Type 2 diabetes: prevention in people at high risk

The references and appendices below are from the guideline on preventing type 2 diabetes in people at high risk (PH38) published in 2012.

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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

Dinesh Nagi

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

Linda Penn

Research Associate, Institute of Health and Society, University of
Newcastle

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 reported[1]. 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 practices[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 1.2 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 years[1]. 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 population[2] 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 score[1] 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 score[2], 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 version[3] 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 study[1] 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 abnormalities[2]. PPVs were similar at 49% and 48% respectively. NPVs were 85% and 76% respectively.

The Danish diabetes risk score[3] 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 population[4].

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 resources[1].

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 reported[2].

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 usedHbA$_{1c}$ alone at a range of optimal cut-off 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 population[3]. 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 study[1] 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/l[4]. 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 population[6]. 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/l[2] and 6.1 mmol/l[7] 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] Herdzik 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 study[2]. The highest specificity (88.4%) was obtained following assessment of risk factors in a stepped strategy[3].

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.

[1]Hu et al. 2009.

[2]Luders et al. 2005.

[3]Coligiuri 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 study[3] 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 10[4]. 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.

[1]Lidfelt et al. 2001.

[2]Luders et al. 2005.

[3]Franciosi et al. 2005.

[4]Rolka et al. 2001.

[5]Colagiuri et al. 2004.

[6]Simmons 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 score[8] and the lowest reported was for the diabetes risk score[1]. 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 OGTT[2].

For blood glucose measures, there was a 52.5% response rate to the first visit for a 1-hour oral glucose tolerance test[4]. 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 sample[6] 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 facilitator[1]. A good uptake rate was considered to be due to confirmation of appointments and follow-up contact with patients by telephone[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.

[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 (+) UK[1], one (++) Chinese[2] and one (-) Australian[3]. The hazard ratio for exercise-only intervention was based on one (++) Chinese study[2]. The hazard ratio for the diet combined with exercise intervention was based on nine studies, one study in each of the following countries, UK[4] (++), Japan[5] (++), China[6] (-), India[7] (++), Netherlands[8] (++), Finland[9] (++), Sweden[10] (++) and two US studies, (one [++][11] and one [+][12]).

[1]Jarrett et al. 1979.

[2] Da Qing et al. 1997.

[3]Wein et al. 1999.

[4] Penn et al. 2009.

[5] Kosaka et al. 2005.

[6] Li et al. 2008.

[7] Ramachandran et al. 2008.

[8] Roumen et al. 2008.

[9] Lindstrom et al. 2006.

[10] Lindahl et al. 2009.

[11] Diabetes Prevention Program Research Group 2009.

[12] Liao 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/Europe[4] (one [++]), Finland[5] (one [++]), Japan[6] (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/Europe[13] (++) and one Swedish[14] (++).

[1] Dream Trial Investigators 2006.

[2] NAVIGATOR Study Group[a] 2010.

[3] NAVIGATOR Study Group[b] 2010.

[4] Chiasson et al. 2002.

[5] Erkisson 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] Heymsfiled 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: US[1] (+), Japan[2] (++), India[3] (++) and China (one [++][4]; and one[-][5]).

For oral diabetes drugs, the hazard ratio was based on four studies in the following countries: Japan[6] (++), India[7] (++) 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: US[2] (+), Finland[3] (++), Netherlands[4] (++) and Sweden[5] (++). The changes in BMI in pharmacological studies are based on four studies: China[6] (++), India[7] (++), US[8] (+) and Finland[9] (++).

[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: Sweden[1] (++), Netherlands[2] (++), Japan[3] (++), 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/Europe[10] (++), US/Europe[11] (++), two US studies (one [++][4] and one [+][12]), Sweden[13] (++), India[14] (++) and China[15] (++).

