired fasting glucose or raised glycated haemoglobin (HbA_{1c}) or any combination of these conditions. In each case, their blood glucose levels are above normal but not high enough for a diagnosis of type 2 diabetes.

Not everyone with impaired glucose regulation progresses to diabetes. However, people with a high blood glucose reading are at greater risk. The more additional risk factors a person has (see People at risk above), the more likely they are to progress to type 2 diabetes (Diabetes UK 2011).

Progression rates also vary between individuals and for different populations, according to a range of other factors. These include:

- ethnicity
- age
- BMI
- co-morbidities
- genetics
- level of deprivation in the area where someone lives.

Blood tests

The oral glucose tolerance test has been regarded as the standard diagnostic tool for type 2 diabetes. The person being tested has to fast overnight before having blood taken. They are tested over a period of 2 hours early the next morning, before and after consuming a glucose

load. The test is time-consuming, for both the person being tested and the health professional (Eborall et al. 2012).

The World Health Organization (WHO) now recommends using the glycated haemoglobin blood test (HbA_{1c}) to diagnose diabetes in most people. This is provided that quality specifications are met and assays are standardised according to international reference values. These requirements are met in the UK. For the HbA_{1c} test, 48 mmol/mol (6.5%) and higher indicates type 2 diabetes (WHO 2011).

WHO does not provide guidance on the HbA_{1c} level that would indicate if someone is at high risk of diabetes. Rather, it states that clinicians should consider the individual's personal risk and provide advice and monitor them accordingly (WHO 2011). However, an expert group in the UK has suggested that HbA_{1c} values between 42–47 mmol/mol (6.0–6.4%) indicate a high risk – while conceding that people with HbA_{1c} values lower than 42 mmol/mol (6.0%) may still be at risk (John et al. 2012).

Progression-rate estimates are based on evidence from the oral glucose tolerance test 2-hour blood glucose values. However, a recent UK study found that the incidence of type 2 diabetes over a 3-year period was 15 times higher among participants with an HbA_{1c} between 42–47 mmol/mol (6.0–6.4%) at the beginning of the study, compared to those with a baseline HbA_{1c} less than 31 mmol/mol (5.0%) (Chamnan et al. 2011).

People with impaired glucose tolerance or elevated HbA_{1c} may have a greater risk of developing type 2 diabetes and cardiovascular disease compared to those with impaired fasting glucose. People with both impaired fasting glucose and impaired glucose tolerance, or an HbA_{1c} of 42 mmol/mol (6.0%), are at an even greater risk of developing diabetes (WHO 2006; The DECODE Study Group 2001). Other risk factors, such as an increased BMI and waist circumference, can more than double the chances (Lindström et al. 2008).

Validated risk-assessment tools, based on multiple factors, can be used to identify people with undiagnosed type 2 diabetes or those at risk. FINDRISC, a self-assessment questionnaire developed in Finland, is the most widely used and validated. It uses weighted scores from eight categories to calculate an overall risk score (Lindström and Tuomilehto 2003). A risk assessment score has been developed from FINDRISC by Leicester University and University Hospitals of Leicester NHS Trust. This has been validated for use in a multi-ethnic population in the UK (Gray et al. 2010). It is now available as the Diabetes Risk Score, from the [Diabetes UK](#) website.

Other risk-assessment tools, such as the Cambridge diabetes risk score, Leicester practice score and the [QDiabetes risk calculator](#), take account of data routinely collected in primary care.

NHS Health Check

Identifying and assessing people at risk of, or with existing (but undiagnosed), diabetes is part of an integrated approach to preventing vascular diseases through the NHS Health Check programme.

This programme is being rolled out throughout England to ensure everyone aged 40–74 who has not been diagnosed with diabetes, cardiovascular disease, stroke or kidney disease is offered an initial risk assessment. If they are at increased risk of diabetes, they will be offered a blood test (either fasting blood glucose or the glycated haemoglobin [HbA_{1c}] test). People identified as being at risk will be advised and helped to lose weight (if appropriate), become more physically active and improve their diet (NHS Health Check Programme 2009).

Diabetes prevention programmes

Large-scale trials in Europe, the US and many other countries have consistently shown that the onset of type 2 diabetes can be prevented or delayed among adults at high risk. A reduction of over 50% in the risk among this group was demonstrated, following structured lifestyle interventions during these trials. The lifestyle programmes used behaviour-change strategies to help people increase their physical activity, eat more healthily and maintain a healthy body weight. The impact was similar, regardless of ethnicity, or gender.

The trials, which all set similar, specific targets (see table 1 below), showed that the greater the number of lifestyle-change goals achieved, the greater the subsequent reduction in risk. They were resource-intensive, typically involving one-to-one sessions delivered by specialists including highly qualified exercise physiologists, dietitians or behavioural psychologists.

Table 1: Goals of the major diabetes prevention trials

Trial	Goals
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	Physical activity	Weight loss	Increase fibre intake	Reduce total fat intake	Reduce saturated fat intake	Other dietary goals
Da-Qing study (China) (Pan et al. 1997)	1 to 2 'units' a day. 1 unit = 30 minutes of: slow walking or housework; or 20 minutes cycling or ballroom dancing; or 10 minutes climbing stairs; or 5 minutes swimming or basketball	Reduce BMI to less than 24 kg/m ² if BMI over 25 kg/m ²		Reduce to 25–30% of energy intake		Carbohydrate 55–65% of energy intake. Increase vegetable intake. Reduce sugar intake. Control alcohol intake
Finnish diabetes prevention study (DPS) (Tuomelihto et al. 2001)	More than 4 hours/week, moderate-intensity	5% or more of initial body weight	Over 15 g per 1000 kcals	Reduce to less than 30% of energy intake	Less than 10% of energy intake	

Diabetes prevention program (DPP) USA (DPP Research Group. 2002)	At least 150 minutes/ week moderate-intensity	7% of initial body weight		Adopt a low-fat diet		Low calorie
Indian diabetes prevention program (IDPP) (Ramachandran et al. 2006)	At least 30 minutes brisk walking or cycling a day		Include fibre rich foods	Reduction in fats		Reduce total calorie and refined carbohydrate intake. Avoid sugar

The challenge in recent years has been to translate these results into the 'real world' of routine clinical and public health practice in ways which reduce costs without sacrificing effectiveness.

Intensive lifestyle change programmes, adapted from the Diabetes Prevention Program, in diverse settings and with different populations, have shown that significant results can be achieved by trained community practitioners, and by encouraging attendance at group sessions (Ali et al. 2012). Similar adaptations are being rolled out nationally in countries such as Finland, Australia and the US

Physical activity

The UK's national minimum physical activity guidelines include recommendations for children, adults aged 19–64 and older adults (Department of Health 2011a). They are consistent with the physical activity goals used in major diabetes prevention trials (see table 1 above).

In a 2008 survey, only 39% of men and 29% of women in the UK were achieving 30 minutes of moderate-to-vigorous activity on at least 5 days a week (The NHS Information Centre for Health and Social Care 2011b). Low activity levels were more prevalent among overweight or obese adults, those with a raised waist circumference, and people from low socioeconomic groups and specific black and minority ethnic groups (Food Standards Agency 2007).

Diet

A diet that helps people who are overweight or obese to lose weight and sustain the weight loss will help them to reduce their risk of diabetes (Paulweber et al. 2010).

In major diabetes prevention trials (see table above), successful dietary changes made by people with impaired glucose tolerance were very similar to, and consistent with, general healthy eating advice.

Data from the 'National diet and nutrition survey' show that, in the period from 2008 to 2010, saturated fat intake provided an average 12.8% of food energy among the general population. This exceeds the recommended level of less than 10% in the prevention trials (DH 2011b).

Among people on a low income, the intake of saturated fat as a proportion of food energy was greater than 13.7%, particularly among those aged 65 years and over (men 14.4%, women 14.5%).

The 2007 'Low income diet and nutrition survey' found that people on a low income were less likely to eat foods high in fibre (vegetables, fruit, wholemeal bread and wholegrain and high-fibre breakfast cereal) than the general population. Among adults, 51% of men and 69% of women ate less than the recommended minimum (Food Standards Agency 2007).

Local authorities

From April 2013, local authorities in England will have lead responsibility for public health and will be allocated ring-fenced budgets by Public Health England to commission and provide a range of services.

All upper tier and unitary authorities will establish a health and wellbeing board consisting of local councillors, directors of public health, clinical commissioning groups and community/patient representatives (DH 2011c).

Services will aim to tackle and prevent obesity via community nutrition initiatives and by encouraging people to be more physically active (so addressing the key risk factors for diabetes). In addition, local authorities will commission and provide risk assessments for those aged 40–74 who are eligible for the NHS Health Check programme. They will also commission and provide

lifestyle interventions, as appropriate, to manage that risk, as part of the NHS Health Check programme.

Local authorities will receive an incentive payment (or 'health premium') to reduce health inequalities and to support progress towards specific public health outcomes (DH 2010; DH 2012).

3 Considerations

The Programme Development Group (PDG) took account of a number of factors and issues when developing the recommendations.

Terminology

- 3.1 Impaired glucose regulation (IGR) refers to blood glucose levels that are above normal, but not high enough for a diagnosis of type 2 diabetes. (This condition is also known as non-diabetic hyperglycaemia or pre-diabetes.) Impaired glucose regulation is used to describe the presence of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), or both. These are states of abnormal glucose regulation that exist between normal blood glucose levels and type 2 diabetes. Impaired glucose regulation is characterised by insulin resistance and impaired insulin secretion which precede the development of type 2 diabetes. However, it has no symptoms and can remain undiagnosed for many years (Diabetes UK 2011). Some prefer the term 'pre-diabetes' because it is a clear way of communicating the presence of impaired fasting glucose, impaired glucose tolerance and impaired glucose regulation – and the associated risks of developing type 2 diabetes. However, some health professionals view the term pre-diabetes as potentially misleading, as progression to diabetes is not inevitable. In the absence of any intervention, some people may remain with impaired glucose regulation and some return to normal glucose tolerance (The American College of Endocrinology and the American Association of Clinical Endocrinologists 2008). Pre-diabetes may also be perceived as implying a disease status, without acknowledging the variation in progression rates. In general, the PDG preferred phrases that reflect the spectrum of risk, such as 'lower' or 'increased risk' which convey the idea that everyone could be at risk at some point in their lives. This guidance refers to people at high risk, in keeping with UK and international professional practice and usage.
- 3.2 The PDG debated at length whether the glycated haemoglobin (HbA_{1c}) test could be used as an alternative to standard glucose tests to define when someone has impaired glucose regulation. It decided to include people identified by HbA_{1c}, if a venous blood sample was tested in laboratories that

meet national quality specifications. The UK expert group on the use of HbA_{1c} testing suggested that a blood glucose measure of 42–47 mmol/mol (6.0–6.4%) could be used to indicate someone is at high risk of type 2 diabetes (John et al. 2011). Using HbA_{1c} to test for type 2 diabetes has advantages (see [Blood tests](#) in the 'Public health need and practice' section).

- 3.3 The PDG took into account that the natural progression from impaired glucose tolerance to type 2 diabetes (and the risk of cardiovascular disease) is well known and well-reported. Much less is known about the natural progression using HbA_{1c} as the marker. HbA_{1c} is less sensitive to weight change than an oral glucose tolerance test. In addition, it does not adequately reflect glycaemic control over the past 2–3 months for people with certain medical conditions. (This includes haematological disorders, renal failure and long-term excessive alcohol consumption.) Finally, certain drugs (for example, steroids or antipsychotics) may cause rapid rises in blood glucose that is not reflected in HbA_{1c}. A blood glucose test is recommended for people who have recently started steroid or antipsychotic treatment, or have symptoms of diabetes (John et al. 2012).
- 3.4 Risk-assessment tools, based on the presence or absence of various risk factors, are used to identify people at high risk of type 2 diabetes among European populations. There are two broad approaches. Either they use the data routinely available in UK general practice computer databases (such as age, gender, body mass index [BMI] and family history of diabetes). Or they comprise self-assessment questionnaires which are completed manually or online. Examples of the former are the Cambridge diabetes risk score, the QDiabetes risk calculator and the Leicester practice score. Examples of the latter are the Diabetes Risk Score assessment tool (available to health professionals on the Diabetes UK website), the online Diabetes Risk Score and FINDRISC. The Diabetes Risk Score was developed and validated in Leicester for identifying those at high risk of impaired glucose regulation and type 2 diabetes in multi-ethnic populations in the UK. It is, in turn, based on FINDRISC, a Finnish self-assessment questionnaire. FINDRISC is based on robust data and has been validated as a risk-assessment tool in cross-sectional studies and, prospectively, in other European populations.

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- 3.5 The PDG focused on risk-assessment tools validated for use in the UK and which help identify people from different ethnic groups who are at high risk of diabetes. It debated the difference between tools measuring current risk (for example, FINDRISC and scores based on it) and prospective risk (for example, QDiabetes risk calculator). This included their use of cross-sectional or prospective cohort data. Both approaches were acknowledged to have limitations. The PDG felt it was important that the tools were validated against blood glucose measures. Equally important was the need to have a range of tools available that are suitable for use in any environment where risk assessment could take place. The PDG concurred that the choice of tool is likely to depend on the population being assessed, whether it has been validated for use with that population, the risk-assessment setting and supporting infrastructure (such as compatibility with IT systems).
- 3.6 As part of the two-stage approach for identifying people at risk of type 2 diabetes, the PDG has advocated the use of a risk-assessment tool (either self-assessment or practice-based) as a first step. Self-administered questionnaires have the advantage that they can be given out in a range of different places (including shopping centres), or downloaded from the Internet. People identified as being at increased risk can then be offered a blood test or lifestyle advice and support.
- 3.7 Practice-based risk-assessment tools, based on routine health service data, have the advantage that all necessary information should already have been collected. The PDG acknowledged that the records would need to be up-to-date and complete to ensure the tools are accurate. The tools allow staff to estimate the percentage of the practice population that is likely to fall into each risk category, and to systematically invite those with a high risk score for further investigation. For example, the top 50% of patients might be designated as high risk and then be invited for a blood test. The remainder can then be divided up accordingly into groups with a low risk score (for example, the lowest quartile who will receive brief advice) and those with an intermediate risk score (who may need more advice about managing their risk).
- 3.8 The PDG debated whether certain at-risk groups should be given a blood test without having a risk-assessment score. It thought this approach might be

appropriate for young people from high-risk black and minority ethnic groups for whom risk-assessment tools have limited validation. However, it conceded that risk-assessment tools could provide false reassurance to younger age groups.

- 3.9 The PDG discussed whether it would be effective to intervene with people identified as being at high risk, if they have only been assessed using a risk-assessment tool. Only a small proportion of people identified in this way may have impaired glucose regulation. People at high risk in the prevention programme trials were identified by blood glucose tests not by risk score. More important, while risk scores can identify those at high risk – and those who may have undiagnosed type 2 diabetes – they cannot be used to give a diagnosis of type 2 diabetes. However, the PDG recognised that a small proportion of people will refuse a blood test and made a recommendation for them accordingly.
- 3.10 The NHS Health Check programme uses BMI (adjusted for ethnic groups at higher risk) and an initially raised blood pressure to identify people at higher risk of having, or developing, type 2 diabetes. This approach was developed with in-depth input from a range of experts. Knowledge in this area is constantly changing and developing and the PDG aimed to further improve the way type 2 diabetes is identified.
- 3.11 Waist measurement is not routinely recorded by risk-assessment tools and it is not taken into account by the NHS Health Check programme. However, it is a good predictor of type 2 diabetes risk and could be used to help monitor people after their risk assessment. It would involve providing simple instructions on how to measure someone's waist correctly.
- 3.12 Type 2 diabetes affects people of South Asian, African-Caribbean, Chinese or black African descent up to a decade or more earlier than white Europeans. Bearing this in mind, the PDG considered that there is a case for local areas to consider providing risk assessment and intensive lifestyle-change programmes for people from these groups from the age of 25 onwards. The prevalence of impaired glucose regulation and undiagnosed type 2 diabetes among people aged 25–39 years of black African or African-Caribbean descent in the UK was

unclear. So the PDG was unable to estimate cost-effectiveness and make specific recommendations for this population subgroup. However, risk assessments are encouraged and health professionals are advised to provide advice and monitoring according to each person's particular risk profile.

- 3.13 A substantial proportion of Asian people at high risk of type 2 diabetes have a BMI lower than the World Health Organization (WHO) recommended cut-off point for being overweight (the same or greater than 25 kg/m²). For example, South Asians tend to have a higher percentage of body fat at a given BMI and a greater risk of developing type 2 diabetes than Europeans. The WHO report suggested that 23–27.4 kg/m² and 27.5–32.4 kg/m² should be used to identify people within different Asian populations who may be at risk of health conditions due to their weight (WHO 2004). The PDG agreed to recommend that all adults from Asian backgrounds with a BMI greater than 23 kg/m² are at increased risk of type 2 diabetes and should be encouraged to reduce their weight.
- 3.14 The PDG considered that people over age 74 from all ethnic groups might benefit from type 2 diabetes risk assessment and prevention, as the risk increases with age. However, it recognised that many of the risk-assessment tools are not validated for this age group and that comorbidities may make participation in lifestyle programmes more difficult for some. Nevertheless, there is evidence that older people can benefit from being more physically active and improving their diet.
- 3.15 There was little evidence about type 2 diabetes risk assessment for adults aged 18–24 years in any population subgroup. The same was true for people of all ages with severe mental illness or learning disabilities and for those from lower socioeconomic groups.
- 3.16 Expert testimony and data suggest that people from lower socioeconomic groups are less likely to attend for a risk assessment or a blood test for type 2 diabetes. The PDG believed this situation could be improved if assessments – and any subsequent prevention programmes – were provided in places they visit regularly. It noted that risk assessment does not need to be carried out by GPs (or in GP surgeries), but can be offered in a range of other settings. This

includes: community pharmacies, occupational health departments, community centres and faith-based centres such as mosques, temples and church halls. However, the PDG noted the importance of ensuring information is passed securely to the person's GP – and that quality assurance and data transfer may be a challenge. In addition, it noted the need for planning to ensure once high-risk people are identified they are monitored and followed up.

- 3.17 Evidence shows that informing someone that they are at risk of type 2 diabetes does not harm them – and may have a beneficial effect on their lifestyle. The PDG acknowledged that not everyone identified with impaired glucose regulation will progress to type 2 diabetes. However, it deemed it better if the majority of people at high risk are identified so they can be offered a prevention programme. It also recommended opportunities to be reassessed at least every 5 years, irrespective of someone's level of risk. This means that surveillance is an ongoing process. It also noted that many people with impaired glucose regulation will have modifiable cardiovascular disease risk factors that would also benefit from a lifestyle intervention.
- 3.18 Frequent monitoring, as carried out in some of the major type 2 diabetes prevention trials, identifies more people as being at high risk of progression to type 2 diabetes. It can also help motivate people to change their lifestyle.
- 3.19 The PDG was aware of the importance of ensuring an intensive lifestyle-change programme is available when conveying someone's risk of progression to type 2 diabetes and their potential to modify that risk. As everyone's level of risk differs (and will be a combination of modifiable and non-modifiable factors) the PDG also noted the importance of tailoring prevention activities to meet individual needs.
- 3.20 There are no 'Read codes' in healthcare computer systems for recording that someone has had a risk assessment, what their level of risk is, and whether or not they have been referred to an intensive lifestyle-change programme. In addition, although there are Read codes for impaired fasting glucose and impaired glucose tolerance testing, there is not one for an HbA_{1c} test. This may make it difficult for practitioners to communicate with each other about a particular individual's level of risk.

Type 2 diabetes prevention

- 3.21 The type 2 diabetes prevention trials that provided evidence for this guidance were conducted among adults with impaired glucose tolerance. Measurement of impaired glucose tolerance requires people to fast and to attend 2 hours of tests. Fasting is inconvenient for many people and may not be complied with. Consequently, oral glucose tolerance test results might not always be reliable and the PDG did not consider this test suitable (or practical) for routine clinical practice. Rather, it recommended a two-stage strategy to identify adults at high risk: a risk assessment followed by a blood test (either HbA_{1c} or fasting plasma glucose).
- 3.22 The PDG is aware that HbA_{1c} testing does not identify the same at-risk population as that identified by the oral glucose tolerance test. There may be regional variations in the populations identified as high risk using HbA_{1c}, compared to those identified at high risk using the glucose tolerance test. The PDG has made research recommendations accordingly.
- 3.23 The US Diabetes Prevention Program (DPP) has been adapted for use in community settings and includes a different range of people from the original trials. For example, women who have had type 2 diabetes during pregnancy and adults with an HbA_{1c} level between 39 and 47 mmol/mol (5.7–6.4%). (This is the range recommended by the American Diabetic Association to indicate an increased risk of diabetes.) The UK expert group on HbA_{1c} testing suggested using 42–47 mmol/mol (6.0–6.4%) to indicate a high risk, despite the fact that someone with lower HbA_{1c} values might also be at risk. The PDG noted that if the HbA_{1c} 39–47 mmol/mol (5.7–6.4%) range were used as an indicator of high risk in the UK, in some parts of the country 50% of adults aged 40–74 years might qualify (Mostafa et al. 2010).
- 3.24 The mean age of participants in evaluated prevention programmes is between 35 and 55 years. However, evidence from the diabetes prevention study in Finland showed that lifestyle interventions were more effective for older participants.

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- 3.25 Large-scale prevention trials, for example, the Diabetes Prevention Study in Finland (Tuomilehto et al. 2001), offered participants an average of 20 one-to-one counselling sessions over a 4-year period. Such intensive programmes can be cost effective over the long term but they are unlikely to be affordable in the short term (Zhuo et al. 2012a). Hence, pragmatic adaptations which translated the studies into real-world settings were also investigated.
- 3.26 Evidence reviews suggested that the more counselling and education sessions on diet and physical activity that someone attends, the better the outcome.
- 3.27 The PDG heard expert testimony from the Division of Diabetes Translation in the United States. The evidence from the translation of research from the DPP and other major diabetes prevention trials has shown that offering fewer education and counselling sessions on diet and physical activity does not mean that people are more likely to attend all of them. People appear to have attended a similar proportion, irrespective of the number offered. However, in the UK PREPARE study the proportion of sessions attended increased if fewer sessions were offered.
- 3.28 Although weight loss was one of the five goals of the major diabetes prevention trials, it may not be appropriate for everyone at high risk of diabetes.
- 3.29 While most people can make changes to their diet and become more physically active, others might find this difficult or even impossible. For example, people whose mobility is severely impaired due to disability, or restricted due to their place of residence, may find it difficult to become more physically active. People who rely on others for their meals might find it difficult to change their diet, for example people living in residential homes. Even if these groups do make lifestyle changes, this might not be enough to reduce their risk. The PDG made recommendations about supporting lifestyle change with medication such as metformin to address this problem. Metformin has been used safely over many years by overweight or obese people with elevated blood glucose levels who took part in the Diabetes Prevention Program Outcomes Study. It is associated with modest and durable weight loss (DPP Research Group 2012). The PDG also took note of NICE's guidance on

obesity (2006). This includes recommendations about the use of orlistat and bariatric surgery for people who need further help to lose weight.

- 3.30 Evaluations of diabetes prevention trials found no evidence about the value of excluding (or including) alcohol as part of a dietary intervention. Hence no recommendations were made on this. However, the PDG acknowledged that alcohol contributes to calorie intake.
- 3.31 Depression may be a barrier to participation in an intensive lifestyle-change programme. However, physical activity (a major component of lifestyle interventions to prevent type 2 diabetes) can help manage mild to moderate depression (see NICE guidance on depression in adults [2009]).
- 3.32 The PDG did not recommend risk-assessment tools for monitoring prevention programme outcomes, as some of the risk factors they cover cannot be modified. Only changes to factors such as weight, diet and physical activity are recommended as outcomes.

Economic modelling

- 3.33 Several scenarios involving people aged 40 to 74 years were examined. The NHS Health Check programme was used as a comparator. For people of South Asian descent aged 25–34, usual practice was the comparator. A two-stage risk-assessment process was carried out. People with a high risk score for diabetes, determined by weight-for-height (measured by BMI), anti-hypertensive use, age, sex, family history of diabetes and ethnicity, were given a blood test (either a fasting plasma glucose or an HbA_{1c} test). As a result of the test they were divided into three groups: those diagnosed with diabetes, those at high risk, and those at low or intermediate risk of progressing to type 2 diabetes. The high-risk group was offered an intensive lifestyle-change programme. When the risk assessment was followed by an intensive lifestyle-change intervention, this was estimated to be cost effective.
- 3.34 The PDG debated whether the cost effectiveness of an intensive lifestyle-change programme might vary between groups with the same risk score but a different HbA_{1c} (specifically an HbA_{1c} of 39 mmol/mol [5.7%] and 42 mmol/mol

[6.0%]). It concluded that it was pragmatic to offer programmes to people with an HbA_{1c} of 42–47 mmol/mol (6.0–6.4%). Recent modelling from the US supports this conclusion (Zhuo et al. 2012b).

- 3.35 The PDG recommended an intensive lifestyle-change programme for people with a fasting plasma glucose of 5.5–6.9 mmol/l, after a consideration of the economic modelling. The modelling also showed that more intensive lifestyle-change programmes were estimated to be more cost effective than less intensive programmes.
- 3.36 The economic modelling included an analysis of the effect of extending testing to people aged 25–39 years of South Asian descent who were deemed at high risk of diabetes. Provision of risk identification and intensive lifestyle-change programmes was estimated to be cost effective after 20 years and cost saving after 25 years. If a BMI equal to or greater than 23 kg/m² was used to indicate risk at the first stage of risk assessment (rather than the scoring system used for those aged 40–74), a similar number would identified to be at high risk. For pragmatic reasons, therefore, a BMI greater than or equal to 23 kg/m² was recommended as the indicator of high risk at the first stage of risk assessment for this group. Lack of data meant the analysis could not include people from other ethnic groups aged 25–39 years. However, the findings are likely to apply to other groups where a high proportion of people have a high risk of progression to type 2 diabetes.

4 Implementation

NICE guidance can help:

- Commissioners and providers in NHS organisations and local authorities meet national priorities and the requirements of the 'Operating framework for the NHS in England 2012–13'.
- National and local organisations improve quality and health outcomes and reduce health inequalities.
- Local authority health and wellbeing boards improve the health and wellbeing of people in their area.
- Local NHS organisations, local authorities and other local partners benefit from any identified cost savings, disinvestment opportunities or opportunities for re-directing resources.
- Provide a focus for integration and partnership working across social care, the NHS and public health organisations.

NICE has developed tools to help organisations put this guidance into practice. For details, see [our website](#).

5 Recommendations for research

The Programme Development Group (PDG) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful/negative side effects.

Identification and monitoring

- 5.1 Which combination of risk-assessment tools and blood tests (HbA_{1c} 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?
- 5.2 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 HbA_{1c} 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 HbA_{1c} 42–47 mmol/mol (6.0–6.4%))?
- 5.3 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.

Lifestyle interventions

- 5.4 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?

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- 5.5 How effective and cost effective are different types of dietary regime 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, 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?
- 5.6 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?

Vulnerable groups

- 5.7 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.

More detail on the gaps in the evidence identified during development of this guidance is provided in [appendix D](#).

6 Updating the recommendations

This guidance will be reviewed 3 years after publication to determine whether all or part of it should be updated. Information on the progress of any update will be posted at the [NICE website](#).

7 Related NICE guidance

Published

Patient experience in adult NHS services. NICE clinical guideline 138 (2012).

Preventing type 2 diabetes – population and community interventions. NICE public health guidance 35 (2011).

Hyperglycaemia in acute coronary syndromes. NICE clinical guideline 130 (2011).

Weight management before, during and after pregnancy. NICE public health guidance 27 (2010).

Prevention of cardiovascular disease. NICE public health guidance 25 (2010).

Type 2 diabetes – newer agents. NICE clinical guideline 87 (2009).

Type 2 diabetes: the management of type 2 diabetes (update). NICE clinical guideline 66 (2008).

Promoting physical activity in the workplace. NICE public health guidance 13 (2008).

Physical activity and the environment. NICE public health guidance 8 (2008).

Behaviour change. NICE public health guidance 6 (2007).

Obesity. NICE clinical guideline 43 (2006).

Diabetes (type 1 and 2) – patient education models. NICE technology appraisal guidance 60 (2003).

Under development

Walking and cycling. NICE public health guidance (publication expected October 2012).

Obesity: working with local communities. NICE public health guidance (publication expected November 2012).

Assessing thresholds for body mass index (BMI) and waist circumference in black and minority ethnic groups. NICE public health guidance (publication expected February 2013).

Physical activity advice in primary care. NICE public health guidance (publication expected May 2013).

Overweight and obese adults: lifestyle weight management services. NICE public health guidance (publication expected January 2014).

Workplace health: older employees. NICE public health guidance (publication date to be confirmed).

Workplace health: employees with chronic diseases and long-term conditions. NICE public health guidance (publication date to be confirmed).

8 Glossary

Behaviour change

Evidence-based behaviour-change advice includes:

- helping people to understand the short, medium and longer-term consequences of health-related behaviour
- helping people to feel positive about the benefits of changing their behaviour
- building the person's confidence in their ability to make and sustain changes
- recognising how social contexts and relationships may affect a person's behaviour
- helping plan changes in terms of easy steps over time
- identifying and planning for situations that might undermine the changes people are trying to make (including planning explicit 'if-then' coping strategies to prevent relapse)
- encouraging people to make a personal commitment to adopt health-enhancing behaviours by setting (and recording) achievable goals in particular contexts, over a specified time
- helping people to use self-regulation techniques (such as self-monitoring, progress review, relapse management and goal revision) to encourage learning from experience
- encouraging people to engage the support of others to help them to achieve their behaviour-change goals.

(This is adapted from NICE's guidance on [behaviour change](#).)

Brief advice

Typically, for diabetes prevention, brief advice might consist of a 5–15 minute consultation. The aim is to help someone make an informed choice about whether to make lifestyle changes to reduce their risk of diabetes. The discussion covers what that might involve and why it would be beneficial. Practitioners may provide written information in a range of formats and languages about the benefits and, if the person is interested in making changes, may discuss how these can be achieved and sustained in the long term.

Brief intervention

Brief interventions for diabetes prevention can be delivered by GPs, nurses, healthcare assistants and professionals in primary healthcare and the community. They may be delivered in groups or on a one-to-one basis. They aim to improve someone's diet and help them to be more physically active. A patient-centred or 'shared decision-making' communication style is adopted to encourage people to make choices and have a sense of 'ownership' of their lifestyle goals and individual action plans. Providers of brief interventions should be trained in the use of evidence-based behaviour-change techniques for supporting weight loss through lifestyle change.

Computer-based risk-assessment tools

These tools identify a set of risk characteristics in patient health records. They can be used to interrogate GP patient databases and provide a summary score to indicate someone's level of risk. Examples include the Cambridge diabetes risk score and the Leicester practice score.

Diabetes prevention programmes

Diabetes prevention programmes comprise two integrated components: first, risk identification services and second, intensive lifestyle-change programmes. Participants are acknowledged as the decision-makers throughout the process. Also see 'Intensive lifestyle-change programmes'.

Glycated haemoglobin (HbA_{1c})

Glycated haemoglobin (HbA_{1c}) forms when red cells are exposed to glucose in the plasma. The HbA_{1c} test reflects average plasma glucose over the previous 8–12 weeks. Unlike the oral glucose tolerance test, an HbA_{1c} test can be performed at any time of the day and does not require any special preparation, such as fasting.

HbA_{1c} is a continuous risk factor for type 2 diabetes. This means there is no fixed point when people are (or are not) at risk. The World Health Organization recommends a level of 48 mmol/mol (6.5%) for HbA_{1c} as the cut-off point for diagnosing type 2 diabetes in non-pregnant adults. For the purposes of this guidance, the range 42–47 mmol/mol (6.0–6.4%) is considered to be 'high risk'.

Impaired fasting glucose (IFG)

Impaired fasting glucose is defined as a fasting plasma glucose between 6.1 and 6.9 mmol/l.

Impaired glucose tolerance

This is a risk factor for future diabetes and/or other adverse outcomes. The current WHO diagnostic criteria for impaired glucose tolerance are: a fasting plasma glucose of less than 7.0 mmol/l and a 2-hour venous plasma glucose (after ingestion of 75 g oral glucose load) of 7.8 mmol/l or greater, and less than 11.1 mmol/l.

Impaired glucose regulation (IGR)

This is a risk factor for future diabetes and/or other adverse outcomes. The term covers blood glucose levels that are above the normal range but are not high enough for the diagnosis of type 2 diabetes. It is used to describe the presence of impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) as defined by the WHO.

- IFG is defined as fasting plasma glucose 6.1 to 6.9 mmol/l IGT is defined as a fasting plasma glucose (FPG) less than 7 mmol/l and 2-hour venous plasma glucose (after ingestion of 75 g oral glucose load) of 7.8 mmol/l or greater and less than 11.1 mmol/l.

Impaired fasting glucose and impaired glucose tolerance can occur as isolated, mutually exclusive conditions or together, that is, fasting plasma glucose between 6.1 and 6.9 mmol/l and 2-hour glucose of 7.8 mmol/l or greater and less than 11.1 mmol/l during the oral glucose tolerance test .

Intensive lifestyle-change programmes

A structured and coordinated range of interventions provided in different venues for people identified as being at high risk of developing type 2 diabetes (following a risk assessment and a blood test). The aim is to help people become more physically active and to improve their diet. If the person is overweight or obese, the programme should result in weight loss. Programmes may be delivered to individuals or groups (or involve a mix of both) depending on the resources available. They can be provided by primary care teams and public, private or community organisations with expertise in dietary advice, weight management and physical activity.

Level of risk

The terms 'high', 'intermediate' and 'low' risk are used to refer to the results from a risk assessment tool. These terms are used instead of specific numerical scores because the tools have different scoring systems. The term 'moderate risk' is used to denote a high risk assessment score where a blood test did not confirm that risk (FPG less than 5.5mmol/l or HbA_{1c} less than 42mmol/mol [6.0%]). A fasting plasma glucose of 5.5–6.9 mmol/l or an HbA_{1c} level of 42–47 mmol/mol [6.0–6.4%] indicates high risk.

Moderate-intensity physical activity

Moderate-intensity physical activity requires an amount of effort and noticeably accelerates the heart rate. Examples include brisk walking, housework and domestic chores. On an absolute scale, moderate-intensity is defined as physical activity that is between 3 and 6 metabolic equivalents (METs).

Oral glucose tolerance test

An oral glucose tolerance test involves measuring the blood glucose level after fasting, and then 2 hours after drinking a standard 75g glucose drink. Fasting is defined as no calorie intake for at least 8 hours. More than one test on separate days is required for diagnosis in the absence of hyperglycaemic symptoms.

Pre-diabetes

Pre-diabetes refers to raised (but not in the diabetic range) blood glucose levels (also known as non-diabetic hyperglycaemia, impaired glucose regulation). It indicates the presence of impaired fasting glucose and/or impaired glucose tolerance. People with pre-diabetes are at increased risk of getting type 2 diabetes. They are also at increased risk of a range of other conditions including cardiovascular disease.

Vigorous-intensity physical activity

Vigorous-intensity physical activity requires a large amount of effort, causes rapid breathing and a substantial increase in heart rate. Examples include running and climbing briskly up a hill. On

an absolute scale, vigorous intensity is defined as physical activity that is above 6 metabolic equivalents (METs).

Weight-loss programmes

Effective weight-loss programmes are structured lifestyle-change programmes to help people lose weight in a sustainable way. They:

- are based on an assessment of the individual
- address the reasons why someone might find it difficult to lose weight
- are tailored to individual needs and choices
- are sensitive to the person's weight concerns
- are based on a balanced, healthy diet
- encourage regular physical activity
- utilise behaviour-change strategies.

Weight management

In this guidance, the term weight management includes:

- assessing and monitoring body weight
- preventing someone from becoming overweight (body mass index [BMI] of 25–29.9 kg/m², or 23–27.4 kg/m² if they are of South Asian or Chinese descent)
- preventing someone from becoming obese (BMI greater than or equal to 30 kg/m², or 27.5 kg/m² or above if they are of South Asian or Chinese descent)
- helping someone who is overweight or obese to achieve and maintain a 5–10% weight loss and progress to a healthy weight (BMI of 18.5–24.9 kg/m², or 18.5 to 22.9 kg/m² if they are of South Asian or Chinese descent) by adopting a healthy diet and being physically active.

9 References

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Appendix A Membership of the Programme Development Group (PDG), the NICE project team and external contractors

Programme Development Group

PDG membership is multidisciplinary. The Group comprises public health practitioners, clinicians, representatives of the public, academics and technical experts as follows.

Pam Brown

General Practitioner, Swansea

Barry Cassidy

Community Member

Christine Cottrell

Clinical Lead for Diabetes, Education for Health, Warwick

Melanie Davies

Professor of Diabetes Medicine, Department of Cardiovascular Sciences, University of Leicester

Colin Greaves

Senior Research Fellow, Peninsula Medical School (Primary Care), University of Exeter

Jill Hill

Diabetes Nurse Consultant, Birmingham Community Healthcare NHS Trust

Richard Holt

Professor in Diabetes and Endocrinology, Faculty of Medicine, University of Southampton

Roger Hughes

Community Member

Deepa Khatri

Clinical Advisor and Dietitian, Diabetes UK

Kamlesh Khunti

(Chair) Professor of Primary Care Diabetes and Vascular Medicine, Department of Health Sciences, University of Leicester

Sally James

Divisional Pharmacist, Royal Liverpool and Broad Green University Hospitals NHS Trust

Phil McEwan

Health Economist, Cardiff Research Consortium

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Consultant in Diabetes/Endocrinology and Associate Medical Director. Mid Yorkshire NHS Trust, Wakefield

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Claire Phipps

Senior Dietitian, Hertfordshire Community NHS Trust

Thomas Yates

Senior Lecturer in Physical Activity, Sedentary Behaviour and Health, Department of Cardiovascular Sciences, University of Leicester

NICE project team

Mike Kelly

CPHE Director

Tricia Younger

Associate Director

Hilary Chatterton

Lead Analyst

Charlotte Haynes

Analyst

Karen Peploe

Analyst

Clare Wohlgemuth

Analyst

Alastair Fischer

Technical Adviser Health Economics

Patricia Mountain

Project Manager

Melinda Kay

Coordinator

Sue Jelley

Senior Editor

Alison Lake

Editor

External contractors

Evidence reviews

Review 1 was carried out by the School of Health and Related Research (SchARR) Public Health Collaborating Centre. The principal authors were: Maxine Johnson, Emma Everson-Hock, Roy Jones, Helen Buckley Woods, Elizabeth Goyder, Jim Chilcott and Nick Payne.

Review 2 was carried out by SchARR. The principal authors were: Roy Jones, Crystal Freeman, Maxine Johnson, Helen Buckley Woods, Louise Guillaume, Clare Gillies, Elizabeth Goyder, Jim Chilcott and Nick Payne.