Maintenance of the weight loss was mentioned briefly by three studies, with one (++) Finnish study[6], saying weight maintenance was satisfactory and two studies – one (++) Japanese[3] and one (++) Netherlands[2] 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 (++) Swedish[1], one (-) Chinese[2] and one (++) study from the Netherlands[3]. The changes in blood pressure in pharmacological interventions were based on seven studies: Finland[4] (++), Sweden[5] (++), India[6] (++), US[7] (+), 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 study[1]. The diet combined with exercise intervention was based on five studies: Netherlands[2] (++), Sweden[3] (++), Finland[4] (++) and China (one [-][5] and one [++][6]). The pharmacological interventions were based on six studies: US[7] (+), Sweden[8] (++), Finland[9] (++), China[10] (++), India[11] (++) and one multi country study[12] (++).

[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: Netherlands[1] (++), Sweden[2] (++), Finland[3] (++) and India[4] (++). The pharmacological interventions were based on one (++) study from Sweden[5].

[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 review[1] 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 review[2] 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.

[1]Baker et al. 2011.

[2]Norris 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 activity[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 characteristics of those delivering interventions cannot be transferable to interventions carried out in the UK.

[1]Baker et al. 2011.

[2]Nield et al. 2008.

[3]Roumen et al. 2009.

Evidence statement 3.3 Mode of intervention delivery
There is evidence from one (++) systematic review of RCTs[1] 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.

[1]Baker 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 review[1] 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 review[2] 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 review[3] 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 trials[4] 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 review[5] 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.

[1]Baker et al. 2011.

[2]Nield et al. 2008.

[3]Norris et al. 2007.

[4]Yuen et al. 2010.

[5]Davies 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 review[1] 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 review[6] 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 types[5] 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.

[1]Baker et al. 2011.

[2]Waugh et al. 2010.

[3]Paulweber et al. 2010.

[4]Burnet et al. 2006.

[5]Davies et al. 2004.

[6]Walker et al. 2010.

[7]Roumen 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 five[1] and seven[2] 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 Japan[1]. 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 trials[3] 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.

[1]Baker et al. 2011.

[2]Paulweber et al. 2010.

[3]Yates et al. 2007.

Evidence statement 3.7 Intensity/duration of physical activity
Evidence exists from one (++) systematic review of RCTs[1].

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 risk[1]. 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.

[1]Waugh 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 review[1]. 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 leaning 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 review[4] 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.

[1]Baker et al. 2011.

[2]Norris et al. 2007.

[3]Yuen et al. 2010.

[4]Burnet 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 trial[1]. 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 population[2].

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 changes[5].

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 goals[4].

Evidence was provided from one Finnish trial of under-reporting food consumption in overweight and obese participants[1]. One

epidemiological study reported a risk of 'rebound' weight gain in this group if there is a reversion to pre-intervention energy intake[4].

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.

[1]Waugh et al. 2010.

[2]Yuen et al. 2010.

[3]Davies et al. 2004.

[4]Walker et al. 2010.

[5]Roumen 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 inclusion[1].

Adherence strategies in three US-based RCTs of physical activity were assessed[2]. 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 types[3] (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.

[1]Baker et al. 2011.

[2]Waugh et al. 2010.

[3]Burnet 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 Germany[1] and the US[2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12].

One RCT[1], 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 trial[11] all adapted the DPP in a range of settings including primary care, YMCA facilities, and churches. Two studies[10, 12] used technology such as theInternet 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/m^2).

All but one DPP-based[7] intervention were delivered using group sessions rather than individual sessions. One study[3] 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.

[1]Kulzer et al. 2009.

[2]Ackermann et al. 2008.

[3]Whittemore et al. 2009.

[4]Almeida et al. 2010.

[5]Faridi et al. 2009.

[6]McTigue et al. 2009a.

[7]Amundsen et al. 2009.

[8]Davis-Smith 2007.

[9]Kramer 2009.

[10]McTigue et al. 2009b.

[11]Seidal et al. 2008.

[12]Vadheim 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 RCT[3], 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 months[4].

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 facilities[3].

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.