Review 3: was carried out by SchARR. The principal authors were: Maxine Johnson, Roy Jones, Crystal Freeman, Helen Buckley Woods, Vishal Ram, Annabel Sidwell, Elizabeth Goyder, Jim Chilcott and Nick Payne.

Review 4 was carried out by SchARR. The principal authors were: Maxine Johnson, Crystal Freeman, Josie Messina, Roy Jones, Helen Buckley Woods, Elizabeth Goyder, Jim Chilcott and Nick Payne.

Cost effectiveness

The review of economic evaluations and the economic modelling was carried out by SchARR. The principal authors were: Mike Gillett, Jim Chilcott, Elizabeth Goyder, Nick Payne, Praveen Thakola, Crystal Freeman, Maxine Johnson and Helen Buckley Woods.

Commissioned report

The commissioned report principal author was Jayne Taylor.

Fieldwork

The fieldwork was carried out by Word of Mouth.

Expert testimony

Expert paper 1 by Heather White, Department of Health Vascular Disease Programme.

Expert paper 2 by Jaakko Tuomilehto, University of Helsinki.

Expert paper 3 by Melanie Davies, University of Leicester.

Expert paper 4 by Tom Yates, University of Leicester.

Expert paper 5 by Peter Schwarz, University of Dresden.

Expert paper 6 by Simon Griffin, MRC Epidemiology Unit, Cambridge.

Expert paper 7 by Ann Albright, Division of Diabetes Translation, Centers for Disease Control and Prevention, Atlanta.

Expert paper 8 by Colin Greaves, Peninsula Medical School, Exeter.

Appendix B Summary of the methods used to develop this guidance

Introduction

The reviews, primary research, commissioned reports and economic modelling report include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Programme Development Group (PDG) meetings provide further detail about the Group's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in [appendix E](#) and are available at the [NICE website](#).

Guidance development

The stages involved in developing public health programme guidance are outlined in the list below.

1. Draft scope released for consultation
2. Stakeholder meeting about the draft scope
3. Stakeholder comments used to revise the scope
4. Final scope and responses to comments published on website
5. Evidence reviews and economic modelling undertaken and submitted to PDG
6. PDG produces draft recommendations
7. Draft guidance (and evidence) released for consultation and for field testing
8. PDG amends recommendations

9. Final guidance published on website

10. Responses to comments published on website

Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PDG to help develop the recommendations. The overarching questions were:

- What are the most effective and cost-effective methods of identifying and monitoring adults with either or both impaired fasting glucose (IFG) and impaired glucose tolerance (IGT)?
- What are the most effective and cost-effective methods – lifestyle, pharmacological and surgical – of preventing or delaying type 2 diabetes in adults with pre-diabetes?

The subsidiary questions were:

- How does effectiveness and cost effectiveness vary between different communities or groups, including disadvantaged groups?
- Which interventions or strategies, and which combinations of interventions or strategies, are the most effective and cost effective in preventing or delaying type 2 diabetes in adults with pre-diabetes within a given community?
- What are the barriers and facilitators that may affect the implementation, effectiveness and cost effectiveness of these interventions or strategies (this should include any barriers and facilitators for specific groups)?

These questions were made more specific for each review (see reviews for further details).

Reviewing the evidence

Evidence reviews

Three reviews of effectiveness were conducted (reviews 1 to 3) and one qualitative review (review 4).

Identifying the evidence

A number of databases were searched in September 2010 for experimental studies, surveys and qualitative studies (1990–2010). See each review for details of the databases searched.

The grey literature was searched via: British Library Integrated Catalogue, Conference Papers Index, Medical Research Council and Economic and Social Research Council.

Searches of a range of websites were carried out for individual reviews (the sites searched varied between reviews – see each review for details).

Selection criteria

Studies were included in the three effectiveness reviews if:

- Review 1: they involved the identification and risk assessment of adults with IFG/IGT or raised glycated haemoglobin (HbA_{1c}).
- Review 2: they were randomised controlled trials that:
 - included people with pre-diabetes
 - investigated lifestyle, drug and surgical interventions to prevent type 2 diabetes
 - reported progression to type 2 diabetes as an outcome.
- Review 3: they included adults diagnosed with pre-diabetes using World Health Organization criteria (World Health Organization 2006) and evaluated interventions focused on:
 - weight-loss (for example, education, motivational support, slimming clubs)
 - diet (for example, low glycaemic index, reduced fat, controlled carbohydrate, low calorie diets)
 - physical activity (for example, cardiorespiratory training, organised programmes, individual programmes).

Studies were excluded from all three reviews if they focused on:

- people under 18 years of age

- people diagnosed with any form of diabetes
- pregnant women.

Studies were included in review 4 if they reported on views and perceptions of the following interventions delivered in primary, secondary and tertiary care, the community, residential care sector and prisons:

- Identification and risk assessment of adults with IFG/IGT or raised glycated haemoglobin (HbA_{1c}).
- Implementation of lifestyle interventions to prevent progression to type 2 diabetes.
- Undertaking behaviour change as a diabetes prevention strategy.

Studies were excluded if they focused on people with any form of diabetes.

Quality appraisal

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Methods for the development of NICE public health guidance' (see appendix E). Each study was graded (++, +, –) to reflect the risk of potential bias arising from its design and execution.

Study quality

++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.

– Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

The evidence was also assessed for its applicability to the areas (populations, settings, interventions) covered by the scope of the guidance. Each evidence statement concludes with a statement of applicability (directly applicable, partially applicable, not applicable).

Summarising the evidence and making evidence statements

The review data was summarised in evidence tables (see full reviews).

The findings from the reviews were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the public health collaborating centre (see [appendix A](#)). The statements reflect the centre's judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

Commissioned report

The commissioned report focused on vulnerable groups whose risk of diabetes may be missed or difficult to manage. They included:

- frail older people
- adults with a physical disability, severe mental illness or learning disabilities
- those not registered with a GP
- prisoners
- travellers, refugees, asylum seekers and recent migrants
- homeless people
- some minority ethnic or cultural groups and some faith communities
- those living in poverty.

Identifying the evidence

The Internet and other networks used by commissioners, managers and practitioners were searched to find relevant UK initiatives. In addition, a referral questionnaire was sent to individuals or groups identified during the searches.

Selection criteria

Only studies which completed an evaluation or reported on outcomes were included. Studies were not quality-assessed. They were reported descriptively and findings were treated as indicative.

Cost effectiveness

There was a review of economic evaluations, including an economic modelling exercise.

Review of economic evaluations

The economic review focused on models and reviews published since 2005 which have addressed three key questions:

- What is the likely cost-effectiveness of interventions to identify and manage pre-diabetes?
- What are the main factors which will influence the cost-effectiveness of risk assessment and intervention in pre-diabetes?
- Is it more cost-effective to identify and actively intervene in risk assessment-detected pre-diabetes or risk assessment-detected diabetes, or both, given that any risk assessment programme will identify both?

Four cost-effectiveness models published in the last 3 years met the inclusion criteria. They made a wide range of assumptions about baseline risk and relevant costs. Nevertheless, cost-effectiveness studies and systematic literature reviews reported that risk assessment (combined with a diabetes test) for people at high risk is likely to be cost effective – at £10,000 per quality-adjusted life year (QALY) or less.

Economic modelling

A two-stage economic model was constructed to include (hypothetically) everyone from 40 to 74 years of age and people of South Asian, Chinese or African/African-Caribbean ethnicity aged 25 to 39. The NHS Health Check programme was used as the comparator. Discount rates of 3.5% for both costs and benefits, a lifetime time-horizon and an NHS perspective, were used.

The first stage divided the population by a risk score (practice-based or self-assessed). In the model, at the second stage those at high risk of progressing to diabetes in the following 10 years were offered an HbA_{1c} or an FPG test. Those at high risk, based on the blood test, were offered an intensive lifestyle-change intervention.

The difference, in terms of costs and health benefits for both groups, as well as future costs saved by those assigned an intervention, were estimated. A cost per quality-adjusted life year (QALY) of less than £20,000 for the intervention was calculated, using data from the reviews of effectiveness and cost effectiveness.

For people of South Asian descent aged 25–39 years, the intervention improved their health and was estimated to be cost saving, compared with normal practice. The results are reported in: 'Prevention of type 2 diabetes: economic review and modelling' available on [NICE's website](#).

Fieldwork

Fieldwork was carried out to evaluate how relevant and useful NICE's recommendations are for practitioners and how feasible it would be to put them into practice. It was conducted with:

- Practitioners delivering the NHS Health Check programme.
- GPs, dietitians, practice nurses, dentists, community pharmacists, public health and obesity specialists.
- Members of shadow health and wellbeing boards and other commissioning groups involved in primary and community-based healthcare services for people at risk of diabetes. This included those working in ophthalmology, diabetology and other secondary healthcare care services in the NHS.

The fieldwork comprised:

- Three discussion groups carried out in Birmingham, London and Manchester by Word of Mouth.
- Thirty telephone interviews carried out by Word of Mouth with some of those who were unable to attend a discussion group.

- An online consultation carried out by Word of Mouth with people who were not selected for the interviews, and were not able to attend a discussion group.

The three studies were commissioned to ensure there was ample geographical coverage. The main issues arising from these studies are set out in [appendix C](#) under fieldwork findings. See also the full fieldwork report 'Prevention of type 2 diabetes: risk identification and interventions for individuals at high risk'.

How the PDG formulated the recommendations

At its meetings from October 2010 to September 2011, the Programme Development Group (PDG) considered the evidence, expert reports and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme/activity can be effective or is inconclusive
- where relevant, the typical size of effect (where there is one)
- whether the evidence is applicable to the target groups and context covered by the guidance.

The PDG developed draft recommendations through informal consensus, based on the following criteria:

- Strength (type, quality, quantity and consistency) of the evidence.
- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).

-
- Balance of harms and benefits.
 - Ease of implementation and any anticipated changes in practice.

The PDG noted that effectiveness can vary according to the context. For example interventions carried out as part of a major research study such as the Diabetes Prevention Programme produced greater changes in behaviour and modifiable risk factors than intervention carried out in real life settings.

Where possible, recommendations were linked to evidence statements (see [appendix C](#) for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

The draft guidance, including the recommendations, was released for consultation in June 2012. At its meeting in February 2012 the PDG amended the guidance in light of comments from stakeholders and experts and the fieldwork. The guidance was signed off by the NICE Guidance Executive in May 2012.

Appendix C The evidence

This appendix lists the evidence statements from four reviews provided by the public health collaborating centre (see [appendix A](#) and [appendix E](#)) and links them to the relevant recommendations. See [appendix B](#) for the meaning of the (++), (+) and (-) quality assessments referred to in the evidence statements.

Appendix C also lists eight expert reports and their links to the recommendations and sets out a brief summary of findings from the economic analysis and the fieldwork.

The evidence statements are short summaries of evidence, in a review, report or paper (provided by an expert in the topic area). Each statement has a short code indicating which document the evidence has come from. The letter(s) in the code refer to the type of document the statement is from, and the numbers refer to the document number, and the number of the evidence statement in the document.

Evidence statement number 1.8 indicates that the linked statement is numbered 8 in review 1.
Evidence statement 3.5 indicates that the linked statement is numbered 5 in review 3.

The four reviews are:

- Review 1: 'Preventing the progression of pre-diabetes to type 2 diabetes in adults. Identification and risk assessment of adults with pre-diabetes'
- Review 2: 'Prevention of type 2 diabetes: systematic review and meta-analysis of lifestyle, pharmacological and surgical interventions'
- Review 3: 'Prevention of type 2 diabetes: reviewing mechanisms of successful interventions and translation of major trial evidence to practice'
- Review 4: Prevention of type 2 diabetes: views, barriers and facilitators that may affect the implementation and effectiveness of interventions'

The reviews and economic analysis are available at the [NICE website](#). Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by **IDE** (inference derived from the evidence).

Where the Programme Development Group (PDG) has considered other evidence, it is linked to the appropriate recommendation below. It is also listed in the additional evidence section of this appendix.

Recommendation 1: evidence statements 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.10, 1.11, 1.13, 1.14, 1.15, 1.18, 1.19, 2.1, 3.1, 3.5, 3.6, 4.1, 4.2, 4.3, 4.4, 4.5, 4.11, 4.12; Additional evidence: cost-effectiveness review, expert paper 1, expert paper 6

Recommendation 2: evidence statements 1.1, 1.5, 1.6, 1.7, 4.1, 4.3, 4.4, 4.5, 4.11, 4.12; Additional evidence: expert paper 1, expert paper 6, commissioned report

Recommendation 3: evidence statements 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.19, 4.5; Additional evidence: cost-effectiveness review, expert paper 1, expert paper 6

Recommendation 4: evidence statements 1.10, 1.11, 1.13, 1.14, 1.15, 1.18, 1.19, 4.5; Additional evidence: cost-effectiveness review, expert paper 1, expert paper 3, expert paper 6

Recommendation 5: evidence statements 2.1, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.5, 4.9, 4.10, 4.11, 4.12, 4.13, 4.15, 4.16, 4.17; Additional evidence: expert paper 2, expert paper 7

Recommendation 6: evidence statements 4.4, 4.17, 4.18; Additional evidence: cost-effectiveness review

Recommendation 7 : evidence statements 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 3.1, 3.2, 3.3, 3.4, 3.11, 3.20, 3.27, 4.7, 4.9, 4.13, 4.14, 4.19; Additional evidence: commissioned report, expert paper 2, expert paper 7

Recommendation 8: evidence statements 2.1, 3.2, 3.3, 3.8, 3.9, 3.10, 4.3, 4.5, 4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.14, 4.15, 4.16, 4.17, 4.18, 4.19; Additional evidence: expert paper 8

Recommendation 9: evidence statements 2.1, 2.6, 2.7, 2.8, 2.9, 2.10, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.8, 3.9, 3.10, 3.11, 3.13, 3.14, 3.15, 3.16, 3.17, 3.18, 3.19, 3.20, 3.22, 3.23, 3.24, 3.25, 3.28, 3.29, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.14, 4.16, 4.17, 4.18; Additional evidence: expert paper 2, expert paper 3, expert paper 5, expert paper 7

Recommendation 10: evidence statements 1.19, 2.6, 2.7, 2.9, 2.10, 4.15, 4.17

Recommendation 11: evidence statements 2.1, 2.3, 2.4, 2.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, 3.17, 4.8, 4.9; Additional evidence: expert paper 2, expert paper 4, expert paper 5, expert paper 7

Recommendation 12: evidence statements 2.1, 2.3, 2.4, 2.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11, 3.17, 4.8, 4.10, 4.14, 4.15, 4.16, 4.18, 4.19; Additional evidence: expert paper 2, expert paper 4, expert paper 5, expert paper 7

Recommendation 13: evidence statements 2.1, 2.2, 2.6, 2.7, 2.10, 3.1, 3.2, 3.5, 3.6, 3.8, 3.10, 3.11, 3.14, 3.15, 3.16, 3.17, 3.19, 3.20, 4.9, 4.13, 4.18; Additional evidence: expert paper 2, expert paper 5, expert paper 7

Recommendation 14: evidence statements 2.1, 2.3, 2.4, 2.5, 2.6, 2.7, 2.10, 3.5, 3.8, 3.11, 4.7, 4.9, 4.10, 4.13, 4.15, 4.18; Additional evidence: commissioned report, expert paper 2, expert paper 5, expert paper 7; IDE

Recommendation 15: Additional evidence: commissioned report; IDE

Recommendation 16: Additional evidence: commissioned report; IDE

Recommendation 17: IDE

Recommendation 18: evidence statements 1.7, 3.2, 3.3, 3.8, 4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.17, 4.18; Additional evidence: commissioned report; IDE

Recommendation 19: evidence statements 2.2, 2.5, 2.9; Additional evidence: cost-effectiveness review

Recommendation 20: evidence statements 2.2, 2.6, 2.7, 3.4

Evidence statements

Please note that the wording of some evidence statements has been altered slightly from those in the evidence review(s) to make them more consistent with each other and NICE's standard house style. The superscript numbers refer to the studies cited beneath each statement. The full references for those studies can be found in the reviews.

Evidence statement 1.1 Approaches to identification based on demographic and routine data

There was moderate evidence of the usefulness of demographic data from routine medical recording systems in identifying people at risk of impaired fasting glucose (IFG) from two observational studies (both [+]) conducted in the UK and the Netherlands^{1,2}. The studies were carried out with mainly Caucasian patient populations and used data on characteristics associated with diabetes risk.

An overall uptake rate of 61% (95% confidence interval [CI] 55.7–65.6) from 15 UK GP practices was reported¹. There was no reported response bias associated with age or gender. BMI data was available in 76.8% (95% CI 71.7–81.9) of cases. There was data misclassification in 20% of these cases. Of the 199 participants with abnormal blood glucose, 100% attended for a follow-up blood test.

The electronic medical record (EMR) with additional risk assessment was successful in identifying risk in 28% of the total population from 11 general practices².

These studies are directly applicable to the UK context, with one being based in the UK. One study was based in the Netherlands. Both studies sampled from general practice populations, though the majority of the samples were Caucasian. Feasibility of the strategy is good since the aim is utilisation of available data.

¹ Greaves et al. 2004.

² Woolthuis et al. 2007.

Evidence statement 1.2 Barriers and facilitators to identification based on demographic and routine data

There was moderate evidence from two observational studies (both [+]) that barriers to using routine data for identification of pre-diabetes risk are inconsistent and inaccurate record keeping. In particular, data referring to obesity and family medical history was often missing, requiring that the practitioner complete the records during patient visits^{1,2}. These studies are directly applicable to the UK context, with one being based in the UK. One study was based in the Netherlands. Both studies sampled from general practice populations, though the majority of the samples were Caucasian. Feasibility of the strategy is good since the aim is utilisation of available data.

¹ Greaves et al. 2004.

² Woolthuis et al. 2007.

Evidence statement 1.3 Approaches to identification based on validated scores for demographic and routine data

There was moderate evidence from two studies for the relative performance of the Cambridge risk score (CRS) (both [+]) conducted in the UK and Denmark^{1, 2}.

One UK evaluation utilised a survey sample of people aged 45 years¹. Of the 84% of respondents that received an HbA_{1c} measurement, 3% were identified as having HbA_{1c} the same or greater than 6.0%. The Cambridge risk score at a cut-off the same or greater than 0.128 was reported to have sensitivity of 78.2%, specificity 63.9%, positive predictive value (PPV) 6.4% (no negative predictive value [NPV] reported), and area under the curve 0.76 for identifying hyperglycaemia (HbA_{1c} the same or greater than 6.0%). A total of 22.6% of the sample were identified as at risk for diabetes compared to BMI alone which identified 23.7%.

An evaluation of the CRS in a general practice population² with a 69% response rate to the initial questionnaire found that 42% of the sample had impaired glucose regulation (IFG and/or impaired glucose tolerance [IGT]) based on assessment of high risk. An optimal cut-off of the same or greater than 0.246 on the risk score gave sensitivity 47.1%, specificity 83.9%, PPV 29.8%, NPV 91.6%, area under the curve 0.74.

These studies are partially applicable to the UK context, with one being based on a UK survey focusing on mid-life women. One study was carried out in a Danish general practice population; characteristics of the sample were not reported. Feasibility of the strategy is good as the risk score was developed in the UK and was designed for use with available data. However, applicability to specific populations other than midlife women cannot be assessed.

¹ Thomas et al. 2006.

² Heldegaard et al. 2006.

Evidence statement 1.4 Barriers and facilitators to identification based on validated scores for demographic and routine data

There was moderate evidence from one study (+)¹ conducted in Denmark that validated scores developed from demographic and routine data (such as the Cambridge risk score) was a convenient method of identifying high-risk individuals. This method does not require a questionnaire to be completed by patients.

This study is partially applicable to the UK context. It was carried out in a Danish general practice population; characteristics of the sample were not reported. Feasibility of the strategy is good as the risk score was developed in the UK and was designed for use with available data. However, applicability to specific populations other than mid-life women cannot be assessed.

¹ Heldegaard et al. 2006.

Evidence statement 1.5 Questionnaire risk scores for the identification of pre-diabetes using adapted versions of the Finnish self-assessment questionnaire (FINDRISC)

There was strong evidence from four studies (one [++] and three [+]) two from Finland, one from Italy and one from the UK of the FINDRISC score^{1, 2, 3, 4}.

The eight-item FINDRISC score¹ with a maximum score of 26 was more sensitive and specific at cut-off point 11 for women than for men in a general population survey for identifying abnormal glucose tolerance (IFG/IGT). The PPV was higher for men (65.9 at cut-off point 11 compared to 45.2 for women) The NPV was correspondingly lower in men (57.7 compared to 72.4). The area under the curve (AuC) was 0.65 in men and 0.66 in women.

The Italian diabetes risk score², adapted for a CVD risk population, had a 77% specificity, 45% specificity at cut-off point 9 for identifying diabetes or IGT, with PPV 48%, AuC 0.67.

A shortened German version³ with a maximum score of 23 was more sensitive and specific at cut-off point 12 than the Finnish version at identifying IFG/IGT in a population with a family history of type 2 diabetes. There was evidence of good association between progressively higher scores and disease progression ($p < 0.01$). 1996 data produced an optimal cut-off point of 12 with 77.5% sensitivity and 67.8% specificity, PPV 19.7% and NPV 96.8%, AuC 0.78. 1997 data

produced an optimal cut-off point of 9, with sensitivity 72.7%, specificity 68.2%, PPV 29.4 and NPV 88.1, AuC 0.74.

In the UK, the Leicester risk assessment (LRA)⁴ with a maximum score of 47 aimed to identify impaired glucose regulation/type 2 diabetes in a lay multi-ethnic population. A sensitivity of 72.1% and specificity 54.1% at cut-off point 16 was reported, with a PPV of 27.7% and an NPV of 88.8%. AuC was not reported.

These studies are partially applicable to the UK context, with one being based in the UK and focusing on multi-ethnic populations. The other three were carried out in EU populations. Feasibility of the LRA is good as the risk score was developed in the UK, though for a specific at-risk population. Two studies were carried out in European countries, with one adapting the score for an at-risk population. Applicability of the FINDRISC may depend upon adaptation to the target population.

¹ Saaristo et al. 2005.

² Franciosi et al. 2005.

³ Schwarz et al. 2007.

⁴ Gray et al. 2010.

Evidence statement 1.6 Questionnaire-based risk scores for the identification of pre-diabetes

There was moderate evidence from three studies (all [+]), two conducted in the US and one in Denmark relating to questionnaire-based risk scores^{1, 3, 4}.

In one US population survey study¹ the US diabetes risk calculator at cut-off point 0.254 had a similar sensitivity (75%) but higher specificity (65%) for identifying IFG/IGT as the Italian diabetes risk calculator (77% and 45% respectively) at a cut-off point of 9 for identifying glucose abnormalities². PPVs were similar at 49% and 48% respectively. NPVs were 85% and 76% respectively.

The Danish diabetes risk score³ at cut-off point 31 and with 50% uptake had sensitivities between 45.2% and 47.8% across the two study groups and pilot. No other data for identifying IGT was given.

The seven-item American Diabetes Association (ADA) questionnaire at cut-off point the same or greater than 10 gave a maximum specificity of 54% for dysglycaemia in a general US population⁴.

These studies are less applicable to the UK context, with none being based in the UK. Implications of feasibility within the UK health service compared with, in particular, the US are therefore a consideration. However, all the studies were carried out in Organisation for Economic Cooperation and Development (OECD) countries.

¹ Heikes et al. 2008.

² Franciosi et al. 2005.

³ Glumer et al. 2004.

⁴ Rolka et al. 2001.

Evidence statement 1.7 Barriers and facilitators to the use of questionnaire-based risk scores for the identification of pre-diabetes

There was strong evidence from one study conducted in Finland (++) to suggest that asking patients to complete a questionnaire-based risk score may require someone to supervise the process. Such supervision has an impact on available resources¹.

These studies are less applicable to the UK context, with none being based in the UK. Implications of feasibility within the UK health service compared with, in particular, the US are therefore a consideration. However, all the studies were carried out in OECD countries.

¹ Saaristo et al. 2005.

Evidence statement 1.10 Studies assessing fasting plasma glucose (FPG)

There was moderate evidence from two studies (both [+]) one conducted in Mexico the other in Italy – relating to the use of FPG measures.

When using FPG to identify IGT, lowering the FPG criterion to 5.6 mmol/l from 6.1–6.9 mmol/l increased the sensitivity from 32.9% to 82%, but lowered specificity from 82.7 to 64.2%, with a related increase in PPV from 31% to 37.5%¹.

Different levels of sensitivity and specificity for men and women were found when identifying IGT using a cut-off point of 6.1 mmol/l, (sensitivity 40.9% and 29.0% respectively; specificity 25.0% and 18.0%). PPV and NPV were not reported².

These studies are partially applicable to the UK context, with one being carried out in Mexico where the target population and the health care system is very different from the UK. One study was carried out in Italy which may differ from the UK in terms of healthcare delivery, but the target population is characteristically similar.

¹ Guerreo-Romero 2006.

² Mannucci et al. 2003.

Evidence statement 1.11 Studies assessing HbA_{1c} alone

There was strong evidence for the performance of HbA_{1c} from four studies (one [++] and three [+]) conducted in the UK, China, India and Germany.

One UK study population, two Asian general population studies and one German high-risk population used HbA_{1c} alone at a range of optimal cut-off points (5.6–6.4%). The range for reported sensitivities was 39% and 65.6% and for specificities was 56.5–84%^{1,2,3,4}.

Lower sensitivities and higher specificities were associated with higher cut-off points. The highest specificity (84%) and PPV (79%) for the highest cut-off point (6.0%) were obtained in a German population at high risk (hypertensive)⁴. One UK study found that the optimal cut-off point and corresponding specificity was higher in south Asian groups than in white Europeans for detection of IGR (PPV 50%)¹. A sensitivity of 65.1%, specificity 63.4% was obtained using the ADA

criterion for identification of IFG (cut-off point 5.6%) in an Indian general population³. However the PPV was only 8.0% as the sample identified with IFG was very small.

Since these studies were published, the World Health Organization has issued a statement that HbA_{1c} at cut-off point 6.5% can be used, in optimal conditions, to diagnose type 2 diabetes.

These studies are partially applicable to the UK context, with one study being carried out in the UK. One study was carried out in a German general practice which may differ from the UK in terms of healthcare delivery, but the target population is characteristically similar. Two studies were carried out in Asia. Feasibility of the test is high with no requirement for fasting.

¹ Mostafa et al. 2010.

² Zhou et al. 2009.

³ Mohan et al. 2010.

⁴ Luders et al. 2005.

Evidence statement 1.13 Studies comparing fasting blood glucose (fasting capillary glucose/fasting plasma glucose) and HbA_{1c} tests

Moderate evidence was available from seven studies (six [+] and one [-]) that compared fasting glucose testing with HbA_{1c} conducted in Poland, China, Japan, US and Germany. All fasting blood measures were taken from plasma apart from one study¹ that measured capillary blood.

In six studies of high-risk populations, FCG/FPG with cut-off points ranging from 5.5 mmol/l to 6.1 mmol/l and HbA_{1c} cut-off points ranging from 5.3% to 6.1%^{1, 3, 4, 5, 6}, the highest sensitivity was for the FPG in a Japanese trial population (69%) using a cut-off point of 5.7 mmol/l⁴. The highest specificity was 99% (obtained via capillary testing applying a low cut-off point of 5.5 mmol/l) and with plasma testing at cut-off point 6.1 mmol/l following risk assessment (100%)¹.

The highest positive predictive value was 79% (NPV 66%) for HbA_{1c} at a cut-off point of 6.0% in a German high-risk population⁶. Sensitivity and specificity were 58% and 84% with AuC 0.614.

Two studies were carried out in the general population^{2, 7}, they used different cut-off points the same or greater than 5.3 mmol/l² and 6.1 mmol/l⁷ for FPG, but the same cut-off point of 5.3% for

HbA_{1c}^{2, 7}. The reported sensitivity for FPG was 66.3%² and 34.6%⁷ and for HbA_{1c} the reported sensitivity was 50.9%² and 42.0%⁷. For FPG the PPV was 36.8% and for HbA_{1c} 46.6%, with an AuC of 0.88 and 0.68, (specificity and NPV were not reported)². In an Australian study, PPV for FPG was 45.5% with an NPV of 100%, for HbA_{1c} PPV 43.2%, (NPV for HbA_{1c} was not reported)⁷.

Since these studies were published, the World Health Organization has issued a statement that HbA_{1c} at cut-off point 6.5% can be used, in optimal conditions, to diagnose type 2 diabetes.

Six of these studies are partially applicable to the UK context, having been carried out in OECD countries. However, healthcare delivery and prevalence for pre-diabetes may differ from the UK, particularly in the Maori and US populations. One study was carried out in China, where the characteristics of the healthcare system and the target population may be very different from the UK.

¹ Herdzyk et al. 2002.

² Simmons 2004.

³ Hu et al. 2009.

⁴ Gomyo 2004.

⁵ Saydah 2002.

⁶ Luders 2005.

⁷ Colagiuri 2004.

Evidence statement 1.14 Studies assessing a combination of fasting blood glucose indicators and HbA_{1c}

Moderate evidence was found in three studies (all [+]) that assessed the combined performances of FBG and HbA_{1c} indicators in high-risk populations conducted in China, Germany and Australia^{1, 2, 3}.

Sensitivity and PPV were highest (61%, 78%) with a combination of FPG cut-off point 6.1 mmol/l and HbA_{1c} 6.0%². Specificities were high in all three studies (greater than 78%), though not as

high as for HbA_{1c} alone in one study². The highest specificity (88.4%) was obtained following assessment of risk factors in a stepped strategy³.

It may therefore be beneficial to combine tests in a staged strategy.

Since these studies were published, the World Health Organization has issued a statement that HbA_{1c} at cut-off point 6.5% can be used, in optimal conditions, to diagnose type 2 diabetes.

Two of these studies are partially applicable to the UK context, having been carried out in OECD countries. However, healthcare delivery and prevalence for pre-diabetes may differ from the UK. One study was carried out in China, where the characteristics of the healthcare system and the target population may be very different from the UK.

¹Hu et al. 2009.

²Luders et al. 2005.

³Coligiuri et al. 2004.

Evidence statement 1.15 Stepped/multi-component strategies

Moderate to good evidence (one [++], five [+]) was found from six studies of multi-component/staged strategies to identify IGT/IFG^{1, 2, 3, 4, 5, 6}.

Three studies were carried out in at-risk populations in Germany, France and Italy^{1, 2, 3}. All six studies utilised assessment of risk prior to evaluation of one or more blood glucose indicators. A combination of FPG cut-off point 6.1 mmol/l, HbA_{1c} cut-off point 6.0% and risk assessment for age gave a sensitivity of 82%, specificity 76%, PPV 79% in one study (++)¹. This compares to sensitivity 58%, specificity 84% for HbA_{1c} alone (the same or greater than 6% cut-off point) and 62%, 57% for FPG alone (6.1 mmol/l cut-off point).

One study³ reported increased specificity (65% at cut-off point the same or greater than 5.6 mmol/l and 84% at cut-off point the same or greater than 6.1 mmol/l) with the addition of the diabetes risk score to FBG compared to the risk score (45% at cut-off point 9) or FBG alone (44% at cut-off point the same or greater than 5.6 mmol, 75% at cut-off point the same or greater than 6.1 mmol/l). PPV was highest (69%) for the FBG at the same or greater than 6.1 mmol/l and the risk score, with NPV 74%. AuC was not reported for this combination.

A similar specificity for the addition of the ADA questionnaire (94–5%) to capillary blood glucose testing at cut-off point 7.8 mmol/l (96–7%) was found, which was higher than that for the ADA questionnaire alone (51–4%) at cut-off point the same or greater than 10⁴. Sensitivity reduced with each stage, from 72–8% for the questionnaire alone, to 28–41% and 32–45% for the capillary blood glucose (CBG) and the CBG with the questionnaire. PPV, NPV and AuC were not reported.

Since these studies were published, the World Health Organization has issued a statement that HbA_{1c} at cut-off point 6.5% can be used, in optimal conditions, to diagnose type 2 diabetes.

All of these studies are partially applicable to the UK context, having been carried out in OECD countries. The target populations will be relatively similar to those in the UK, though health systems may vary.

¹Lidfelt et al. 2001.

²Luders et al. 2005.

³Franciosi et al. 2005.

⁴Rolka et al. 2001.

⁵Colagiuri et al. 2004.

⁶Simmons et al. 2004.

Evidence statement 1.18 Uptake

Moderate evidence was found from nine studies (eight [+] and one[-]) two conducted in the UK, two in the US, two in India and one each in Denmark, New Zealand and China. For risk assessment, response rates ranged between 50% and 89%. The highest response rate reported was for the Cambridge risk score⁸ and the lowest reported was for the diabetes risk score¹. In an evaluation of the Leicester risk assessment, 22% of the initial South Asian sample remained in the study following a series of tests including the OGTT².

For blood glucose measures, there was a 52.5% response rate to the first visit for a 1-hour oral glucose tolerance test⁴. Random/point-of-care testing was reported to have a response rate of 89%⁷ and 61%⁵.

Response rates for assessment of the HbA_{1c} were reported as 87%⁹ and 93%³, though the Chinese-based study also included assessment of fasting blood glucose, for which there was a response of 91%⁹.

When OGTT, fasting blood glucose and HbA_{1c} measures were performed from one blood sample⁶ the response rate was 68% in those aged 40–59 years and 71% in those aged 60–79 years. There were no reported differences in response between Maori, European and Pacific islander groups or between age groups. Response rate was reported to be similar between males and females apart from in the European group, where males were less likely to respond (66.5% rate compared to females 73.9%, $p=0.012$).

These studies are partially applicable to the UK context, with two being carried out in the UK. In the remaining studies, healthcare delivery and prevalence for pre-diabetes may differ from the UK. Uptake rates may differ due to a range of factors, including targeting a study population rather than the general population.

¹ Glumer et al. 2004.

² Gray et al. 2010.

³ Mohan et al. 2007.

⁴ Phillips et al. 2009.

⁵ Rush et al. 2008.

⁶ Simmons et al. 2004.

⁷ Somanavaar 2009.

⁸ Thomas et al. 2006.

⁹ Zhou et al. 2010.

Evidence statement 1.19 Barriers and facilitators to uptake for strategies for identification of pre-diabetes

Potential facilitators to increasing uptake were suggested in two studies (both [+]). Carrying out risk assessment in a familiar clinic environment was identified as a facilitator¹. A good uptake rate was considered to be due to confirmation of appointments and follow-up contact with patients by telephone².

These studies are directly applicable to the UK context, with one being based in the UK. One study was based in the Netherlands. Both studies sampled from general practice populations, though the majority of the samples were Caucasian.

¹ Woolthuis et al. 2007.

² Greaves et al. 2004.

Evidence statement 2.1 Lifestyle interventions

A meta-analysis of hazard ratios (HR) shows that lifestyle interventions (pooled HR 0.51 95% CI 0.43–0.62) can reduce the progress to diabetes for people with IGT. Each type of lifestyle intervention, whether diet (HR 0.67 95% CI 0.49–0.92), exercise (0.53 95% CI 0.34–0.83), or a combination of diet and exercise (HR 0.47 95% CI 0.37–0.59) had a beneficial effect, although a combination of diet and exercise appeared to have more effect than either diet or exercise alone.

The HR for diet-only interventions was based on three studies, one (+) UK¹, one (++) Chinese² and one (-) Australian³. The hazard ratio for exercise-only intervention was based on one (++) Chinese study². The hazard ratio for the diet combined with exercise intervention was based on nine studies, one study in each of the following countries, UK⁴ (++) , Japan⁵ (++) , China⁶ (-), India⁷ (++) , Netherlands⁸ (++) , Finland⁹ (++) , Sweden¹⁰ (++) and two US studies (one [++]¹¹ and one [+]¹²).

¹ Jarrett et al. 1979.

² Da Qing et al. 1997.

³Wein et al. 1999.

⁴Penn et al. 2009.

⁵Kosaka et al. 2005.

⁶Li et al. 2008.

⁷Ramachandran et al. 2008.

⁸Roumen et al. 2008.

⁹Lindstrom et al. 2006.

¹⁰Lindahl et al. 2009.

¹¹Diabetes Prevention Program Research Group 2009.

¹²Liao et al. 2002.

Evidence statement 2.2 Pharmacological interventions

The meta-analysis of hazard ratios shows that pharmacological interventions (pooled HR 0.64 95% CI 0.53–0.76) can reduce the progress to diabetes for people with IGT. Both types of intervention, oral diabetes drugs (HR 0.60 95% CI 0.44–0.82), and anti-obesity drugs (HR 0.67 95% CI 0.55–0.81) had a beneficial effect.

The HR for oral diabetes drugs was based on twelve studies: three multi-country studies (all [++])^{1, 2, 3}; studies in each of the following countries – Canada/Europe⁴ (one [++]), Finland⁵ (one [++]), Japan⁶ (one [++]), US (one [++]⁷ and one [+]⁸); two Indian^{9, 10} (both [++]) and two Chinese^{11, 12} (both [++]).

For anti-obesity drugs, the HR was based on two studies, one US/Europe¹³ (++) and one Swedish¹⁴ (++).

¹Dream Trial Investigators 2006.

² NAVIGATOR Study Group^a 2010.

³ NAVIGATOR Study Group^b 2010.

⁴ Chiasson et al. 2002.

⁵ Erkkisson et al. 2006.

⁶ Kawamori et al. 2009.

⁷ Diabetes Prevention Program Research Group 2009.

⁸ DeFronzo et al. 2011.

⁹ Ramachandran et al. 2006.

¹⁰ Ramachandran et al. 2009.

¹¹ Li et al. 1999.

¹² Pan et al. 2003.

¹³ Heymsfield et al. 2000.

¹⁴ Torgerson et al. 2004.

Evidence statement 2.3 Network meta-analysis

The network meta-analysis comparison of the effect of diet only and diet plus exercise for short-term and medium-term interventions showed a greater effect in short-term studies (diet versus placebo: population HR 0.63 95% credible intervals (CrI) 0.29–1.34; diet plus exercise versus placebo: population HR 0.43 95% CrI 0.31–0.59) compared to medium-term studies (diet versus placebo: population HR 0.73 95% CrI 0.37–1.79; diet plus exercise versus placebo: population HR 0.56 95% CrI 0.30–0.93).

The network meta-analysis comparison of diet versus placebo incorporates indirect evidence about the treatment effect from related studies as well as direct evidence from one short-term

study (-)¹ and two mid-term studies (one [++]² and one[+]³). The network meta-analysis comparison of diet plus exercise versus placebo incorporates indirect evidence about the treatment effect from related studies as well as direct evidence from five short-term studies (four [++]^{4, 5, 6, 7} and one [+]⁸) and three medium-term studies (all [++])^{9, 10, 11}.