[1]Kulzer et al. 2009.

[2]Whittemore et al. 2009.

[3]Ackermann et al. 2008.

[4]Davis-Smith 2007.

[5]Seidal 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 control[1]. 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 months[4].

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 programme[5].

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 intervention[6].

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-up[9]. 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 loss[10]. One (+) study that targeted underserved populations also achieved and sustained 5–7% weight loss in over 65% of the sample at 6 months[11].

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.

[1]Kulzer et al. 2009.

[2]Ackermann et al. 2008.

[3]Almeida et al. 2010.

[4]Whittemore et al. 2009.

[5]McTigue et al. 2009a.

[6]Vadheim et al. 2010.

[7]Kramer et al. 2009.

[8]Amundsen et al. 2009.

[9]Davis-Smith 2007.

[10]McTigue et al. 2009b.

[11]Seidal et al. 2008.

[12]Faridi 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/m^2 in the intervention group compared to 0.5 kg/m^2 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/m^2 in the intervention group compared with 1.4 kg/m^2 at 12 months (p=0.002)[2]. One (+) non-randomised controlled feasibility trial reported a reduction of 2.7 kg/m^2 in the 'tele-health' group compared to 2.5 kg/m^2 in the on-site group. Both of these groups received a lifestyle intervention[3]. One (-) non-randomised church-based study achieved reduction in BMI of 0.63 kg/m^2 in the intervention group compared to a gain of 0.13 kg/m^2 in the control group at 12 months[4].

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/m^2 (p< 0.001) at 12 months[5]. A single group study of a church-

based intervention achieved a reduction of 1.9 kg/m^2 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/m^2 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.

[1]Kulzer et al. 2009.

[2]Ackermann et al. 2008.

[3]Vadheim et al. 2010.

[4]Faridi et al. 2009.

[5]Kramer et al. 2009.

[6]Davis-Smith 2007.

[7]Amundsen 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 Germany[1] 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 group[1]. One (+) pre-test/post-test single group study reported significant changes in waist circumference (around -4.3 cm; p< 0.001) after 12 months[2]. 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.

[1]Kulzer et al. 2009.

[2]Kramer et al. 2009.

[3]Seidal 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 Germany[1] 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 group[1]. A non-randomised controlled feasibility trial (+) reported an increase in physical activity by a mean of 80 minutes from week 6 to week 16[2].

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 (mean197 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 controls[5].

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 group[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 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.

[1]Kulzer et al. 2009.

[2]Amundsen et al. 2009.

[3]Vadheim et al. 2010.

[4]Whittemore et al. 2009.

[5]Faridi 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 weeks[2].

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.

[1]Amundsen et al. 2009.

[2]McTigue 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.

[1]Seidal 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 Australia[2]. All three studies were set in primary care and selected populations using a risk score.

One study delivered a mix of individual and group sessions[3], 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 guidelines[2].

Follow-up ranged from 12 months[2, 3] to three years[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 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.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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 Australia[2].

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 3[1].

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 diabetes[3].

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.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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 Australia[2]. 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.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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 Australia[2].

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/m^2 to 0.93 kg/m^2. At 3 years, a further reduction of 0.2 kg/m^2 was observed in one study[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 BMI management achieved using DPS adaptations in the UK.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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 Australia[2].

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 study[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 waist circumference reduction achieved using DPS adaptations in the UK.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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 Australia[2].

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 conditions[2]. 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.

[1]Absetz et al. 2009.

[2]Laatikainen et al. 2007.

[3]Saaristo 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/m^2) at 12 months was maintained at 3 years (1.0 kg and 0.5 kg/m^2), 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.

[1]Absetz 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 Germany[2].

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 group[1]. One (++) RCT based on the DPP achieved 3.8 kg weight loss in the intervention group[2].

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 group[3] and 5.19 kg compared to a weight increase of 0.21 kg in controls at 12 months[4]. 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 group[5].

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 Australia[7]. 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 kg[6].