¹ Wein et al. 1999.

² Pan et al. 1997.

³ Jarrett et al. 1979.

⁴ Roumen et al. 2008.

⁵ Ramachandran et al. 2006.

⁶ Kosaka et al. 2005.

⁷ Knowler et al. 2002.

⁸ Liao et al. 2002.

⁹ Lindahl et al. 2009.

¹⁰ Penn et al. 2009.

¹¹ Lindstrom et al. 2006.

Evidence statement 2.4 Probability of treatment ranking

The network meta-analysis of the short-term trials showed that, of all 12 interventions being compared, diet plus exercise plus 0.6 mg voglibose (daily) had the greatest probability of being the most effective intervention (probability=0.589) followed by diet plus exercise plus 20 mg pioglitazone (daily) (probability=0.324). When considering the evidence in the network meta-analysis about lifestyle interventions, diet plus exercise had the greatest probability of being the most effective intervention (probability=0.900).

For the mid-term trials, the network meta-analysis showed that, of all interventions being compared, diet plus 50 mg phenformin had the greatest probability of being the most effective intervention (probability 0.345), followed by diet plus exercise plus up to 60 mg nateglinide (3 times daily) (probability 0.338) and 50 mg phenformin (probability 0.153). When considering the evidence in the network meta-analysis about lifestyle interventions, diet plus exercise had the greatest probability of being the most effective intervention (probability 0.812).

There was insufficient evidence over the short and mid-term to suggest that age and BMI were treatment effect modifiers.

Evidence statement 2.5 South Asian populations

For populations comprising of south Asian individuals (Asian Indian, Chinese, Japanese and Japanese Americans), both a diet combined with exercise intervention and oral diabetes drug interventions have an effect on the progression from IGT to diabetes. The diet and exercise lifestyle intervention seems to have more effect on the progression from IGT to diabetes (overall pooled effect of 0.58, 95% CI 0.47–0.73), than pharmacological interventions (overall pooled effect of 0.72, 95% CI 0.52–0.99).

The hazard ratio for diet combined with exercise intervention was based on five studies in the following countries: US¹ (+), Japan² (++) , India³ (++) and China (one [++]⁴; and one[-]⁵).

For oral diabetes drugs, the hazard ratio was based on four studies in the following countries: Japan⁶ (++) , India⁷ (++) and China^{8,9} (both [++]).

¹ Liao et al. 2002.

² Kosaka et al. 2005.

³ Ramachandran et al. 2006.

⁴ Li et al. 1997.

⁵ Li et al. 2008.

⁶ Kawamori et al. 2009.

⁷ Ramachandran et al. 2009.

⁸ Li et al. 1999.

⁹ Pan et al. 2003.

Evidence statement 2.6 Reduction in BMI

In the short term (2 to 5 years), both lifestyle intervention and pharmacological interventions, showed a greater reduction in BMI than control groups. Lifestyle interventions (range -1.3 to +0.8) had a smaller range effect on BMI than pharmacological interventions (range -1.6 to +1.4).

The changes in BMI in the diet intervention are based on one Australian study (-)¹ and the diet combined with lifestyle interventions are based on four studies: US² (+), Finland³ (++) , Netherlands⁴ (++) and Sweden⁵ (++) . The changes in BMI in pharmacological studies are based on four studies: China⁶ (++) , India⁷ (++) , US⁸ (+) and Finland⁹ (++) .

¹ Wein et al. 1999.

² Liao et al. 2002.

³ Lindstrom et al. 2003.

⁴ Roumen et al. 2008.

⁵ Lindahl et al. 2009.

⁶ Li et al. 1999.

⁷ Ramachandran et al. 2009.

⁸ DeFronzo et al. 2011.

⁹ Eriksson et al. 2006.

Evidence statement 2.7 Weight change

In the short term (2 to 5 years), both lifestyle intervention and pharmacological interventions showed a greater weight change than control groups. Lifestyle interventions appear to have a greater weight change (range -5.6 kg to +0.16 kg) than pharmacological interventions (range -2.9 kg to +3.8 kg).

The changes in weight in lifestyle interventions were based on seven studies: Sweden¹ (++) , Netherlands² (++) , Japan³ (++) , US (one [++]⁴ and one [+] ⁵) and Finland (both [++]^{6, 7}).

The changes in weight in pharmacological interventions were based on nine studies: two multi-country studies (both [++]^{8, 9}), Canada/Europe¹⁰ (++) , US/Europe¹¹ (++) , two US studies (one [++]⁴ and one [+] ¹²), Sweden¹³ (++) , India¹⁴ (++) and China¹⁵ (++) .

Maintenance of the weight loss was mentioned briefly by three studies, with one (++) Finnish study⁶, saying weight maintenance was satisfactory and two studies – one (++) Japanese³ and one (++) Netherlands² saying weight decreased after 1 year but increased slightly afterwards.

¹ Lindhal et al. 2009.

² Roumen et al. 2008.

³ Kosaka et al. 2005.

⁴ Knowler et al. 2002.

⁵ Liao et al. 2002.

⁶ Lindstrom et al. 2003.

⁷ Lindstrom et al. 2006.

⁸ NAVIGATOR Study Group^a 2010.

⁹ NAVIGATOR Study Group^b 2010.

¹⁰ Chiasson et al. 2002.

¹¹ Heymsfield et al. 2000.

¹² DeFronzo et al. 2011.

¹³ Torgerson et al. 2004.

¹⁴ Ramachandran et al. 2009.

¹⁵ Pan et al. 2003.

Evidence statement 2.8 Change in blood pressure

In the short term (2 to 5 years), both lifestyle and pharmacological interventions showed a slightly greater reduction in systolic blood pressure (a range of -10.0 to 4.4 mmHg, compared to a range of -4.3 to 5.5 mmHg) and diastolic blood pressure than control groups (a range of -6.2 to 2.0 mmHg, compared to a range of -4.0 to 3.6 mmHg).

In the long term, based on one study with a 20-year follow-up, the diet and exercise intervention had a slightly smaller increase in systolic blood pressure than the control group (11 mmHg and 13 mmHg respectively) as well as having a slightly greater reduction in diastolic blood pressure than the control group (-7 mmHg and -5 mmHg respectively). However, this follow-up is vastly different to the other studies in this review, and with a 20-year follow-up many of these participants would be well into their 60s and therefore a rise in blood pressure would naturally be expected.

The changes in blood pressure in lifestyle interventions were based on three studies, one (++) Swedish¹, one (-) Chinese² and one (++) study from the Netherlands³. The changes in blood pressure in pharmacological interventions were based on seven studies: Finland⁴ (++) , Sweden⁵ (++) , India⁶ (++) , US⁷ (+) , two from China (both [++])^{8, 9} and two multi-country studies (both [++])^{10, 11}.

¹ Lindahl et al. 2009.

² Li et al. 2008.

³ Roumen et al. 2008.

⁴ Eriksson et al. 2006.

⁵ Torgerson et al. 2004

⁶ Ramachandran et al. 2009.

⁷ DeFronzo et al. 2011.

⁸ Li et al. 1999.

⁹ Pan et al. 2003.

¹⁰ NAVIGATOR Study Group^b 2010.

¹¹ NAVIGATOR Study Group^a 2010.

Evidence statement 2.9 Change in blood glucose

In the short term (2 to 6 years), both lifestyle and pharmacological interventions tended to show a slightly greater reduction in fasting blood glucose and 2-hour glucose than control groups. In the long term, based on one study with a 20-year follow-up, the diet and exercise intervention had a slightly smaller increase in both fasting blood glucose and 2-hour glucose than the control group.

For diet only and exercise only interventions, these were based on one (++) Chinese study¹. The diet combined with exercise intervention was based on five studies: Netherlands² (++) , Sweden³ (++) , Finland⁴ (++) and China (one [-]⁵ and one [++]⁶). The pharmacological interventions were based on six studies: US⁷ (+), Sweden⁸ (++) , Finland⁹ (++) , China¹⁰ (++) , India¹¹ (++) and one multi country study¹² (++) .

¹ Pan et al. 1997.

² Roumen et al. 2008.

³ Lindahl et al. 2009.

⁴ Lindstrom et al. 2003.

⁵ Li et al. 2008.

⁶ Pan et al. 1997.

⁷ DeFronzo et al. 2011.

⁸ Torgerson et al. 2004.

⁹ Eriksson et al. 2006.

¹⁰ Li et al. 1999.

¹¹ Ramachandran et al. 2009.

¹² NAVIGATOR Study Group^b 2010.

Evidence statement 2.10 Change in waist circumference

Both lifestyle and pharmacological interventions tended to show a slightly greater reduction in waist circumference than control groups.

The diet combined with exercise intervention was based on four studies: Netherlands¹ (++) , Sweden² (++) , Finland³ (++) and India⁴ (++) . The pharmacological interventions were based on one (++) study from Sweden⁵.

¹ Roumen et al. 2008.

² Lindahl et al. 2009.

³ Lindstrom et al. 2003.

⁴ Ramachandran et al. 2006.

⁵ Torgerson et al. 2004.

Review 2: Applicability and transferability of evidence to the UK

This applicability statement applies to all of the evidence statements from review 2 (see above).

A total of two studies were carried out in the UK. The remaining 20 studies represent a range of populations from Europe, US, Australia, south and eastern Asia. Therefore caution is required when interpreting findings regarding the interventions carried out in populations that may have different prevalence and risk for pre-diabetes, as well as the interventions having different durations and settings.

In terms of transferability to clinical practice, it should be remembered that the lifestyle interventions in the randomised controlled trials (RCTs) in this review were generally very intensive. Also patients were sometimes selectively recruited (baseline risk levels may differ from those identified by an NHS screening programme), and patients may have been paid to participate in the RCTs resulting in a relatively high level of motivation and adherence.

Evidence statement 3.1 Intervention settings

Evidence was found from two systematic reviews of RCTs (both [++]) of diabetes prevention programmes that effective programmes can be delivered in a range of clinical (in-patient and outpatient) and community settings.

However, there is a lack of evidence that directly compares intervention effectiveness between different settings, therefore it was not possible to determine whether any particular setting is better than another in terms of outcomes, or the potential scale of the impact this might have.

One review¹ reported that four major trials delivered successful interventions (which we have defined here as delivering significant reduction in diabetes incidence or significant weight loss at a minimum of 12 months follow-up compared to controls) in clinical outpatient settings. The trials were conducted in Japan, India, Italy and China. The quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from another review² provides examples of three trials that were effective in reducing the incidence of type 2 diabetes in clinical and community settings (no further details given), as well a combination of the two. These trials were carried out in the US, Finland and China. Quality

rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials. All three trials were described as adequately powered.

Trials were carried out in a range of settings in different countries, but mainly in outpatient clinics, so there is partial applicability to UK settings. The populations that were included in the trials were at risk of type 2 diabetes and so individual effects may be transferable to the UK at-risk population.

¹Baker et al.2011.

²Norris et al.2009.

Evidence statement 3.2 Characteristics of those delivering interventions

Evidence was extracted from two systematic reviews of RCTs (both [++])^{1,2} and weak evidence from one non-systematic review of a range of study types (-)³ for an observational association of high levels of skill and/or a relevant professional qualification with intervention effectiveness for diabetes prevention.

However, there is a lack of evidence that directly compares or that statistically examines difference in intervention effectiveness between providers with different characteristics. Hence, it is not currently possible to determine the optimal characteristics of intervention providers or the scale of the impact this might have.

The two systematic reviews present the observation that high levels of skill and relevant professional qualifications were characteristics of successful interventions in a total of seven trials that resulted in a reduction of diabetes incidence. The trials were conducted in the US, Finland, China, India, Japan, Italy and Sweden^{1,2}.

In the non-systematic review based on a qualitative study of UK general practitioner knowledge, the authors suggest that awareness of the importance of reducing the incidence of type 2 diabetes as well as being able to effectively assess and counsel recipients about diet and physical activity may be important contributors to sustainable changes in diet and/or physical activity³.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the characteristics of those delivering interventions cannot be transferable to interventions carried out in the UK.

¹Baker et al.2011.

²Nield et al.2008.

³Roumen et al.2009.

Evidence statement 3.3 Mode of intervention delivery

There is evidence from one (++) systematic review of RCTs¹ relating to the mode of intervention delivery. However, there is a lack of evidence that directly compares intervention effectiveness between individual or group delivery, therefore it was not possible to determine whether individual delivery is better than group delivery in terms of outcomes, or the potential scale of the impact this might have.

The review reported that seven trials achieving a reduction in the incidence of type 2 diabetes and with a follow-up of at least 12 months delivered an initial individual assessment followed by either individual or group counselling. In five out of seven of these trials, counselling was delivered mainly on an individual basis. These trials were based in the US, Finland, Japan, India and Sweden. Two trials delivered counselling in small groups following the initial individual assessment. These trials were carried out in China and Italy. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the mode of delivery of interventions (that is, group or individual) is not transferable to interventions carried out in the UK.

¹Baker et al.2011.

Evidence statement 3.4 Frequency of contacts

Evidence was extracted from four systematic reviews of RCTs (all [+])^{1, 2, 3, 4} and one non-systematic review of lifestyle and medication studies (+)⁵. Contact is defined here as individual

face-to-face counselling, assessments or telephone contact between intervention participants and those facilitating the intervention or assessing outcomes.

There is a lack of evidence that directly compares intervention effectiveness between the frequencies of contact, therefore it was not possible to determine the potential scale of the impact that different frequencies might have.

One review¹ reported that of seven included trials that achieved successful reduction in diabetes incidence, the frequency of contacts during the first 12 months of implementation ranged from six in one Japanese trial and one Italian trial to more than 22 in one Swedish trial and one US based trial. When supervised physical activity sessions were included in one Finnish trial, this number extended to 165.

Another review² recommended access to dietary support and guidance at least 3–6-monthly based on its review of two RCTs. One trial was carried out in the Netherlands and assessed weight reduction as the primary outcome. One trial was based in China. The authors assessed the quality of these trials as quite poor based on the Jadad score.

One review³ reported total contact frequencies ranging from four (over 1 year in one trial based in the UK and France that demonstrated a small weight loss [less than 0.5 kg] compared to the control group) to 78 over 2 years in one US trial that demonstrated greater than 2 kg weight loss compared to controls. One included Finnish trial achieved a 58% reduction in relative risk for diabetes incidence with 15 contacts over 3.2 years (p less than 0.001). One Swedish-based trial assessed the effects of a 28-day residential course. The number of dietary and physical activity intervention contacts in three well powered studies (carried out in the US, Finland and China) that achieved reduction in diabetes incidence also significantly correlated with weight loss ($p=0.015$). Quality rating was not detailed, though it was noted that randomisation procedures were only described in one of the three trials.

A review of three trials⁴ carried out in the US, India, China and internationally speculated that lifestyle advice reinforced regularly might be more effective because it encourages sustained participation. Studies were assessed for risk of bias, with all four trials having at least two elements out of six that were rated as high risk. The diabetes prevention programme (DPP) (US) was rated lowest risk of bias. This trial also reported similar diabetes incidence rates at two different time points.

One non-systematic review⁵ that assessed six trials comparing lifestyle interventions or lifestyle and medication reported that successful interventions included individual counselling on at least seven sessions during the first year followed by individual or group sessions every 3 months for the remainder of the study. The trials were carried out in China, US, Finland, Brazil and internationally. One trial was carried out with women who had a history of gestational diabetes. There was no quality rating reported for the studies.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the effect of frequency of contacts is not transferable to interventions carried out in the UK.

¹Baker et al. 2011.

²Nield et al. 2008.

³Norris et al. 2007.

⁴Yuen et al. 2010.

⁵Davies et al. 2004.

Evidence statement 3.5 Dietary interventions

There was evidence from four systematic reviews of RCTs (three [++] and one [+])^{1, 2, 3, 4} and three non-systematic reviews of a range of study types (two [+] and one [-])^{5, 6, 7} for dietary components of lifestyle interventions for the prevention of type 2 diabetes.

On review¹ assessed seven RCTs in which all participants were advised individually to modify their diet. All the interventions advised a reduction in fat (with four studies carried out in the US, Finland, China and Sweden) specifying a reduction to less than 20–30% of total energy intake, and six studies advised adjustment of portion control. Four studies (carried out in the US, India, Italy and Sweden) recommended an increase in fibre intake, and all seven studies advised increased fibre intake in the form of fruit and vegetables. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from three systematic reviews of RCTs^{2, 3, 4} and one non-systematic review⁶ report similar detail from between five and nine diabetes prevention trials. These were carried out in the US, Finland, China, Japan, Sweden, Australia, India, Netherlands and the UK and aimed to sustain a weight reduction of 5–7% when combined with physical activity goals. They included the consumption of 55% total energy intake as carbohydrates; fat 30–35% of total energy with saturated fat at the same or less than 10%; protein 10–15 % of total energy intake and fibre the same or greater than 15 g per 1000 kcal. Quality ratings are not available.

There was also evidence from epidemiological studies included in two reviews of a range of study types^{4, 6} that a diet of fruits, vegetables, legumes, fish and wholegrains was associated with a lower diabetes risk. The 'Mediterranean' diet is described as rich in fat, but mainly in the form of olive oil, and includes a wide range of vegetables and legumes, fruit and nuts. They provide evidence from cohort studies, two of which were carried out in Spain and US, that adherence to the diet was associated with up to 15% reduced diabetes risk, weight maintenance or weight loss. One Spanish arm of an international cohort study reported a decreased risk for obesity at 3 years in those that adhered well to the Mediterranean diet (odds ratio [OR] 0.68, 95% CI 0.53–89 in men, OR 0.69, 95% CI 0.54–0.89 in women). These reviews did not report quality ratings for the epidemiological studies.

Epidemiological evidence from one non-systematic review of a range of study types⁵ suggests that the frequency of fruit and vegetable intake was inversely associated with HbA_{1c} levels in the UK-based EPIC study and that in the US, an increased intake of wholegrains was associated with decreased diabetes risk, though there was no clinical significance reported. Quality ratings were not reported for these studies.

Findings from reviews of epidemiological studies need to be viewed with caution due to the risk of bias.

There is a lack of quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in the incidence of type 2 diabetes and/or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular dietary intervention may have on outcomes.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the dietary advice provided is not transferable to interventions carried out in the UK.

¹Baker et al. 2011.

²Waugh et al. 2010.

³Paulweber et al. 2010.

⁴Burnet et al. 2006.

⁵Davies et al. 2004.

⁶Walker et al. 2010.

⁷Roumen et al. 2009.

Evidence statement 3.6 Physical activity interventions

Evidence was obtained from two systematic reviews of RCTs (both [++])^{1,2} and one review of randomised and non-randomised controlled trials (+)³.

Evidence is provided from five¹ and seven² RCTs in which participants had been advised to increase their level of physical activity. All trials reviewed reported a reduction in incidence of type 2 diabetes. The advice was to increase physical activity to a level of at least 150 minutes per week at moderate intensity in trials carried out in US, Italy, and Sweden. It was also reported that up to 30–40 minutes of moderate activity (for example, brisk walking) per day was advised in one trial carried out in Japan¹. The US-based and Chinese trial allowed participants to reduce the volume of activity if it was carried out more vigorously. Resistance training was included in some US and Finnish-based clinics. A Swedish trial included counselling on the importance of muscular strengthening twice a week. Supervised physical activity was included free of charge 2 days per week in the US and Finnish trials. The Swedish trial included a residential component of 2.5 hours per day for 1 month. Quality of the trials was assessed but not reported in detail; however the quality seems to be good since only trials that met threshold criteria were included in the review.

Evidence from one systematic review of randomised and non-randomised controlled trials³ suggests that, from four included RCTs that assessed the reduction of type 2 diabetes incidence (carried out in US, China, Finland and Sweden), risk of diabetes was reduced by 42–63% compared to the control groups. Quality assessment was not reported on the studies. Issues that

may have impacted on the findings include self-reporting of physical activity and use of physical activity questionnaires that lack validity.

There is a lack of good quality evidence that assesses the effect of diet and physical activity alone in trials that have demonstrated reduction in type 2 diabetes incidence and/or weight reduction. Therefore, it is difficult to make inferences about the impact that any particular form, volume or intensity of physical activity may have on outcomes.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the physical activity advice provided is not transferable to interventions carried out in the UK.

¹Baker et al. 2011.

²Paulweber et al. 2010.

³Yates et al. 2007.

Evidence statement 3.7 Intensity/duration of physical activity

Evidence exists from one (++) systematic review of RCTs¹.

There is a lack of evidence that directly compares intervention effectiveness between different intensities and duration of physical activity, therefore it was not possible to determine the potential scale of the impact that different intensities may have.

At least 150 minutes of moderate activity a week was reported as being required to have an effect on diabetes risk¹. However, even 10 minutes activity in sedentary individuals can show improvement in risk profile. There was evidence of a dose response in one Finnish trial. Those who increased their physical activity were 60% less likely to develop diabetes, though this decreased to 51% after adjusting for weight loss. Those that increased their physical activity the most were 59% less likely to develop diabetes than those with least change in exercise patterns. There was no quality assessment grading available for included studies.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the effect of frequency or duration of physical activity carried out is not transferable to interventions carried out in the UK.

¹Waugh et al. 2010.

Evidence statement 3.8 Behavioural components

There was evidence from four systematic reviews of RCTs (three [++] and one [+])^{1, 2, 3, 4} for the use of behavioural strategies to enhance effectiveness of interventions.

There is a lack of evidence that directly compares different intervention effectiveness between behavioural components, therefore it was not possible to determine the potential scale of the impact that different components may have.

An analysis of intervention versus control data was conducted in one systematic review¹. While it is stated that the trials included in the review use few behavioural strategies relating to the 'Theory of planned behaviour', there was a focus on behavioural intention and evidence of strategies that were common to more than one theoretical model. It was suggested that information and advice alone is insufficient to bring about lifestyle change compared to theoretically-based detailed lifestyle interventions such as those used in the major diabetes prevention trials. These include: providing information and tailoring programmes to individual needs; using multiple sessions to reinforce information; delivery to small groups or individuals; delivering written information as well as verbal advice; encouraging self-monitoring; and logging of physical activity, diet and weight change.

For dietary behaviour change, taking small steps and providing both observational and vicarious learning opportunities as well as encouraging the identification of barriers and problem-solving were reported as strategies used in prevention programmes that had achieved reduction in diabetes incidence. For physical activity, a prescriptive approach that gradually increased the frequency and volume of activity over time as well as providing observational and vicarious learning opportunities and encouraging self-monitoring were suggested. Three of the successful trials also included direct supervision of physical activity.

Two systematic reviews^{2, 3} included RCTs for the prevention of diabetes (carried out in the US, UK, India, France, Finland, the Netherlands and Japan) and reported on the importance of gradually increasing volume and frequency of physical activity levels and of the importance of encouragement through direct supervision. Regular reinforcement of set goals was reported as an important strategy in the early stages of an intervention.

One review⁴ from three trials carried out in the US, Finland and Sweden reported that self-monitoring through the use of regular weighing, and recorded measurement of dietary input and physical activity increased self-efficacy and empowerment. Family was a key social support in prevention efforts. Trials carried out in the US, Finland, China and Sweden encouraged spouses, where appropriate, to participate in counselling sessions.

Trials in two reviews were quality assessed and rated as generally having high risk for bias^{2, 3}.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the behavioural components of interventions are not transferable to interventions carried out in the UK.

¹Baker et al.2011.

²Norris et al.2007.

³Yuen et al. 2010.

⁴Burnet et al. 2006.

Evidence statement 3.9 Characteristics of intervention recipients

There was evidence from two systematic review of RCTs (both [++])^{1, 2} and three non-systematic reviews (two [+] and one [-])^{3, 4, 5}. No quality assessment ratings are available for the included studies within these reviews.

There is a lack of evidence that directly compares the characteristics of intervention recipients in relation to intervention effectiveness, therefore it was not possible to determine the potential scale of the impact that different characteristics may have.

A greater readiness to change physical activity levels correlated with higher levels of baseline physical activity (p less than 0.0001), 1 year and the end of one US-based trial¹. The same US trial also reported, that the sample was more physically active at baseline and at a later stage of readiness to change than a representative IGT population².

Cross-sectional evidence from one non-systematic review of a range of study types suggests that recipients that are aware of the potential impact of the lifestyle choices they make are more likely make sustained changes⁵.

One Finnish trial found that lifestyle interventions were more effective in participants who achieved more of their dietary and physical activity goals. However, these changes needed to be sustained. Overall diabetes reduction in the intensive intervention group was 58%, with no new cases of diabetes reported in those that achieved at least four of their goals⁴.

Evidence was provided from one Finnish trial of under-reporting food consumption in overweight and obese participants¹. One epidemiological study reported a risk of 'rebound' weight gain in this group if there is a reversion to pre-intervention energy intake⁴.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that the potential effect of the characteristics of participants is not transferable to the UK.

¹Waughet al.2010.

²Yuen et al.2010.

³Davies et al.2004.

⁴Walker et al.2010.

⁵Roumen et al. 2009.

Evidence statement 3.10 Strategies to encourage attendance/adherence

There was evidence from two systematic reviews of randomised controlled trials (both [++])^{1, 2} and one review of RCTs and other study types (+)³.

Three RCTs (carried out in the US, Finland and Sweden) were successful in reducing the incidence of diabetes by logging physical activity, calorie intake and fat intake to provide feedback to participants and maintain motivation. Providing free supervised physical activity sessions for the duration of the programme was implemented to encourage take-up of structured physical activity in two trials carried out in the US, and Finland. No data are available on the rate

of attendance at these sessions. While no formal quality assessment is available, included studies were required to meet minimum criteria for inclusion¹.

Adherence strategies in three US-based RCTs of physical activity were assessed². Adherence to physical activities in one RCT of 2-year duration was more likely in programmes delivered over 3–4 days rather than 5–7 days per week. Another RCT reported that lower intensity activities at 6-month follow-up were related to better adherence compared to higher intensity activity, possibly due to perceived risk of injury with high-intensity activities. Findings from a third RCT of 3-years duration with 10-year follow-up suggest that incorporating activity into daily life, such as walking regularly, might be easier to achieve than high-intensity sport. There was no quality assessment available for these studies.

There was evidence from one review of RCTs and other study types³ (no quality assessment ratings reported) that family was a key social support in prevention efforts. Three of the four trials carried out in the US, Finland, China and Sweden encouraged spouses, where appropriate, to participate in counselling sessions. While this approach has a wider value than encouraging adherence and attendance, evidence from one review of factors linking family with clinical outcomes, reports that family can affect willingness to make use of healthcare services. The three trials also incorporated follow-up efforts such as active encouragement from staff, computer monitoring and development of a personal 'toolbox' of problem-solving strategies for each participant.

Trials were carried out in a range of settings in different countries, so there is partial applicability to UK settings. There is no reason to assume that strategies carried out with the aim of encouraging attendance or adherence to interventions is not transferable to interventions carried out in the UK.

¹Baker et al.2011.

²Waugh et al. 2010.

³Burnet et al. 2006.

Evidence statement 3.11 Translational studies based on the Diabetes Prevention Programme (DPP) – modifications to the DPP interventions

There was strong evidence from 12 studies (four [++], seven [+], and one [-]) for successful modifications of the DPP protocol conducted in Germany¹ and the US^{2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12}.

One RCT¹, two pilot cluster RCTs^{2, 3}, two matched pair and one controlled cohort study^{4, 5, 6}, five pre-test/post-test single group studies^{7, 8, 9, 10}, and one non-randomised controlled feasibility trial¹¹ all adapted the DPP in a range of settings including primary care, YMCA facilities, and churches. Two studies^{10, 12} used technology such as the Internet and video conferencing to access the target audience.

Eight DPP-based studies selected populations with a raised BMI (the same or greater than 25 kg/m²).

All but one DPP-based⁷ intervention were delivered using group sessions rather than individual sessions. One study³ also provided phone-in sessions.

Three pre-test/post-test single group studies^{6, 9, 11} modified the DPP from 16 sessions to between 12–15. A further three studies delivered six or fewer sessions^{3, 4, 8}.

DPP-based sessions included both a dietary and physical activity component and all aimed to reduce body weight by 5–7% and increase physical activity to a moderate level (for example, brisk walking) for 150 minutes per week as specified in the DPP protocol. Modifications included the introduction of pedometers early in the programme than in the DPP^{9, 11}. Follow-up in the DPP-based studies ranged from 4–12 months.

The evidence is partially applicable since most studies were carried out in the US where health service delivery differs from that in the UK. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, though the YMCA network appears to be stronger in the US. There is no reason to assume that the adaptation of trial protocols in terms of mode of delivery (for example, group rather than individual) and number of sessions could not be transferred to the UK.

¹Kulzer et al.2009.

²Ackermann et al.2008.

³Whittemore et al.2009.

⁴Almeida et al. 2010.

⁵Faridi et al.2009.

⁶McTigue et al.2009a.

⁷Amundsen et al. 2009.

⁸Davis-Smith 2007.

⁹Kramer 2009.

¹⁰McTigue et al. 2009b.

¹¹Seidal et al.2008.

¹²Vadheim et al. 2010.

Evidence statement 3.13 Translational studies based on the DPP – changes in blood glucose levels

There was mixed evidence for reductions in blood glucose following interventions translated into community settings from two (++) RCTs^{1, 2} conducted in Germany and the US, one (+) pilot cluster RCT³, and two pre-test/post-test single group studies (both [+]) all conducted in the US^{4, 5}.

In one primary care-based RCT (++)¹ fasting blood glucose was reported to decrease by 4.3 mg/dl (standard deviation [SD] 11.3) over the 12 month intervention period from 105.7 mg/dl (SD 12.4) to 101.4 mg/dl (SD 11.3) in the intervention group compared to a reduction of 1.8 mg/dl (SD 13.1) in the control group (p=0.001). There was no change in HbA_{1c} in the intervention group and a rise of 0.1% in the control group (p=0.165).

Fasting blood glucose was reported to decreased by 9 mg/dl in one (+) church-based single group study and by 1.5 mg/dl (p=0.52) in a primary care-based study at 12 months⁴.

A reduction in mean HbA_{1c} of 0.1% compared to no change in the controls (p=0.28) was reported at 12 months follow-up in a (+) pilot cluster randomised controlled trial carried out using YMCA facilities³.

Rises in monthly OGTT measurements were reported to be lower in the intervention group (0.28 mg/dl) than in the control group (1.50 mg/dl) over 6 months in one (++) pilot cluster RCT though this finding was not statistically significant between groups (p=0.30)².

There was however, evidence from one (+) pre-test/post-test single group study carried out in a low socioeconomic population for an increase in those with a fasting blood glucose of the same or greater than 100 mg/dl in more than half of the sample at 3 months (51.0%) and 6 months (61.2%; p=0.06)⁵.

The evidence is only partially applicable to UK settings as most studies were carried out in the US where health service delivery differs from that in the UK. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, although the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK. Findings relating to blood glucose levels were modest; this may be part due to short follow up and part to the lower intensity of interventions as well as the range of study designs.

¹Kulzer et al.2009.

²Whittemore et al.2009.

³Ackermann et al.2008.

⁴Davis-Smith 2007.

⁵Seidal et al. 2008.

Evidence statement 3.14 Translational studies based on the DPP – weight change

There was strong evidence (three [++] and seven [+]) from 11 studies based on the DPP protocol for achievement of weight loss and weak evidence (-) from one non-randomised study of a small weight gain at 12 months^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11}.

An RCT (++) achieved a weight loss of 3.8 kg (SD 5.2) in the intervention group at 12 months, compared to 1.4 kg in the control¹. One pilot cluster randomised trial (+) achieved significant weight loss (6%) in the intervention group at 4–6 months, which was sustained at 12 months. Mean weight loss was 5.7 kg at both measurement points ($p=0.008$)².

A matched pair cohort study (++) with a large sample size ($n=1520$) found that an intervention group were 1.5 times more likely to lose more than 5% body weight than matched controls after 12 months. Mean body weight loss was 1.4 kg in the intervention group and 0.6 kg in controls ($p<0.001$)³. A pilot randomised trial (++) delivered by nurse practitioners achieved the same or greater than 5% weight loss in 25% of the intervention group compared to 11% of the control group at 6 months⁴.

One controlled cohort study (+) achieved a mean weight loss of 5.19 kg in the intervention group compared to a mean weight gain of 0.21 kg in the control group at 12 months ($p<0.001$). The intervention population were obese at baseline and the control group comprised non-enrollees onto the programme⁵.

One non-randomised controlled feasibility trial (+) compared 'tele-health' (video conferencing) with an on-site intervention, and found similar weight loss for the two groups at 16 weeks (48% versus 50%; $p=0.84$). However, in this study both groups received a lifestyle intervention⁶.

Mean weight loss in two pre-test/post-test single group studies (both [+]) was greater than 4.5 kg at 12 months. However, these studies had no comparator groups^{7, 8}. Other single group studies included one church-based single group intervention of 6-week duration (+), which achieved mean weight loss of 4.8 kg at 12 months follow-up⁹. Another that utilised the Internet to deliver the intervention (+) achieved a mean weight loss of 4.79 kg, with over 30% of those completing the intervention achieving at least 5% weight loss¹⁰. One (+) study that targeted underserved populations also achieved and sustained 5–7% weight loss in over 65% of the sample at 6 months¹¹.

No reduction in weight was found at 12 months following a church-based intervention for an African-American population. Intervention and control sites gained less than 0.5 kg, with the intervention group gaining least (0.14 kg versus 0.37 kg)¹².

The evidence is only partially applicable to UK settings as most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches and the YMCA

may be utilised for delivery of interventions within the UK, although the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK or that the protocol could not be delivered using available technologies. Longer follow-ups would be required to assess the sustainability of weight management achieved using DPP adaptations in the UK.

¹Kulzer et al. 2009.

²Ackermann et al.2008.

³Almeida et al. 2010.

⁴Whittemore et al. 2009.

⁵McTigue et al. 2009a.

⁶Vadheim et al. 2010.

⁷Kramer et al. 2009.

⁸Amundsen et al.2009.

⁹Davis-Smith 2007.

¹⁰McTigue et al.2009b.

¹¹Seidal et al. 2008.

¹²Faridi et al. 2009.

Evidence statement 3.15 Translational studies based on the DPP – changes to BMI

There was strong evidence (two [++] and four [+]) from six studies based on the DPP for reduction in BMI following intervention and mixed evidence (-) from one non-randomised study.

One (++) RCT reported a reduction in BMI of 1.3 kg/m² in the intervention group compared to 0.5 kg/m² in the control (P less than 0.002)¹. One (++) pilot cluster randomised trial carried out in YMCA settings reported a mean reduction of 6.7 kg/m² in the intervention group compared with 1.4 kg/m² at 12 months (p=0.002)². One (+) non-randomised controlled feasibility trial reported a reduction of 2.7 kg/m² in the 'tele-health' group compared to 2.5 kg/m² in the on-site group. Both of these groups received a lifestyle intervention³. One (-) non-randomised church-based study achieved reduction in BMI of 0.63 kg/m² in the intervention group compared to a gain of 0.13 kg/m² in the control group at 12 months⁴.

Three pre-test/post-test single group studies (all [+]) also found reductions in BMI. One study found a significant reduction in BMI of 1.6 kg/m² (p< 0.001) at 12 months⁵. A single group study of a church-based intervention achieved a reduction of 1.9 kg/m² at 12 months (p<0.05)⁶ and one (+) pre-test/post-test single group study achieved a significant reduction in BMI of 2.4 kg/m² after 16 weeks (p <0.001)⁷.

The evidence is only partially applicable to UK settings as most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches and the YMCA may be utilised for delivery of interventions within the UK, although the YMCA network appears to be stronger in the US. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK or that the protocol could not be delivered using available technologies. Longer follow ups would be required to assess the sustainability of BMI management achieved using DPP adaptations in the UK.

¹Kulzer et al.2009.

²Ackermann et al.2008.

³Vadheim et al.2010.

⁴Faridi et al.2009.

⁵Kramer et al.2009.

⁶Davis-Smith 2007.

⁷Amundsen et al. 2009.

Evidence statement 3.16 Translational studies based on the DPP – changes in waist circumference

Moderate evidence for reduction in waist circumference following intervention exists in three studies (one [++] and two [+]) one conducted in Germany¹ and two in the US^{2, 3}.

One (++) RCT reported a reduction of 4.1 cm (SD 11.3) in the intervention group compared to 0.4 cm in the control group¹. One (+) pre-test/post-test single group study reported significant changes in waist circumference (around -4.3 cm; $p < 0.001$) after 12 months². One (+) pre-test/post-test single group study found evidence of a reduction in abdominal obesity from 90% at baseline to 68% in their sample at 6 months ($p = 0.006$)³.

The evidence is only partially applicable to UK settings as most studies were carried out in the US and one in Germany, where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK. Longer follow-ups would be required to assess the sustainability of waist circumference reduction achieved using DPP adaptations in the UK.

¹Kulzer et al.2009.

²Kramer et al.2009.

³Seidal et al.2008.

Evidence statement 3.17 Translational studies based on the DPP – changes in achievement in goals

There was strong evidence for achieving goals following intervention from five studies (two [++], two [+] and one [-]) one conducted in Germany¹ and four conducted in US^{2, 3, 4, 5}.

One (++) RCT reported a mean increase of 46.6 (SD 95.5) minutes per week physical activity in the intervention group compared to 17.9 (SD 63.8) minutes in the control group¹. A non-randomised controlled feasibility trial (+) reported an increase in physical activity by a mean of 80 minutes from week 6 to week 16².

One (+) non-randomised controlled feasibility trial reported a greater mean weekly increase in physical activity with their on-site group (mean increase 243 minutes; SD 146) than in the 'tele-

health' group (mean 197 minutes; SD 103) ($p=0.37$). There was evidence of reduced fat intake for both intervention groups, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the 'tele-health' group (54% versus 38%) ($p=0.49$)³. A (-) non-randomised controlled trial church-based intervention targeted at an African–American sample showed greater achievements in all eight dietary goals compared to controls⁵.

A (++) pilot RCT reported a monthly increase in physical activity in both groups ($p=0.001$) with a tendency toward greater improvement in the intervention group (0.10 minutes versus 0.05 minutes) ($p=0.8$). The physical activity goal was achieved by 29% of the intervention group at baseline, rising to 46% at 6 months. This compares to almost no change in the proportion achieving physical activity goals in the control group (39% to 40%). In addition, both groups improved their dietary intake ($p=0.001$)⁴.

In terms of dietary goals, one (+) non-randomised controlled feasibility trial reported reduced fat intake following both 'tele-health' and on-site interventions, with a greater proportion of those in the on-site group achieving the goal of fat reduction compared with the 'tele-health group' (54% versus 38%) ($p=0.49$)⁴. One (++) pilot RCT reported that both intervention and control groups improved their dietary intake ($p=0.001$)⁴. A (-) non-randomised controlled trial church-based intervention showed greater achievements in all eight dietary goals compared to the control group⁵.