[1]Ackermann et al. 2008.

[2]Kulzer et al. 2009.

[3]Almeida et al. 2010.

[4]McTigue et al. 2009.

[5]Faridi et al. 2009.

[6]Absetz et al. 2009.

[7]Laatikainen et al. 2007.

[8]Saaristo 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 whole[1].

Evidence from one (++) interview study[2] and one (++) mixed-method study[3] 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 training[3].

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.

[1]Graffy et al. 2010.

[2]Williams et al. 2004.

[3]Wylie 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 practice[1].

In one (++) mixed method[1] and one (++) interview[2] 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 efficiency[3].

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.

[1]Wylie et al. 2002.

[2]Williams et al. 2004.

[3]Graffy 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 assessment[1].

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.

[1]Graffy et al. 2010.

[2]Williams et al. 2004.

[3]Wylie 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 reported[1].

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.

[1]Graffy 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 identified[1].

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 work[2].

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 diabetes[1]. 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.

[1]Eborall et al. 2007.

[2]Adriannse 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 identified[1].

One survey of family physicians reported that practitioners viewed lack of time as a barrier to implementing lifestyle interventions[2].

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.

[1]Santana et al. 2010.

[2]Harris 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-morbidities[1].

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.

[1]Harris 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 study[3] 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 Australia[1].

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 activity[2].

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 interventions[3].

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.

[1]Hume et al. 2010.

[2]Korkinkanga et al. 2011.

[3]Penn 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 study[3] 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 members[1]. Evidence from another survey suggested that 'laziness' might be a barrier to change[2].

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 change[3].

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.

[1]Brekke et al 2004.

[2]Korkinkanga et al 2011.

[3]Satterfield 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 activity[2]. 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 diabetes[3].

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.

[1]Satterfield et al. 2003.

[2]Penn et al. 2008.

[3]Hume 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 strategies[1].

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 done[2].

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 behaviours[3].

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 achievement[4].

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.

[1]Eborall et al. 2007.

[2]Troughton et al. 2008.

[3]Jallinoja et al. 2007.

[4]Penn 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 study[3]. 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 disease[3]. 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 health[1].

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.

[1]Troughton et al. 2008.

[2]Penn et al. 2008.

[3]Satterfield 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 study[3] and one (+) focus group study[4] 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 changes[4].

In terms of physical activity changes, a focus group study found that environments favouring vehicular transport over walking facilities make physical activity inaccessible[4].

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 study[3].

The Australian survey[1] found that pollution was a potential barrier to taking physical activity. One UK interview[3] study and one Finnish survey[2] 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.

[1]Hume et al. 2010.

[2]Korkinkanga et al. 2011.

[3]Penn et al. 2008.

[4]Satterfield 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 activity[1].

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

[1]Penn 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 goals[1].

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 reported[2].

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.

[1]Penn et al. 2008.

[2]Korkinkanga 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 study[1], two focus group studies (one [++] and one [+]) and one (++) survey study[4], 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 activity[2]. One UK interview study identified social relationships as an important factor in maintaining changes[1], and a survey study in Finland identified peer support as a facilitator to behaviour change[4].

Stories of known individuals relating to the challenges of having diabetes were motivators for change in the UK interview study[1] and the US (+) focus group study[3].

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.

[1]Penn et al. 2008.

[2]Jallinoja et al. 2007.

[3] Satterfield et al. 2003.

[4]Korkinkanga 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 study[3]. 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 changes[1].

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 behaviour[2].

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.

[1]Penn et al. 2008.

[2]Troughton et al. 2008.

[3]Jallinoja 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 study[1] and one (++) focus group study[2] 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 adviser[2].

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 goals[1].

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.

[1]Penn et al. 2008.

[2]Jallinoja 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 facilities[1].

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.

[1]Penn 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 For details, go to the fieldwork section in [appendix B](#) and the full fieldwork report [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.

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 (see [supporting evidence](#)).

- 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).