The evidence is only partially applicable to UK settings as most studies were carried out in the US where health service delivery differs from the NHS. Settings such as churches or the utilisation of available technologies may be adapted for delivery of interventions within the UK. There is no reason to assume that modifications of the DPP protocol could not be transferred to the UK. Longer follow-ups would be required to assess the sustainability of goals achieved using DPP adaptations in the UK.

¹Kulzer et al.2009.

²Amundsen et al.2009.

³Vadheim et al.2010.

⁴Whittemore et al.2009.

⁵Faridi et al.2009.

Evidence statement 3.18 Translational studies based on the DPP – participation/attendance/adherence

Moderate evidence for adherence to intervention aims was found from two (both [+]) pre-test/post-test single group studies conducted in the US.

One (+) study reported a mean of 10.1 (SD 4.0) weeks completion of dietary self-monitoring (range 0–14). Men were significantly more likely to complete (mean 11.6 weeks; SD 3.2) than women (9.7 weeks SD 4.1; $p=0.001$). Older participants (60 years or over) were more likely to complete their records than younger participants (10.3 weeks SD 4.7; $p=0.02$). There was an eight-fold likelihood that those completing self-monitoring during all 16 weeks of the programme would achieve their weight-loss goal (odds Ratio [OR], 7.60; 95% CI 2.75–21.01)¹.

One study reported a mean completion of 12.8 (SD 7.29) Internet-based lessons, with self-monitoring recorded on an average of 27.32 weeks over 12 months. 40% of participants reported weight online for at least 40 weeks².

The evidence is only partially applicable to UK settings as most studies were carried out in the US where health service delivery differs from the NHS. Participation in prevention studies and adherence to intervention aims would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

¹Amundsen et al. 2009.

²McTigue et al.2009b.

Evidence statement 3.19 Translational studies based on the DPP – sustainability

There was moderate evidence from one (+) pre-test/post-test single group study conducted in the US with the achievement of a 5–7% weight reduction by 46.4% of participants following the lifestyle intervention. This was sustained at 6 months follow-up (66.7% achieved 5% weight reduction and 87.5% achieved 7% reduction)¹.

The evidence is only partially applicable to UK settings as this study was carried out in the US where health service delivery differs from the NHS. Sustainability of intervention achievements would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

¹Seidal et al. 2008.

Evidence statement 3.20 Translational studies based on the Diabetes Prevention Study (DPS) –modifications to the DPS interventions

There was moderate evidence for successful modifications of the DPS protocol from three (all [+]) pre-test/post-test studies conducted in Finland^{1,3} and Australia². All three studies were set in primary care and selected populations using a risk score.

One study delivered a mix of individual and group sessions³, while two delivered just group sessions^{1,2}. They all delivered an average of six sessions over 2 months compared to the seven-session DPS protocol. Most sessions were for an average of 60 minutes.

Sessions were based on either the DPS lifestyle objectives^{1,3} or the Australian dietary guidelines².

Follow-up ranged from 12 months^{2,3} to three years¹.

The evidence is only partially applicable to UK settings as studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that the adaptation of the DPS protocol in terms of mode of delivery (for example, group rather than individual) and number of sessions could not be transferred to the UK.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2007.

Evidence statement 3.22 Translational studies based on the DPS – changes in blood glucose levels

There was moderate evidence for positive changes in blood glucose levels following intervention from three (all [+]) pre-test/post-test studies conducted in Finland^{1, 3} and Australia².

In the Finnish pre-test/post-test study the mean change in fasting plasma glucose at 12 months was +0.1 mmol/l (SD 0.6; $p < 0.001$) and at 3 years 0.0 1 mmol/l (SD 0.8; not significant). Mean change in OGTT at 12 months was +0.1 mmol/l (SD 1.7; not significant), and at 3 years +0.1 (SD 1.9; not significant). Fifty five per cent of participants had normal glucose tolerance at baseline. By year 3, 10.9% of these had developed IGT. Of the 65 participants (18%) that had IGT at baseline, 12% had developed type 2 diabetes and 43% had reverted to normal glucose tolerance at year 3¹.

The Australian pre-test/post-test study reported a mean change in fasting plasma glucose of -0.14 mmol/l (95% CI -0.20 to -0.07), at 12 months, representing a -2.5% change. Mean change in OGTT was -0.58 (95% CI -0.79 to -0.36), representing a change of -8.6%. At baseline, 66% of participants had normal baseline glucose levels and 34% had impaired levels. At 12 months, 78% had normal glucose values and 19.8% impaired values. Of the 79 who had impaired values at baseline, 42 (18%) reverted back to normal levels.

The second Finnish pre-test/post-test study did not report changes in blood glucose levels in their pre-test/post-test study. 1.6% of those with normal glucose levels at baseline developed impaired glucose tolerance at 14 months. Of those with IFG at baseline, type 2 diabetes developed in 10.5%. In those with IGT at baseline, type 2 diabetes developed in 14%. The authors conclude that the study identified individuals with a very high early conversion rate from IGT to type 2 diabetes³.

The evidence is only partially applicable to UK settings as studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Findings relating to blood glucose levels were modest; this may be part due to short follow-up and part to the lower intensity of interventions as well as the range of study designs.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2010.

Evidence statement 3.23 Translational studies based on the DPS – weight change

There was moderate evidence for weight loss following translational interventions based on the DPS protocol from three (all [+]) pre-test/post-test studies. Two were conducted in Finland^{1,3} and one in Australia². However, none of these studies included a comparator.

Mean weight was reduced in all three studies at 12 months follow-up. Two studies achieved a mean weight loss of 2.5 kg (95% CI, 1.85 to 3.19)² and 1.2 kg ($p<0.0001$)³ respectively. In the other study mean weight reduction of 0.8 kg at 12 months ($p=0.002$) was maintained at 3 years (1.0 kg; $p=0.003$)¹.

The evidence is only partially applicable to UK settings as studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow-ups would be required to assess the sustainability of weight management achieved using DPS adaptations in the UK.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2007.

Evidence statement 3.24 Translational studies based on the DPS – changes to BMI

Moderate evidence for reduction in BMI at 12 months following intervention exists from three (all [+]) pre-test/post-test studies. Two were conducted in Finland^{1,3} and one in Australia².

Mean BMI was reduced from baseline to 12 months follow-up in all three studies^{1,2,3} with reductions ranging from 0.3 kg/m² to 0.93 kg/m². At 3 years, a further reduction of 0.2 kg/m² was observed in one study¹.

The evidence is only partially applicable to UK settings as studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow-ups would be required to assess the sustainability of BMI management achieved using DPS adaptations in the UK.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2007.

Evidence statement 3.25 Translational studies based on the DPS – changes in waist circumference

Moderate evidence exists for reduction in waist circumference following intervention based on the DPS from three (all [+]) pre-test/post-test studies. Two were conducted in Finland^{1,3} and one in Australia².

Waist circumference was reported to decrease in all three studies, ranging from -1.6 cm to -4.2cm at 12 months^{1,2,3}. However, the reduction at 12 months was not sustained at 3 years in one study¹.

The evidence is only partially applicable to UK settings as studies were carried out in Europe and Australia where health service delivery differs from the NHS. There is no reason to assume that modifications of the DPS protocol could not be transferred to the UK. Longer follow-ups would be required to assess the sustainability of waist circumference reduction achieved using DPS adaptations in the UK.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2007.

Evidence statement 3.27 Translational studies based on the DPS – participation/attendance

There was moderate evidence of reasonable to good attendance rates at interventions based on the DPS from three (all [+]) pre-test/post-test studies. Two were conducted in Finland^{1,3} and one in Australia².

One Finnish study reported that 57% of the participants attended all six sessions with the final session being least well attended (81% compared to 90%)¹. The Australian study reported that 43% of participants attended all six sessions with reasons for non-attendance given as lack of transport, fuel costs, time constraints, low literacy and health conditions². The second Finnish study reported 29.1% of participants achieving at least three visits. In this study, weight loss was associated with more intervention visits ($p < 0.001$)³.

The evidence is only partially applicable to UK settings as these studies were carried out in Europe and Australia where health service delivery differs from the NHS. Participation in prevention programmes and adherence to intervention aims would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

¹Absetz et al. 2009.

²Laatikainen et al. 2007.

³Saaristo et al. 2007.

Evidence statement 3.28 Translational studies based on the DPS – sustainability

There is moderate evidence on sustainability of outcomes beyond the 12-month follow-up of an intervention based on the DPS from one (+) pre-test/post-test study conducted in Finland. Only one study had a follow-up longer than 12 months. While weight loss (0.8 kg) and BMI reduction (0.3 kg/m²) at 12 months was maintained at 3 years (1.0 kg and 0.5 kg/m²), waist circumference reduction at 12 months (1.6 cm) was not sustained (0.1 cm)¹.

The evidence is only partially applicable to UK settings as this study was carried out in Finland where health service delivery differs from the NHS. Sustainability of intervention achievements

would need to be addressed in respect of the target UK population and the likely barriers for specific groups.

¹Absetz et al. 2009.

Evidence statement 3.29 Weight-loss achievement in translational studies compared with the DPP and DPS

There was strong evidence from four randomised controlled translational studies (two [++] and two [+]) for similar trends in weight-loss achievements to those achieved in the DPP and DPS at 12 months, though effects were generally weaker. Three were conducted in the US^{1, 3, 4} and one in Germany².

None of the translational studies achieved the 7 kg weight loss of the DPP at 1-year follow-up, although one pilot RCT utilising YMCA facilities reported a loss of 6.0 kg in the intervention group¹. One (++) RCT based on the DPP achieved 3.8 kg weight loss in the intervention group².

There was mixed evidence (one [++], one [+] and one [-]) from non-randomised translational studies for weight losses ranging from 1.4 kg in a primary care-based intervention compared to 0.6 kg in the control group³ and 5.19 kg compared to a weight increase of 0.21 kg in controls at 12 months⁴. One church-based intervention that targeted African–American communities did not report weight loss in either intervention or control groups, although the increase was less than 0.5 kg in both groups and was greater in the control group⁵.

There was moderate evidence for a trend in weight loss at 12 months in an intervention based on the DPS from three (all [+]) translational studies. Two were conducted in Finland^{6, 8} and one in Australia⁷. The effect was weaker than in the DPS.

The three studies did not include controls or comparators. None achieved the 4.2 kg (SD 5.1) weight loss at 12 months reported from the DPS. Weight change ranged from -0.8 kg to -2.36 kg across the three studies^{6, 7, 8}. At 3 years, one study reported a sustained change from -0.8 kg to -1.0 kg⁶.

¹Ackermann et al.2008.

²Kulzer et al.2009.

³Almeida et al. 2010.

⁴McTigue et al. 2009.

⁵Faridi et al. 2009.

⁶Absetz et al. 2009.

⁷Laatikainen et al. 2007.

⁸Saaristo et al. 2010.

Evidence statement 4.1 Provider understanding and attitudes toward risk assessment

There was evidence on the impact of provider understanding of risk-assessment aims on its implementation from two interview studies (one [++] and one [+]) and one mixed method study (++) conducted in the UK.

Findings from one (+) interview study that formed part of a risk-assessment programme suggest that providers that are more involved in implementing a programme develop increased understanding of programme aims, as well as of the general issues around risk assessment. Staff not involved at the planning stage may feel that they do not have a grasp of the risk-assessment programme as a whole¹.

Evidence from one (++) interview study² and one (++) mixed-method study³ carried out in routine practice highlighted concerns that primary care was an inappropriate setting to address pre-diabetes because of its perception as a social, rather than medical, problem. Instead, there were suggestions that prevention activity was the responsibility of agencies and individuals outside the NHS, such as the government^{2, 3}.

The mixed method study reported that some GPs are unaware of the extent of pre-diabetes cases in their practice population. In the questionnaire findings, almost half the sample (47%) lacked awareness of the risk of progression from impaired glucose tolerance to type 2 diabetes. There was uncertainty regarding how to manage patients with pre-diabetes which, according to the authors, has implications for training³.

This evidence is directly applicable to the UK as both studies were carried out in UK general practices with populations at risk of type 2 diabetes. One study was carried out as part of a screening programme therefore the participants may have different knowledge levels and motivation to those interviewed in routine practice.

¹Graffy et al. 2010.

²Williams et al. 2004.

³Wylie et al. 2002.

Evidence statement 4.2 Identification of increased numbers of individuals with pre-diabetes

There was evidence of reported concerns about increased cases arising from risk assessment from two (one [++] and one [+]) interview and one (++) mixed method studies conducted in the UK.

There were concerns reported in one (++) mixed method study that the role of primary care was moving from general to specialised practice, and that practitioners were concerned that guidelines were not available to support such practice¹.

In one (++) mixed method¹ and one (++) interview² study carried out in routine practice, increased numbers of cases were a concern for practitioners who did not believe that adequate resources were available to address additional activities.

An (+) interview study reported mixed views from nurses in primary care units participating in a screening programme. In units that did not offer adequate administrative and software support there were reports of having to work in their own time. By contrast, those units that did provide such support reported better efficiency³.

This evidence is directly applicable to the UK as all three studies were carried out in UK general practices with populations at risk of type 2 diabetes. One study was carried out as part of a screening programme therefore the participants may have different knowledge levels and motivation to those interviewed in routine practice.

¹Wylie et al. 2002.

²Williams et al. 2004.

³Graffy et al. 2010.

Evidence statement 4.3 Practitioner perceptions of barriers and facilitators to intervention implementation

There was evidence from one (+) interview study, one (++) focus group study and one (++) mixed-methods study conducted in the UK.

One (+) study using screening programme interviews reported that practitioners perceived a good relationship between user and practitioner facilitated attendance for risk assessment¹.

However, two (++) studies^{2,3} reported that practitioners in routine practice were concerned that patients with pre-diabetes but without symptoms lack the motivation to ultimately make lifestyle changes despite the efforts of practice staff. There was the perception that trying to encourage patients that have low motivation to change their lifestyle behaviours would be time-consuming.

This evidence is directly applicable to the UK as all three studies were carried out in UK practices with populations at risk of type 2 diabetes. However, one study was carried out as part of a screening programme therefore the participants may have different knowledge levels and motivation to those interviewed in routine practice.

¹Graffy et al. 2010.

²Williams et al. 2004.

³Wylie et al. 2002.

Evidence statement 4.4 Strategies to facilitate risk assessment attendance

Evidence for strategies used to increase service-user motivation to attend for risk assessment was reported in one (+) interview study conducted in the UK.

Providers were using strategies to increase attendance for assessment. These included: raising awareness and discussing lifestyle issues with service users during consultations and arranging a specific appointment to attend rather than inviting users to make their own appointment –

which was reported to facilitate the engagement of service users. A range of strategies around reaching users was evident, such as addressing risk assessment during consultations for other conditions, or following up user invitations with phone call reminders were also reported¹.

This evidence is directly applicable to the UK as the study was carried out in UK general practices. The findings are more applicable to practices that are developing a screening programme.

¹Graffy et al. 2010.

Evidence statement 4.5 Perceived risk and seriousness of type 2 diabetes and engagement with prevention activities

Evidence from two (both [+]) interview studies – one conducted in the UK and one in the Netherlands, suggests that service-user engagement with risk-assessment programmes is negatively affected by low perceived personal risk of type 2 diabetes as well as the low perceived seriousness of the condition.

Screening was generally considered to be 'good' by people at risk of type 2 diabetes who were participating in a 'stepwise' screening programme. This involved identifying the risk and then following a protocol for measuring blood glucose at set criteria – with the OGTT being the final diagnostic test if all other tests show positive. There was evidence from this study of mixed understanding of the aims of risk assessment and the meaning of the blood test results. Those with pre-diabetes tended to lack awareness of the meaning of the term and the implications of having the condition identified¹.

A lack of understanding of the meaning of raised blood glucose was identified in more than two thirds of the sample in another study. Those with most understanding had family members affected by diabetes. For those without prior experience relating to diabetes, there was no personal meaning of the impact of having impaired glucose measures. Lack of understanding could also lead to acceptance of the facts being presented by practitioners without questioning them. Only one of the interviewees found the process bothersome, and two reported that time could be an issue if participants were in paid work².

In one study the 'stepwise' approach was reported to provide users with an opportunity to gradually adapt psychologically to the possibility or reality of a diagnosis of pre-diabetes or type 2 diabetes¹. Evidence from the two studies showed that the first stage was less of a concern to

users, who generally expect a negative result, particularly in the absence of symptoms. Receiving a positive result at the first stage of risk assessment did not necessarily heighten expectations of a second positive result, though in some users this shift was made^{1, 2}.

This evidence is partially applicable to the UK as one study was carried out in UK general practices and one in the Netherlands. Both studies were part of a programme with a shared protocol. The findings are more applicable to practices that are developing a screening programme.

¹Eborall et al. 2007.

²Adriannse et al. 2001.

Evidence statement 4.6 Organisational factors

There was evidence for organisational barriers to lifestyle intervention from one case study and one survey study (both [+]) conducted in the US and Canada respectively^{1, 2}.

One case study of an intervention translated from a diabetes prevention initiative (DPI) to a community health centre identified the lack of a shared definition of pre-diabetes and purpose of testing in those organising and implementing the initiative as a barrier. In addition, lack of sustained funding was a barrier to quality improvement. The amount of extra workload involved in sustained programmes was perceived to require additional resources. Lack of cohesive aims between the planning team and the rest of the programme staff was a barrier as the clinic staff felt excluded from decision-making. The importance of early involvement in planning was mentioned by only one participant. Sustainability of a programme was reported to be reduced if the programme was not integrated into usual practice. Lack of time, space and finances were considered as barriers, as well as the prospect of not being able to meet the needs of patients with more cases being identified¹.

One survey of family physicians reported that practitioners viewed lack of time as a barrier to implementing lifestyle interventions².

This evidence is only partially applicable to the UK as the studies were carried out in the US and Canada where health service delivery and funding differs from the NHS.

¹Santana et al. 2010.

²Harris et al. 2004.

Evidence statement 4.7 Perceived barriers to intervention implementation in practice

There was evidence on perceived barrier to implementation from one (+) survey study conducted in Canada.

Practitioners' lack of awareness of available intervention tools meant that behaviour change techniques were less likely to be used than generic advice or handouts. Practitioners suggested that service-user motivation to make lifestyle changes was a barrier to implementing interventions. There was a perception among practitioners that service users may not engage in lifestyle change due to lack of motivation and commitment, lack of interest and the presence of co-morbidities¹.

This evidence is only partially applicable to the UK as the study was carried out in Canada where health service delivery and funding differs from the NHS.

¹Harris et al. 2004.

Evidence statement 4.8 Physical health

There was evidence on physical health factors as a barrier to carrying out physical activity from two (both [++]) survey studies^{1,2} and one (++) interview study³ conducted in Australia, Finland and the UK respectively.

One survey reported injury, disability and increasing age as barriers to physical activity, particularly for those with abnormal glucose metabolism. The survey was part of a population-based cross-sectional study in Australia¹.

A survey that focused on physical activity that was carried out with a subset of the Finnish Diabetes Prevention Study sample, showed that health problems could become a barrier to physical activity. However, barriers in this study were few compared to the facilitators reported from carrying out physical activity².

Deteriorating physical health or injury caused setbacks when attempting to maintain physical activity behaviour changes, according to one UK interview study linked to an RCT of diet and physical activity interventions³.

This evidence is partially applicable to the UK as one study was carried out in UK general practice, one in Australia and one in Finland. All three studies were part of diabetes prevention programmes that assessed high-risk individuals. Therefore the findings are more applicable to practices that are developing intervention programmes.

¹Hume et al. 2010.

²Korkinkanga et al. 2011.

³Penn et al. 2008.

Evidence statement 4.9 Habitual activities

There is evidence that existing habitual practices are difficult for service users to change from two (++) surveys ^{1,2} and one (+) focus group study³ conducted in Sweden, Finland and the US respectively.

In one survey respondents reported that forgetfulness and reverting to old habits were barriers to change. There were reports of lacking ideas when cooking healthy foods and also that healthy foods were not liked by other family members¹. Evidence from another survey suggested that 'laziness' might be a barrier to change².

Evidence from the focus group study showed that sedentary behaviours such as watching TV, or using the computer, as well as consuming fast food had become habitual and were difficult to change³.

This evidence is not directly applicable to the UK as the studies were carried out in the US, Finland and Sweden where healthcare services and funding arrangements differ from those in the UK.

¹Brekke et al 2004.

²Korkinkanga et al 2011.

³Satterfield et al 2003.

Evidence statement 4.10 Lack of time and other commitments

There was evidence that making lifestyle changes was hindered by other daily commitments and priorities from one survey study (+), one interview study (++) and one focus group study (+) conducted in Australia, UK and US respectively.

One focus group study with a diverse American population (+)¹ and one interview study (++) highlighted that job and family responsibilities were barriers to carrying out physical activity². This was supported by an Australian survey (+) which showed that lack of time, busy schedules, work commitments, hobbies and community priorities were barriers to making lifestyle changes in people at risk of type 2 diabetes³.

This evidence is partially applicable to the UK as one study was carried out in UK general practice. One survey was carried out in Australia and one focus group in the US where healthcare differs from the UK. The US study included Latino populations which are less likely to be among the practice population in the UK.

¹Satterfield et al. 2003.

²Penn et al. 2008.

³Hume et al. 2010.

Evidence statement 4.11 Health beliefs

There was evidence that some health beliefs can hinder healthy lifestyle change from four (three [++] and one [+]) interview studies, three conducted in the UK and one in Finland.

In one UK interview study (+) there were no reported expressions of intent in respect of changing lifestyle despite high blood glucose readings. Type 2 diabetes was perceived as 'mild' by some users, which may reduce the likelihood of engaging with prevention strategies¹.

Another UK interview study reported that individuals at risk may fail to recognise the relevance of diabetes and the impact that lifestyle changes might have on their lives. There was a belief that sufficient care was already being taken and that there was no more that could be done².

A Finnish interview study reported that for a range of attitudes among those attempting to manage their weight. Those who presented with a 'hopelessness' attitude might give up trying due to their belief that changing behaviour was not working compared to those with a 'self-governing' approach who did not find it a struggle to change health-related behaviours³.

A third UK interview study reported that some individuals who found great difficulty in managing their weight reported a sense of unfairness, particularly if they perceived that a lot of effort was being made for little achievement⁴.

This evidence is partially applicable to the UK as two studies were carried out in UK general practice, and one in Finland. All three studies were part of diabetes prevention programmes that assessed high-risk individuals. Therefore the findings are more applicable to practices that are developing intervention programmes.

¹Eborall et al. 2007.

²Troughton et al. 2008.

³Jallinoja et al. 2007.

⁴Penn et al. 2008.

Evidence statement 4.12 Lack of information and advice

There was evidence that identified lack of optimum advice and information as barriers to lifestyle change from two (both [++]) interview studies^{1, 2} and one (+) focus group study³. Two were conducted in the UK and one in the US respectively. Participants in the focus group study spoke of the lack of public awareness of the potential impact of diabetes upon health and how diabetes can be prevented. This was compared to the higher recognition given to some other conditions such as coronary heart disease³. The interview studies reported on the uncertainty that users have about the risks and seriousness of diabetes and pre-diabetes, relating this to unhelpful advice and information from general practitioners and the media. Pre-diabetes in particular was regarded as a 'grey area' that had little meaning. There was also uncertainty in service user's understanding of the effectiveness of lifestyle change for overall health¹.

This evidence is partially applicable to the UK as two studies were carried out in UK general practices. One study was carried out in the US where healthcare delivery and funding differ from

that in the UK. One UK study was part of a diabetes prevention programme. Therefore the findings are more applicable to practices that are developing intervention programmes.

¹Troughton et al. 2008.

²Penn et al. 2008.

³Satterfield et al. 2003.

Evidence statement 4.13 Environmental factors

There was evidence to suggest that certain aspects of the environment provide barriers to lifestyle change from two (both [++]) survey studies^{1,2}, one (++) interview study³ and one (+) focus group study⁴ conducted in Australia, Finland, UK and US respectively.

Focus groups in the US reported that low availability of local inexpensive food choices was a barrier to making healthy dietary changes⁴.

In terms of physical activity changes, a focus group study found that environments favouring vehicular transport over walking facilities make physical activity inaccessible⁴.

Physical activity could also be discouraged by lack of accessibility to local facilities such as inconvenient opening times, absence of a swimming pool or a perceived lack of safety in one UK interview study³.

The Australian survey¹ found that pollution was a potential barrier to taking physical activity. One UK interview³ study and one Finnish survey² found that outside activities may be hindered by adverse weather conditions.

This evidence is only partially applicable to the UK as one study was carried out in UK general practices. One study was carried out in the US and one in Finland where healthcare delivery and funding differ from that in the UK. In addition, weather conditions are more severe in Finland than in the UK. The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention programmes.

¹Hume et al. 2010.

²Korkinkanga et al. 2011.

³Penn et al. 2008.

⁴Satterfield et al. 2003.

Evidence statement 4.14 Cost

There was evidence that costs are a barrier to carrying out some physical activities and that reducing costs might facilitate access and therefore uptake from one (++) interview study conducted in the UK.

Even when physical activities are offered free of charge, there is often a requirement for special equipment or clothing. Supplying free bus passes can reduce the cost of accessing places to carry out physical activity¹.

The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention.

¹Penn et al. 2008.

Evidence statement 4.15 Positive impact of behaviour change

There was evidence for the positive effects of behaviour change on wellbeing in one interview study and one survey study (both [++]) conducted in the UK and Finland respectively.

Interviews in the UK found that feeling better or fitter following the accomplishment of change helped sustain physical activity behaviour changes. There was also a sense of satisfaction expressed by participants that had achieved their goals. While social occasions could present a challenge to maintaining healthy dietary changes, deviation from such practices could sometimes be accommodated, which allowed a balance to be achieved between optimal and realistic goals¹.

In the Finnish survey study, the motivational effect of carrying out physical activity, such as the continuation of functional ability in later life, and generally feeling good were reported².

This evidence is only partially applicable to the UK as one study was carried out in UK general practices. One study was carried out in Finland where healthcare delivery and funding differ from

that in the UK. The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention.

¹Penn et al. 2008.

²Korkinkanga et al. 2011.

Evidence statement 4.16 Social support

There was evidence that family and social support was a facilitator in carrying out behaviour change from one (++) interview study¹, two focus group studies (one [++] and one [+]) and one (++) survey study⁴, one conducted in the UK, two in Finland and one in US.

One (++) focus group study in Finland found that families could be supportive by giving encouragement to engage in physical activity². One UK interview study identified social relationships as an important factor in maintaining changes¹, and a survey study in Finland identified peer support as a facilitator to behaviour change⁴.

Stories of known individuals relating to the challenges of having diabetes were motivators for change in the UK interview study¹ and the US (+) focus group study³.

This evidence is only partially applicable to the UK as one study was carried out in UK general practices. Two studies were carried out in Finland and one in the US where healthcare delivery and funding differ from that in the UK. The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention programmes.

¹Penn et al. 2008.

²Jallinoja et al. 2007.

³Satterfield et al. 2003.

⁴Korkinkanga et al. 2011.

Evidence statement 4.17 Information and support from professionals

There was evidence that health information and support could facilitate healthy lifestyle changes from two (both [++]) interview studies^{1,2} and one (++) focus group study³. Two were conducted in the UK and one in Finland. Interviews in the UK found that professional support was appreciated and was helpful in keeping to plans. Motivational interviewing, a style of counselling that encourages behaviour change, was particularly appreciated. They also found that attention to the optimal timing of information-giving allowed gradual absorption of change and therefore was a facilitator in allowing adjustment to changes¹.

Focus group participants in Finland found check-up visits helpful in maintaining new behaviours. The prospect of undergoing formal measurements was a motivator to increase efforts. Similarly, interviewees in the UK reported that having repeat tests was reassuring in terms of maintaining efforts to change behaviour².

This evidence is applicable to the UK as two studies were carried out in UK general practices. One study was carried out in Finland where healthcare delivery and funding differ from that in the UK. The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention programmes.

¹Penn et al. 2008.

²Troughton et al. 2008.

³Jallinoja et al. 2007.

Evidence statement 4.18 Autonomy and control

There was evidence that a sense of individual autonomy and control was a facilitator to behaviour change from one (++) interview study¹ and one (++) focus group study² conducted in the UK and Finland respectively.

Increased autonomy and control over behaviour was identified in Finnish focus group participants that were able to manage their weight. These individuals did not associate weight management with a battle in the same way as those who found it difficult to lose weight. They were able to motivate themselves and plan their own lifestyle without the aid of a clinician or adviser².

Interviews in the UK found that self-efficacy was an important factor in changing behaviour that was eventually incorporated into daily routines. Self-monitoring was a way of keeping to plans and allowing a balance between optimal and realistic goals¹.

This evidence is only partially applicable to the UK as one study was carried out in UK general practices. One study was carried out in Finland where healthcare delivery and funding differ from that in the UK. The UK study was part of a diabetes prevention programme, therefore the findings may be more applicable to practices that are developing intervention programmes.

¹Penn et al. 2008.

²Jallinoja et al. 2007.

Evidence statement 4.19 Environmental factors

There was evidence on the influence of environmental factors on carrying out physical activity from one (++) interview study conducted in the UK. The evidence suggests that individuals can be motivated to carry out physical activity by the presence of a stimulating environment such as a coastal walk, or the provision of good facilities¹.

This evidence is directly applicable to the UK as the study was carried out in UK general practices. The findings may be more applicable to practices that are developing intervention programmes.

¹Penn et al. 2008.

Additional evidence

Expert paper 1: 'NHS Health Check'.

Expert paper 2: 'Implementing diabetes prevention programmes'.

Expert paper 3: 'Community-based diabetes prevention'.

Expert paper 4: 'Community-based diabetes prevention: The pre-diabetes risk education and physical activity recommendation and encouragement (PREPARE) study'.

Expert paper 5: 'Translation of major trial evidence into practice across Europe'.

Expert paper 6: 'Type 2 diabetes: preventing the progression from pre-diabetes'.

Expert paper 7: 'Primary prevention of type 2 diabetes in high risk persons: translating established science into sustainable programmes on a national scale'.

Expert paper 8: 'Supporting lifestyle change for adults at risk of type 2 diabetes'.

Commissioned report: 'A pragmatic review of methods to identify and monitor adults at high risk of developing type 2 diabetes, and interventions to prevent progression to type 2 diabetes, in disadvantaged and vulnerable groups'.

Cost-effectiveness review: 'Prevention of type 2 diabetes: economic review and modelling'.

Economic modelling

The economic modelling estimated that it was cost effective to offer intensive lifestyle-change programmes to people aged 40 to 74 years who have a Leicester practice risk score above 5.25. This is the case provided they also have an HbA_{1c} level of between 42–47 mmol/mol (6.0% and 6.4%) or an FPG between 5.5 and 6.9 mmol/l.

The cost per quality-adjusted life year (QALY) gained was estimated to lie between £10,000 and £20,000 for both HbA_{1c} and FPG testing.

The South Asian group aged 25 to 39, with the same range of risk scores and blood tests, had as its comparator 'normal practice', because people of this age did not qualify for the NHS Health Check programme. The intervention improved the health of this group and it was estimated that the resulting future cost savings would more than offset the cost of finding, testing and undertaking an intensive lifestyle-change intervention with them.

Lack of data meant that the analysis could not be extended to people within the same age range from other high-risk groups.

Fieldwork findings

Fieldwork aimed to test the relevance, usefulness and feasibility of putting the recommendations into practice. The PDG considered the findings when developing the final recommendations.

Fieldwork participants who work with people at high risk of type 2 diabetes were very positive about the recommendations and their potential to help prevent the condition. Most found them clear, understandable, relevant and useful.

Participants repeatedly expressed concern that it was becoming more difficult to argue the case for investment in preventive measures. But most believed that the guidance would be helpful in building a case for investment.

Participants were in no doubt that the recommendations could potentially save money in the longer term, although concerns were expressed about the costs and the capacity needed to implement the guidance. Many saw a case for incorporating diabetes prevention with activities to prevent other chronic diseases.

The importance of training – to undertake risk assessments and to deliver intensive lifestyle-change programmes – was a common theme. Participants also stressed the need for coordination of the range of potential services involved and the development of a supportive infrastructure.

For details, go to the fieldwork section in [appendix B](#) and 'Prevention of type 2 diabetes: risk identification and interventions for individuals at high risk '.

Appendix D Gaps in the evidence

The Programme Development Group (PDG) identified a number of gaps in the evidence related to the programmes under examination (apart from those proposed as 'Recommendations for research'). This was based on an assessment of the evidence, stakeholder comment and fieldwork. The gaps are set out below.

1. Intensive lifestyle-change programmes

a) There is limited evidence on both the short- and long-term effectiveness and cost effectiveness of translating prevention trials into UK practice.

(**Source:** evidence reviews 3 and the review of economic evaluations and economic modelling).

2. Joint risk assessment and intensive lifestyle-change programmes

a) There is limited evidence on the effectiveness and cost effectiveness of identification strategies linked to lifestyle-change programmes in UK populations.

(**Source:** evidence reviews 2, 3 and the review of economic evaluations and economic modelling)

b) There is a lack of evidence on the role of patient and provider incentives in aiding the provision and uptake of risk assessments and referral to (and participation in) lifestyle-change programmes.

(**Source:** evidence reviews 2, 3, 4 and the review of economic evaluations and economic modelling).

3. Identification and monitoring

a) There is a lack of validated risk-assessment tools for use with: people aged 18–24, 25–39 and 75 and over; different high-risk black and minority ethnic groups such as African–Caribbeans; and for other, high-risk vulnerable adults.

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- b) There is a lack of evidence on the most effective and cost-effective methods of identifying changes in blood glucose levels over time.
- c) There is a lack of evidence on the most effective and cost-effective methods of predicting rates of progression to type 2 diabetes. For example, it is unclear whether a risk-assessment tool alone and/or a fasting plasma glucose (FPG) or HbA_{1c} blood test is more effective.
- d) There is a lack of evidence on the most effective and cost-effective methods (and frequency intervals) for monitoring those identified as at risk of type 2 diabetes. This includes evidence on how this varies for different black and minority ethnic groups, people aged 18–24 and 25–39 years, and for high-risk vulnerable adults.
- e) There is a lack of evidence to determine how frequently those at high risk of type 2 diabetes should be reassessed, according to whether the risk assessment involved a tool and/or a blood test. This includes a lack of evidence on how this may vary for different black and minority ethnic groups, people aged 18–24 and 25–39 years, and for high-risk vulnerable adults.
- f) There is a lack of evidence on how the demographic characteristics of people identified as being at high risk of type 2 diabetes differ according to how they were assessed.
- g) There is a lack of evidence on the effectiveness and cost effectiveness of self-monitoring by those at high risk of modifiable risk factors to prevent type 2 diabetes.

(**Source:** evidence review 1 and the review of economic evaluations and economic modelling)

- h) There is a lack of evidence on the barriers to, and facilitators for, identifying and monitoring the risk of type 2 diabetes. This is the case for both patients and providers.
- i) There is a lack of evidence on the psychological effects associated with type 2 diabetes risk assessment, based on validated measures of anxiety and depression.

(**Source:** evidence review 4)

4. Lifestyle interventions

a) There is a lack of evidence on the effectiveness and cost effectiveness of lifestyle-change programmes in preventing or delaying type 2 diabetes, according to the cut-off point used for both risk-assessment tools and blood tests.

b) There is a lack of evidence on the effectiveness and cost effectiveness of intensive lifestyle-change programmes in preventing or delaying type 2 diabetes for those with HbA_{1c} levels of 38.8–42 mmol/mol (5.7–5.99%).

c) There is a lack of evidence on the psychological effects of an intensive lifestyle-change programme on those at high risk of type 2 diabetes. Specifically, there is a lack of evidence on the effects as gauged using validated measures of anxiety and depression.

(**Source:** evidence reviews 2 and 3)

d) There is a lack of evidence on the barriers to, and facilitators for, implementing intensive lifestyle-change programmes. There is also a lack of evidence on how these programmes affect the behaviour of those at high risk of type 2 diabetes.

(**Source:** evidence review 4)

5. Pharmaceutical and surgical interventions

a) There is a lack of evidence on the long-term effectiveness and cost effectiveness of pharmaceutical and surgical interventions to aid weight loss. Specifically, there is a lack of evidence when this forms part of an intensive lifestyle-change programme to prevent type 2 diabetes among people who have been unable to change their lifestyle enough.

b) There is a lack of evidence on the psychological effects associated with pharmaceutical and surgical interventions to prevent type 2 diabetes among those at high risk. Specifically, there is no evidence based on validated measures of anxiety and depression.

(**Source:** evidence review 2)

Appendix E Supporting documents

Supporting documents include the following.

- Evidence reviews:
 - Review 1: 'Preventing the progression of pre-diabetes to type 2 diabetes in adults. Identification and risk assessment of adults with pre-diabetes'
 - Review 2: 'Prevention of type 2 diabetes: Systematic review and meta-analysis of lifestyle, pharmacological and surgical interventions'
 - Review 3: 'Prevention of type 2 diabetes: reviewing mechanisms of successful interventions and translation of major trial evidence to practice'
 - Review 4: 'Prevention of type 2 diabetes: views, barriers and facilitators that may affect the implementation and effectiveness of interventions'
- Review of economic evaluations and economic modelling: 'Prevention of type 2 diabetes: economic review and modelling'
- Commissioned report: 'A pragmatic review of methods to identify and monitor adults at high risk of developing type 2 diabetes, and interventions to prevent progression to type 2 diabetes, in disadvantaged and vulnerable groups'

- Expert papers:
 - Expert paper 1: 'NHS Health Check'
 - Expert paper 2: 'Implementing diabetes prevention programmes'
 - Expert paper 3: 'Community-based diabetes prevention'
 - Expert paper 4: 'Community-based diabetes prevention: The pre-diabetes risk education and physical activity recommendation and encouragement (PREPARE) study'
 - Expert paper 5: 'Translation of major trial evidence into practice across Europe'
 - Expert paper 6: 'Type 2 diabetes: preventing the progression from pre-diabetes'
 - Expert paper 7: 'Primary prevention of type 2 diabetes in high risk persons: translating established science into sustainable programmes on a national scale'
 - Expert paper 8: 'Supporting lifestyle change for adults at risk of type 2 diabetes'
- Fieldwork report: 'Prevention of type 2 diabetes: risk identification and interventions for individuals at high risk'
- A [pathway](#) for professionals whose remit includes public health and for interested members of the public.

For information on how NICE public health guidance is developed, see:

- '[Methods for development of NICE public health guidance \(second edition, 2009\)](#)'.
- '[The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public \(second edition, 2009\)](#)'.

About this guidance

NICE public health guidance makes recommendations on the promotion of good health and the prevention of ill health.

This guidance was developed using the NICE [public health programme](#) guidance process.

The recommendations from this guidance have been incorporated into a [NICE Pathway](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Your responsibility

This guidance represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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